Sensing the Pressure: Providing Evidence for Adoption of Automatic Blood Pressure Monitoring in Primary Care

Kara Fore-Flores, RN, MSN, DNP-S

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Approved by:

Dr. Cheryl Wicker	Project Team Leader
Dr. Autumn Henson	DNP Program Director
Dr. Wanda Williams	Director of Advanced Nursing Programs, Interim Director for Advanced Nursing Education

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Dedication and Acknowledgments

There are so many that have helped me through this process, that it is hard to acknowledge them all. I am so grateful to my husband for his unwavering support and patience; my children for putting up with a devoted mother, divided in attention; my parents and brother, for cheering me on, listening to me, and packing my lunches; my friends, including my dear Julie Barney, who helped picked me up when cancer threatened to take me out of the running; the UNCG faculty, especially Dr. Cheryl Wicker for giving me the idea and support for my project, Dr. Kathryn Lawrence, whose kind words always made my day, Dr. Amita Mittal for her assistance with data analysis; and God, whose grace and peace have carried me through a challenging and rewarding time.

Abstract

Background: Many primary care practices rely on manual blood pressure measurement (MOBP) for diagnosis and management of patients with hypertension, despite evidence and expert panel consensus in favor of automatic blood pressure monitoring (AOBP). Hypertension affects nearly half of adults in the United States and is directly linked to heart disease, stroke, and chronic kidney disease. Despite this, roughly 75% are not well-controlled. Diagnosis, and subsequent decisions regarding life-long pharmacologic treatment, are based solely on clinic blood pressure measurement, and thus accuracy is critical to appropriate management. **Purpose:** The purpose of this project is to optimize the accuracy of blood pressure measurement in a suburban primary care clinic that relies on manual blood pressure measurement. **Methods:** A set of two MOBP readings were collected on a group of 40 patients at different time points at the same visit. These data points were then analyzed, using a paired T-test, for significant variability between readings. Results, along with a literature review of current peer-reviewed evidence, were presented to the clinic to help them in their decision to purchase an automated blood pressure monitor. **Results:** Systolic blood pressure readings were significantly lower on the second reading. Diastolic blood pressure readings did not show a significant change. **Recommendations & Conclusion:** The results of this project exhibited significant variability in systolic blood pressure readings at one primary clinic after a rest period with MOBP. AOBP has been known for some time to be more closely correlated with home blood pressure readings; more prognostic of end-organ damage; less dependent on a rest period for accuracy; less impacted by "white coat hypertension;" and can be taken unattended, eliminating talking and observer effects. Additionally, it requires less skill and time to perform accurately.

Recommendations are for clinics to obtain AOBP devices for use in diagnosis and management of patients with hypertension.

Key Words: hypertension, automated blood pressure monitoring, manual blood pressure monitoring, auscultatory blood pressure monitoring, ambulatory blood pressure monitoring, white coat hypertension, observer effect, blood pressure rest period

Background and Significance

Hypertension affects nearly half of adults in the United States (U.S.) and one third of individuals worldwide, and is implicated in poor cardiovascular outcomes, including heart attack, stroke, chronic kidney disease, and death (Bo, et al., 2021; Boonyasai, et al., 2019; CDC, 2022a). Heart disease is the leading cause of death in the United States, with stroke falling in fifth place and kidney disease tenth (CDC, 2022b). The treatment of hypertension and associated illness incurs more than $131 billion healthcare dollars per year (CDC, 2022a). Accurate diagnosis and management of this insidious and ubiquitous disease is critical to optimal health, yet three quarters of U.S. adults with the disease are estimated to be not well-controlled (CDC, 2022a).

Diagnosis, and subsequent decisions regarding life-long treatment, are based solely on blood pressure measurement (Stergiou et al., 2018). Even minor errors in measurement can lead to mis-categorization of disease state with inappropriate medication management. Overtreatment, especially in older patients can lead to hypoperfusion issues such as syncope and acute kidney injury; undertreatment can lead to cardiac ischemia and death (Park et al., 2022). The gold standard for blood pressure measurement in the primary care setting was once manual, auscultatory office blood pressure monitoring (MOBP); however, data has emerged over the last 25 years that this method is highly inconsistent and generally leads to overestimation of blood pressure (Muntner, Shimbo, et al., 2019). Automated, oscillometric office blood pressure monitoring (AOBP), when used properly, has been shown to be more consistent across readings, best correlate with out-of-office blood pressure readings, to minimize “white coat” and “masked” hypertension, and to be highly prognostic of end-organ damage (Boonyasai et al., 2019; Muntner, Shimbo, et al., 2019).

Despite this evidence, and expert panel consensus (Muntner, Einhorn, et al., 2019; Muntner, Shimbo, et al., 2019) in favor of automatic blood pressure monitoring, many primary care practices still rely on manual blood pressure measurement for diagnosis and management of patients with hypertension (Roerecke et al., 2019; Stergiou et al., 2018). A recent survey of three large professional organizations involved in the treatment of hypertension found that only 61% of practices, including cardiology and primary care clinics, used AOBP (Gulati et al., 2021). This is thought to be due to a combination of factors, including outdated perceptions, expense of AOBP equipment, lack of quality assurance indicators for its use, and lack of clear guidance on standards for use of AOBP in clinical practice (Muntner, Einhorn, et al., 2019). As an example, guidelines vary between diagnostic BP cut-off values of 130/80 vs. 140/80, but do not specify whether modifications should be made for type of device used, despite evidence that MOBP consistently reads roughly 10-15/5-7 mm Hg higher for Systolic Blood Pressure (SBP) and Diastolic Blood Pressure (DBP) respectively (Myers et al., 2018; Pappaccogli et al., 2019; Roerecke et al., 2019). The AHA supports the use of AOBP, so it is perhaps implied that their recommended goal BP of 130/80 is to be obtained based on this method, but they do not give modified values for offices that do not employ this technology (Muntner, Shimbo, et al., 2019). A comprehensive review of the evidence in favor of AOBP in clinical practice, as well as recommended standards for its adoption in primary care, is needed to properly manage patients with hypertension.

Purpose

The purpose of this project is to optimize the accuracy of blood pressure measurement in a suburban primary care clinic that relies on manual blood pressure measurement. This will be accomplished by: providing a synthesis of current peer-reviewed literature related to the superiority of automated versus manual blood pressure measurement for the diagnosis and management of hypertension in primary care; clinic-level, de-identified data on the potential variability of manual blood pressure readings at different time points and with different types of clinic staff; and a protocol for adoption of automatic blood pressure monitoring in clinical practice, as well as visual references for providers and patients related to best practices for accurate blood pressure monitoring.

Review of Current Evidence

Search Strategy

The literature search was conducted in Google Scholar and PubMed, using the following search terms: automatic/automated/auto*/oscillometric vs. manual/traditional/mercury/auscultatory/Korotkoff blood pressure measurement, diagnosis of hypertension in primary care, measurement of blood pressure in primary care, accurate blood pressure measurement/assessment, accurate diagnosis of hypertension, blood pressure measurement debate, blood pressure/hypertension measurement methods/recommendations/consensus/guidelines.

The search was limited to peer-reviewed articles, published within the last five years, for which full-text versions were available. Snowballing was used to look for additional sources and to assess degree of source penetration and overlap. The search resulted in 12 articles, the majority of which (11) were large-scale systematic reviews of a mixture of randomized controlled trials (RCTs), nonexperimental studies, observational studies, and non-randomized cross-sectional studies. One study was a large retrospective cohort study.

In general, the search found that AOBP is superior to MOBP for diagnosis and management of hypertension in both primary care and specialty practice. Articles discussed rationale behind the superiority of AOBP, including sources of error in MOBP, and barriers to adoption of AOBP in clinical care.

Variables, Factors, and Concepts

The independent variable of interest is blood pressure measurement modality (automated vs. manual), and the dependent variable is the accuracy of the subsequent blood pressure reading (Systolic/Diastolic or SBP/DBP). Confounding variables to be considered for both AOBP and MOBP include (but are not limited to) rest periods, observer training, white coat hypertension, masked hypertension, timing of medication administration, body positioning, proper cuff size, talking during the procedure, and environmental distractions. These concepts will be explored and defined in more depth along with a description of the pros and cons of each method below. Evidence suggests that manual blood pressure readings are on average at least 10/5 (SBP/DBP) mm Hg higher than automated readings (Myers et al., 2018; Pappaccogli et al., 2019; Roerecke et al., 2019). To understand the clinical significance of this difference, it is helpful to first define what hypertension is, and what the consensus is on blood pressure cut-offs for diagnosis of the disease. Sources of error that lead to these differences will also be explored, as well as the body of literature related to the two measurement modalities, and finally, methods of overcoming barriers to adoption of AOBP in primary care practice.

Guidelines on Blood Pressure Cut-Off Values for Diagnosis of Hypertension

Both the eighth report from the Joint National Committee on Hypertension (JNC 8) and the European Society of Cardiology/European Society of Hypertension (ESC/ESH) blood pressure/hypertension guidelines consider hypertension to be 140/90 (James et al., 2014; Whelton et al., 2022). JNC 8 considers treatment of hypertension in anyone younger than 40 or with chronic kidney disease or diabetes with this cutoff, while individuals older than 60 are treated above 150/90, to balance the risk of orthostatic hypotension and falls in this population (James et al., 2014). The American College of Cardiology (ACC) in conjunction with the American Heart Association (AHA), however, lowered the threshold to 130/90 in all adults aged 18 or older in their 2017 update (Whelton et al., 2018). This was based on evidence from the landmark SPRINT trial (Systolic Blood Pressure Intervention Trial) of 2015, showing a linear relationship between blood pressure and cardiovascular risk, and linking early aggressive treatment of hypertension with statistically significant reductions in cardiovascular outcomes, such as heart disease, myocardial infarction, heart failure, stroke, and all-cause mortality (*New Guidance on Blood Pressure Management in Low-Risk Adults with Stage 1 Hypertension - American College of Cardiology*, 2021). If a reduction or addition of only 10 mm mercury (Hg) is considered clinically significant in terms of preventing cardiovascular outcomes or risk of falls, it can be inferred that this same 10 mm Hg discrepancy between manual and automated blood pressure measurement is indeed clinically meaningful with potentially significant impacts on patient well-being.

Consensus on Use of Automated or Manual Blood Pressure Methods

In 2017, the ACC, in collaboration with the AHA, published a joint consensus statement on the diagnosis and management of hypertension in primary care (Whelton et al., 2018). Nine other organizations were involved in the development of this statement, including: The American Board of Cardiovascular Medicine American College of Preventive Medicine, American Geriatric Society, American Public Health Association, American Society of Hematology, Association of Surgeons in Primary Care, National Medical Association, Preventive Cardiovascular Nurses Association, and the American Association of Physician’s Assistants (Whelton et al., 2018). The ACC/AHA report is in congruence with both the ESC/ESH and the

World Health Organization (WHO) in that it recommends automated blood pressure monitoring as the preferred modality (John et al., 2021; Whelton et al., 2018; Whelton et al., 2022; World Health Organization [WHO], 2020). All bodies recognize the ease, but potential for multiple errors, in the use of "traditional" manual auscultatory blood measurement, as well as a growing evidence base in favor of automated oscillometric monitors (John et al., 2021; Whelton et al., 2018; Whelton et al., 2022; WHO, 2020). Considering these factors, they recommend automated blood pressure monitors that allow multiple measurements with the patient alone and undisturbed; however, devices should be approved by a validating body and periodically calibrated (Whelton et al., 2018, p. E140). They go on to recommend that for optimum accuracy, the patient should be: seated quietly; with feet supported; using a proper-sized cuff on bare skin; and that measurements should be taken in both arms on the first visit, with the arm that reads higher to be used on subsequent visits (Whelton et al., 2018, p. E140). Both U.S. and British groups also recommend validation of blood pressure outside of the clinic, to eliminate potential for white coat or masked hypertension (Whelton et al., 2018; Whelton et al., 2022). ACC/AHA, in alignment with JNC 8, recommends at least two office readings on at least two different visits before diagnosing hypertension, while the ESC/ESH recommends three office readings, with additional measurements if the first two differ by more than 10 points (Whelton et al., 2022). The JNC 8 gives very specific treatment thresholds and treatment recommendations, however they do not provide any recommendations for type of measurement device (James et al., 2014).

Sources of Error and Pros and Cons of Each Method

One of the most consistent themes that arise in the literature related to pitfalls of manual blood pressure reading is the required skill and time to perform it correctly (Elias & Goodell, 2021; Meidert & Saugel, 2018; Whelton et al., 2018; Zhang et al., 2019). A proper manual reading takes 14 minutes to perform (Boonyasai et al., 2019), versus the three-seven minutes (Myers et al., 2018) required by an automated device. While nurses, certified nursing assistants, and medical technicians receive thorough training in how to properly perform a manual blood pressure reading, due to their primary role in intake and monitoring of patients (Elias & Goodell, 2021), medical schools typically only provide brief training to students in technique. If an intake blood pressure is high, whether automated or manual, it is often repeated manually by a physician, which would potentially read even higher and consequently lead to misclassification of blood pressure and related treatment category. Skill and ability needed to perform an accurate MOBP include proper patient positioning, adequate hearing, knowledge of the Korotkoff sounds, proper cuff inflation, avoiding rapid cuff deflation, awareness of the auscultatory gap, and knowledge of when to read the diastolic value with end inflation sound fading (Boonyasai et al., 2019). AOBP requires less skill and is not dependent on individual hearing (Elias & Goodell, 2021).

The additional time needed to perform a proper manual reading involves not only technique, but also a second theme in the literature of required rest periods that allow the body to come back to homeostasis after movement. MOBP requires at least a five-minute rest period before measurement and requires longer intervals between subsequent readings (Boonyasai et al., 2019). AOBP should ideally be performed after a rest period (Andreadis et al., 2020; Elias & Goodell, 2021; Whelton et al., 2018), but several meta-analyses of published studies have shown that it can be performed with equal accuracy regardless of rest period (Myers et al., 2018; Pappaccogli et al., 2019), and that intervals should be two-three minutes for repeat measurements (Boonyasai et al., 2019). Due to the additional time required for MOBP, repeat readings are often not taken, which is a technique that has been shown to improve correlation with out-of-office readings.

An additional effect that pertains to skill involves recording of accurate blood pressure readings. Studies show that MOBP has a high level of “end-zero preference,” which means that the observer will tend to round readings off to the nearest zero, occurring in more than 50 percent of cases (Myers et al., 2018). AOBP has not been shown to be as strongly associated with this tendency (Myers et al., 2018).

MOBP inherently requires a medical provider to be present during measurement, which introduces the concepts of “white coat hypertension, the “Hawthorne Effect,” “masked hypertension,” and the potential for interference from talking and interacting. White coat hypertension is one of the predominant factors cited in the literature regarding MOBP and involves a subset of people who have higher blood pressure readings in the clinical setting than they would at home, due in part to fear or anxiety. A related principle, the Hawthorne effect, involves a modification of behavior when being observed. “Masked Hypertension” refers to a subset of patients whose blood pressure is conversely lower in the clinical setting than at home. Studies have shown that these factors are more closely associated with MOBP, especially white coat hypertension (Bo et al., 2021; Boonyasai et al., 2019; Myers et al., 2018; Pappaccogli et al., 2019; Roerecke et al., 2019), even when AOBP is attended (Andreadis et al., 2020; Myers et al., 2018). AOBP has been found to enhance diagnosis of “masked hypertension (Bo et al., 2021; Boonyasai et al., 2019). This is perhaps due to the physical contact, closeness, and additional time requirement of MOBP. It is important for both MOBP and AOBP to sit in a quiet room and not talk or interact (Andreadis et al., 2020; Boonyasai et al., 2019; Elias & Goodell, 2021; Roerecke et al., 2019). Recommended AOBP devices for the clinical setting are programmable to take repeated pressures automatically (Boonyasai et al., 2019; Elias & Goodell, 2021), which are then averaged, overcoming the effect of a provider needing to be present and their impact on the reading. On the contrary, the lack of observer in AOBP sequential readings can lead to the patient not adhering as closely to movement and body positioning requirements that interfere with accuracy. Two studies recommended that a method of overcoming this was increased patient education on the importance of accurate readings and the role they play, verbal reminders from staff, and visual aids in the room where measurements are taken (Boonyasai et al., 2019; Elias & Goodell, 2021)

AOBP and MOBP both require periodic equipment calibration, but automatic devices are more likely to suffer from miscalibration over time (Elias & Goodell, 2021), and the literature suggests that protocols should be put in place in practice settings to schedule this activity. Both modalities also require use of an appropriate cuff size (Meidert & Saugel, 2018) and proper body positioning with feet flat and supported, to increase accuracy of readings (Boonyasai et al., 2019; Elias & Goodell, 2021).

The literature is additionally very clear in relation to increased accuracy through averaging of multiple readings, regardless of modality, through confirmation with home or ambulatory monitoring and repeated measures on a different visit or day before starting or making changes to treatment (Andreadis et al., 2020; Pappaccogli et al., 2019; Roerecke et al., 2019; Zhang et al., 2019). Some clinics use a "screen and confirm" approach to select patients for sequential AOBP readings (Boonyasai et al., 2019). If the first BP reading is over 140/90 (or any threshold set by the location) by any means, it is confirmed with serial AOBP readings and then averaged to verify presence of potential hypertension. Research suggests that serial BP readings generally do not change the hypertensive classification of an individual if the initial BP is under 140/90 but do have an impact on 30% of those with an initial reading of over 140/90 (Boonyasai et al., 2019).

AOBP, especially unattended, has been shown to be more closely correlated with both ambulatory blood pressure readings (Bo et al., 2021; Pappaccogli et al., 2019) and risk for end-organ damage and cardiovascular outcomes (Andreadis et al., 2020; Elias & Goodell, 2021; Myers et al., 2018; Pappaccogli et al., 2019). Downsides cited in the literature include cost, incorporating protocols into busy practices, and the potential for increased time and space (Elias & Goodell, 2021). Sequential measurements at the same visit adds time, and ideally a quiet, designated space would be available, with a comfortable chair that allows for proper body positioning. This would streamline the process and standardize readings. AOBP has also been found in some studies to underestimate blood pressure at lower ranges (<130 SBP) (Bo et al., 2021), and to have reduced accuracy with irregular pulses; however, averaging of results counteracts this effect (Boonyasai et al., 2019).

Literature Regarding Automated versus Manual Blood Pressure Readings

Eleven of twelve studies reviewed concluded in favor of AOBP measurement over MOBP due to the factors described above, and most with the caveat that AOBP should be performed according to ACC/AHA recommended standards with a validated and calibrated device, capable of multiple sequential readings, while having the patient seated, with feet flat, in a quiet room, having rested for five minutes, with a properly sized cuff, on both arms, with arm below heart, without talking or interacting, and should be validated by a home blood pressure reading and/or one other office reading on a different day (Andreadis et al., 2020; Bo et al., 2021; Boonyasai et al., 2019; Elias & Goodell, 2021; Meidert & Saugel, 2018; Muniyandi et al., 2022; Muntner, Einhorn, et al., 2019; Myers et al., 2018; Pappaccogli et al., 2019; Roerecke et al., 2019; Sakhuja et al., 2022).

Two studies looked at sensitivity and specificity; one found both AOBP and MOBP similar in these indices (Bo et al., 2021), while the other found AOBP moderately accurate for diagnosing hypertension, with a sensitivity of 65.7% and a specificity of 95.9% (Muniyandi et al., 2022). One study compared both techniques to intraarterial blood pressure and found both to be lacking in accuracy, but with equal clinical utility in monitoring trends over time, especially in the outpatient setting (Meidert & Saugel, 2018). Two studies suggested that systematic error in blood pressure measurement, introduced through human error in MOBT, has resulted in gross overdiagnosis and misclassification of adult hypertension (Myers et al., 2018; Sakhuja et al., 2022).

Only one study, a systematic review of mixed quantitative studies, did not endorse AOBP over MOBP (Zhang et al., 2019). The authors pointed out that evidence linking AOBP with health outcomes were primarily retrospective in nature and that rigorous prospective studies were needed (Zhang et al., 2019). They also were concerned that using an AOBP-based treatment goal, which reads considerably lower than MOBP, would potentially result in adverse effects in the elderly, such as falls and kidney dysfunction (Zhang et al., 2019). Additionally, they suggested that if both modalities needed to be verified by a home BP, that the outcome would be similar and potentially not worth the investment of incorporating AOBP into standard practice (Zhang et al., 2019). They agreed that differences between the two methods were due to lack of training of staff and suggested that a cost-benefit analysis might conclude that investment in training on MOBP might be found to be cheaper than purchasing and implementing widespread AOBP in primary care settings (Zhang et al., 2019).

This analysis offers a unique perspective on some of the conclusions found in other literature in the field and proposes a valid gap in the debate: the lack of a “universally endorsed protocol” on how to incorporate and perform AOBP into clinical practice (Zhang et al., 2019). This gap in part helps explain the lack of adoption of AOBP in primary care settings, despite a wealth of evidence that shows better accuracy and health outcomes.

Barriers to adoption of AOBP in Primary Care

Barriers identified in the literature related to adoption of AOBP in clinical care fall into the domains of knowledge, attitudes, external factors, and clinical workflow challenges (Boonyasai et al., 2019). Knowledge barriers include lack of training programs for staff on AOBP equipment and use; and patient lack of knowledge on the data supporting AOBP, and the importance of their participation in the process (Boonyasai et al., 2019). Healthcare provider attitudes can be a barrier in that many were taught that MOBP is superior and may have developed a level of pride in their skill, as well as feeling that it facilitates closer connection with the patient (Boonyasai et al., 2019). Additionally, older and/or rural patients may not have a high level of trust in technology. External barriers include not having a designated space, equipped with a range of cuff sizes and furniture that allows for ergonomic body positioning (Boonyasai et al., 2019). Many may perceive a time barrier in workflow to incorporate AOBP into practice, without understanding that the ability to schedule unattended BP saves time overall (Boonyasai et al., 2019). Finally, the cost for a validated automated device that can take multiple sequential readings ranges from $550-1200, which could be perceived as a barrier (Boonyasai et al., 2019).

Gaps and Future Directions

Literature supporting the superiority of automated vs. manual blood pressure measurement for diagnosis and management of hypertension has been generated for nearly 20 years, and the endorsement of this method by most national and international healthcare organizations reflects the quality of evidence supporting its use. Opportunities to help progress adoption in primary care include development of policy and protocols for its use; and the provision of clinic level guidance, including evidence of blood pressure differentials and high-level literature syntheses to help clinicians digest a vast amount of peer-reviewed data.

Conceptual Model

The conceptual model that will guide this evidence-based practice project is Roger's Diffusion of Innovation theory (Rogers, 2003). This theory is often applied to research driven healthcare innovations (Dearing & Cox, 2018). Diffusion is defined as a social process of communication and adoption that occurs after introduction of an innovation and can often take many years to run the full course (Dearing & Cox, 2018). While time to adoption was the dependent variable of interest to Rogers, implementation itself is the focus for most healthcare initiatives (Dearing & Cox, 2018). Factors that are theorized to influence earlier implementation include societal and governmental attention to the problem, monetary factors, readiness for change, influential individuals or groups, targeted and organized efforts, and a general positive perception of the innovation (Dearing & Cox, 2018). Individual level factors include cost, time constraints, resource availability, simplicity of implementation, compatibility with current practices, and observable benefit (Dearing & Cox, 2018). Levels of adoption proposed by Rogers include innovators, early adopters, early majority, late majority, and laggards, with 68% of the population divided evenly between early and late majority (Dearing & Cox, 2018). Assessing and addressing these barriers, as well as enhancing awareness of incentives, is important when attempting to standardize an innovation (Dearing & Cox, 2018).

Extensive research supporting the use of automated blood pressure measurement (AOBP) over manual (MOBP) for diagnosis and management of hypertension in primary care practice has existed for 25 years, and yet only 61% of practices are estimated to use this technology in practice (Gulati et al., 2021; Muntner et al., 2019). Multiple healthcare organizations promote AOBP in primary care practice, including the American Heart Association, and the World Health Organization (Muntner et al., 2019; World Health Organization [WHO], 2020). Lack of standards and policies dictating exclusive use of AOBP, with guidelines on proper usage is proposed as a significant impediment to its adoption (Ordunez et al., 2022). This represents a lack of organized effort that was outlined above as a necessary factor in diffusion of an innovation (Dearing & Cox, 2018). In this scenario, the new innovation is evidence-based practice related to accurate blood pressure measurement, with governmental and societal influencers being large healthcare lobbying entities. This project will focus on one primary care clinic, located in the Piedmont area of North Carolina, and thus individual or clinic-level barriers to adoption. As per Rogers' model, they would fall in the Late Majority adopter range (Dearing & Cox, 2018). A needs assessment highlighted the following as primary barriers: perceived utility and benefit of the AOBP over MOBP; and perceived cost. An analysis of research related to the superiority of AOBP, as well as a proposed research-based protocol for its use in primary care practice is therefore needed to assist the clinic in performing a cost-benefit analysis that will allow them to make an informed decision on whether to adopt this technology into their practice.

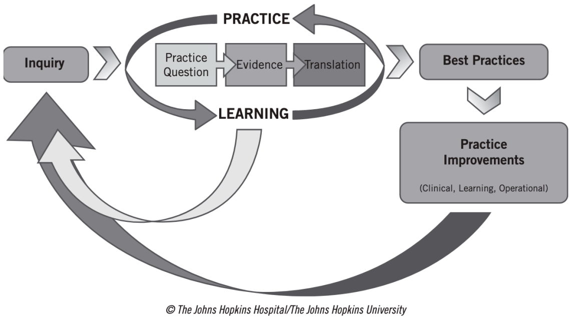
Methods

An analysis of published peer-reviewed literature, and clinical guidelines that draw upon that evidence, leads to a consensus that blood pressure measurements taken with an automated blood pressure monitor capable of multiple, timed, unattended measurements are more closely correlated with out-of-office blood pressure than those obtained through manual auscultatory modalities. This evidence will be combined with clinic-level measurement data to offer rationale for purchase of an automated blood pressure monitor and adoption of its use in primary care practice.

Design

Translational Framework

The translational framework selected for this project is the Johns Hopkins Evidence-Based Practice Model, which is commonly used for evidence-based practice (EBP) projects in healthcare settings (Dearholt & Dang, 2018).



(Dearholt & Dang, 2018, p. 36)

This framework, pictured in the image above, conceptualizes evidence-based practice changes to occur in three areas: Inquiry, Practice, and Learning, the entire process of which is cyclical in nature and may generate information that leads back to earlier stages (Dearholt & Dang, 2018). The process of Inquiry involves an individual or group formulating a question regarding whether their practice is based on current research. For this project, clinic staff have expressed their desire to evaluate the evidence regarding AOBP vs. MOBP for identification and management of hypertension in primary care practice. Inquiry leads to the PET process: Practice Question, Evidence, and Translation (Dearholt & Dang, 2018). This stage can cycle back to Inquiry, or lead to generation of Best Practices, and Process Improvements. Implementation of

EBP requires organizational support, effective leadership, internal champions, and development of process standards. Each stage of the PET process has a set of steps (Dearholt & Dang, 2018). The first stage, Practice Question, involves putting together a multidisciplinary team, defining the problem, developing the PICOT question, identifying stakeholders, outlining project leadership and roles, and scheduling team meetings (Dearholt & Dang, 2018). The next stage, Evidence, involves carrying out a literature review, appraising the level of quality, summarizing and synthesizing findings, and finally developing recommendations for change in practice (Dearholt & Dang, 2018). The final step of PET, Translation, includes evaluating the fit and feasibility of the recommendations for the organization, creating a plan to enact them, ensuring support and requisite resources, carrying out the plan, evaluating outcomes, reporting of outcomes to stakeholders, planning next steps, and finally disseminating findings to the broader public (Dearholt & Dang, 2018).

Population

The population for this project included adults, age 40 or older, who were patients at a primary care clinic located in a suburban area of North Carolina. While the United States Preventive Services Task Force recommends screening for hypertension in all adults over age 18 (United States Preventive Services Task Force [USPSTF], 2021), the prevalence of hypertension increases with age (Centers for Disease Control and Prevention [CDC], 2017). According to the CDC, only 7.5% of those age 18-39 have the disease, increasing to over one-third of those age 40-59, and 63% of those over age 60 (2017). Physiologic changes related to the cardiovascular system with age could convey greater variability in blood pressure readings, for which selection criteria were tailored. Gender, race, and chronic medical conditions were not exclusionary factors. The goal was to obtain measurements on a sample of at least 20 patients, to ensure a statistically meaningful effect size.

Setting

This project was conducted in a family-focused, primary care practice located in the Piedmont area of North Carolina. The practice is a subsidiary of a larger area medical system. Patient characteristics include a mix of suburban and rural status, income levels, and insurance coverages. The practice is served by six providers (three physicians, two nurse practitioners, and one physician's assistant), five certified medical assistants, one licensed practical nurse that conducts Medicare Wellness exams, one pharmacist, three front desk staff, and an office manager.

Project Implementation

The project involved provision of two items to the clinic that would assist them in their decision to purchase an automated blood pressure monitor: a summary of pertinent peer-reviewed literature, and clinic-level data on potential variation in manual blood pressure readings. In collaboration with the office manager, and approved by the medical director, a plan was developed to collect data that involved minimal deviation from established workflows. A meeting was held with office staff that would be involved in data collection, to discuss the project, and to obtain buy-in. The proposed plan involved selection of a subset of patients that would receive an additional manual blood pressure reading. Office protocol already dictated that patients with an elevated initial blood pressure reading would receive a second reading for verification. Data were based solely on variation in manual blood pressure readings, given the lack of automatic monitor at this site for comparison.

Material resources needed to carry out this project were minimal, including refreshments provided for the staff meeting, and printing of data collection sheets and protocol brochures. Time and effort for office staff to carry out data collection were also minimal, as a baseline blood pressure is normally collected on every patient for intake. Time to record minimal demographic data by the medical assistant or nurse, and a second manual blood pressure collection were the only additional time requirements.

An intake form, developed in collaboration with a University of North Carolina Greensboro (UNCG) data science consultant and the office manager of the clinic, was used to collect basic demographic data and blood pressure measurements.

Timeline and Critical Milestones

Milestones:	**Aug-Dec 2022**	**Jan-May 2023**	**June-July 2023**	**Aug-Dec 2023**	**Jan-May 2024**
Informal Needs Assessment	🟩				
Project Planning, including meeting with stakeholders	🟩	🟩			
Lit Review	🟩	🟩	🟩	🟩	🟩
Lit Synthesis	🟩	🟩			🟩
IRB Submission and Approval		🟩	🟩		
Data Collection			🟩	🟩	
Data Analysis			🟩	🟩	
Final revision and submission				🟩	🟩

IRB Approval

Patient data collected for this project was anonymous and de-identified. Patients were selected for inclusion based on a convenience sample of individuals 40 years of age or older, visiting the designated primary care clinic, for routine follow-up or episodic assessment of any health condition. Patient selection was performed by staff, who were instructed to, when feasible, select a group balanced in gender, with a broad range of ages from 40+, and with a variety of health conditions. Protocol at the clinic dictates that patients who have an initial BP reading greater than 140/90 automatically receive a recheck by the provider, and thus these patients were likely to be selected for data measurement. The data collected were part of normal care for these individuals, and involved minimal, if any, psychological, social, or economic risk, thus a waiver of consent was granted by both the UNCG and organizational IRB. Data intake forms were assigned a sequential number and did not include identifying information.

Steps implemented/How data were collected

The form used to collect data, included in the attachments, was developed in coordination with the office manager and the data science consultant at University of North Carolina Greensboro (UNCG), and includes a sequential number in place of an identifier; baseline demographic information such as age, gender, race, and hypertension diagnosis status; and space for recording first and second manual blood pressure readings, with the time recorded and type of provider noted. The goal was to analyze potential variation in manual blood pressure measurements over time and between observers that lend evidence to its variability per individual.

A project meeting was held for office staff and was attended by all medical assistants. This meeting involved reviewing the project, why it was being conducted, how it would be carried out, and their role in data collection. Intake for every patient at this clinic involves seating of the patient in the examination room, with a medical assistant taking vital signs that include a manual blood pressure. These staff members, assisted by the office manager, oversaw selection of at least 20 patients to receive a second manual blood pressure reading by any type of provider. The staff member would then fill out the basic demographic information for that patient and inform the PCP of the initial elevated blood pressure and need for recording of a second reading. Forms were collected in deposit box in a convenient clinic location. This process was carried out over a three-month period. Forty de-identified patients received two blood pressure readings with recording on the project data collection form.

Data Analysis

A two-sample paired T-test for equality of means was carried out, using the data analysis package in Microsoft Excel, to assess whether there was a statistically significant difference between the first and second systolic and diastolic blood pressure readings that were recorded on the same patient at the same visit. A result, or P-value, is considered significant if it is less than an alpha level set at 0.05. The hypothesis is that there will be a significant difference between the two blood pressure readings (both systolic and diastolic) recorded on the same patient at the same visit. The null hypothesis is that there is no significant difference between first and second blood pressure readings taken on the same patient at the same visit. To reject the null hypothesis, the resulting P value must be less than 0.05.

Results

Age	# of individuals
40's	3
50's	7
60's	14
70's	12
80's	1
Unknown	1

Table 1: Age distribution of Participants by Decade

Ethnicity	# of individuals
Black	17
Hispanic	2
White	18
Other	1
Blank	1

Table 2: Ethnicity distribution of participants

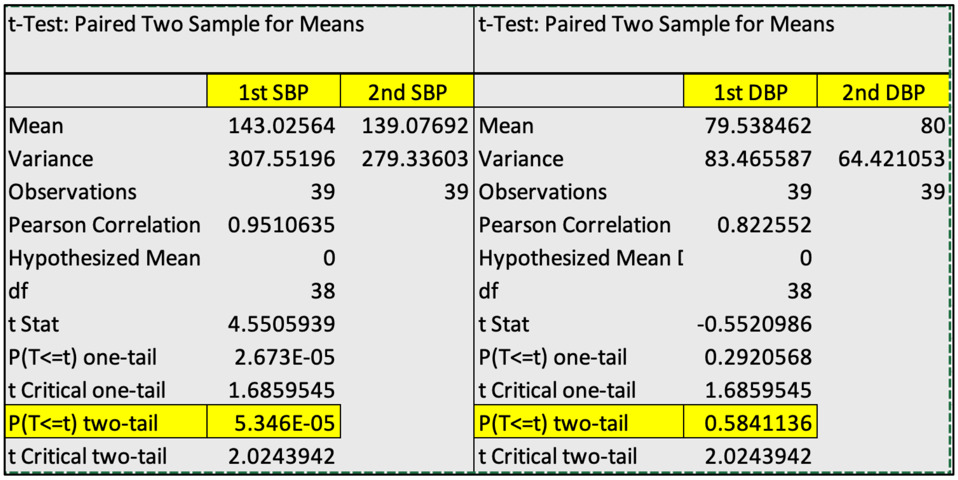
A minimum population of 15 individuals was determined to be needed to lend validity to the results. A sample population of 40 was randomly selected by staff for a second manual blood pressure measurement, however there was no second blood pressure reading recorded for one individual, and hence the final sample size was 39. The sample was balanced in gender, with 18 female, 20 male individuals, and one left blank. The age range was 42-81, with the average age being 63. Table 1 above describes age distribution by decade; Table 2 describes ethnicity distribution.

Eight individuals had not already been diagnosed with hypertension, while 29 were already known to be hypertensive, and two were left blank on diagnostic status. All blood pressures were collected by certified medical assistants (CMAs), and while the data was not collected, it was relayed that in most cases the second reading was by the same CMA.

A two-sample paired T-test for equality of means yielded a P score of 5.34577E-05 for the variance between first and second manual systolic blood pressure readings, and a P score of 0.58 for the variance between first and second manual diastolic blood pressure readings. The systolic P score is a negative number, which is less than the alpha level of significance set at 0.05, for which we would reject the null hypothesis that there is no significant difference between the first and second systolic blood pressure readings, taken on the same patient at the same visit. Therefore, this data supports the hypothesis that manual systolic blood pressure readings vary on the same patient over time on a single visit.

The diastolic P value is greater than 0.05, and therefore we must accept the null hypothesis that there is no significant difference between diastolic blood pressure readings under these same circumstances. The data does not support the hypothesis that diastolic blood pressures will vary over time.

Table 3 below shows the P statistic calculations for systolic and diastolic blood pressures respectively. Table 4 shows the box plots of differences in means for systolic and diastolic blood pressures and illustrates that there was an even distribution without outliers.



t-Test: Paired Two Sample for Means

	1st SBP	2nd SBP
Mean	143.02564	139.07692
Variance	307.55196	279.33603
Observations	39	39
Pearson Correlation	0.9510635	
Hypothesized Mean	0	
df	38	
t Stat	4.5505939	
P(T<=t) one-tail	2.673E-05	
t Critical one-tail	1.6859545	
P(T<=t) two-tail	5.346E-05	
t Critical two-tail	2.0243942	

t-Test: Paired Two Sample for Means

	1st DBP	2nd DBP
Mean	79.538462	80
Variance	83.465587	64.421053
Observations	39	39
Pearson Correlation	0.822552	
Hypothesized Mean	0	
df	38	
t Stat	-0.5520986	
P(T<=t) one-tail	0.2920568	
t Critical one-tail	1.6859545	
P(T<=t) two-tail	0.5841136	
t Critical two-tail	2.0243942	

Table 3: Two-Sample t-test for Means Systolic and Diastolic Blood Pressure Values

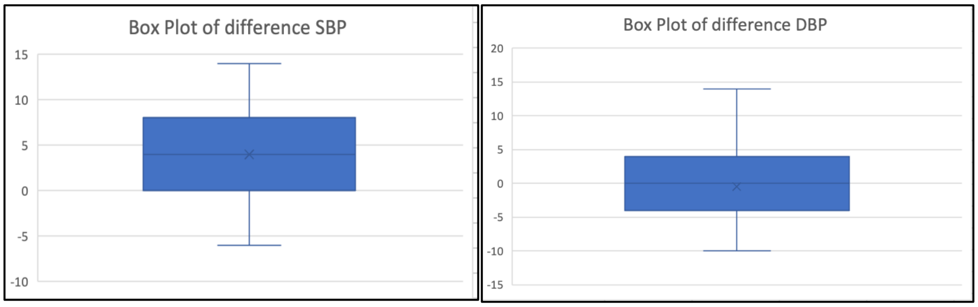


Table 4: Box Plots of differences in means for Systolic and Diastolic Blood Pressure Values

Barriers to Success

The original PICOT question asked whether there would be a difference in blood pressure readings taken on the same patient, at the same visit, at two different time points, and by two different types of providers. The flow of the clinic where this was conducted, however, typically involved the same certified medical assistant (CMA) retaking the blood pressure on a patient if the first one was elevated. In retrospect, a tracking element could have been added to the data collection form to verify whether it was the same person who collected the second blood pressure reading. This data point would have given information on variability between individuals collecting manual blood pressure readings. The results show variability as a factor of time only.

After conceptualization of the project, the clinic staff received an in-service training on how to properly collect a manual blood pressure reading, which could have led to minimization of variability in blood pressure readings collected during the data collection period.

Strengths to Overcome Barriers

The number of data points needed to lend statistical validity to the results was estimated to be 15. Full data was collected on 39 patients, which increases the validity of the results. All project activities were conducted within the projected timeline, and no modifications to the process were necessary.

Discussion

Overview of Project Design

The purpose of this project was to optimize the accuracy of blood pressure measurement in a suburban primary care clinic that relies on manual blood pressure measurement. A discussion with the office manager revealed an interest in purchasing an automated monitor, but a need for clinic-level data showing variability in manual blood pressure readings, as well as an updated review of the literature concerning the superiority of automated monitoring, that would help them to justify their decision. To obtain requisite clinic-level data, a set of two manual blood pressure readings were collected on a group of 40 patients at different time points at the same visit. These data points were then analyzed for variability between readings.

Summary of Results and Interpretation

The results of this project exhibited statistically significant variability in systolic blood pressure readings at this primary care clinic after a rest period with manual measurement, with systolic BP readings being consistently lower on the second reading. While not documented, anecdotally it was conveyed that the same individual measured both BP readings in most circumstances, and thus a drop in systolic and stable diastolic reading would be expected after a rest period and reflects the literature. If the two readings had been obtained by two different individuals, then there might have been greater variability in both systolic and diastolic readings, due to inter-reader differences, such as hearing, training, cuff-inflation, or interaction.

While automated office blood pressure monitoring should ideally be performed after a rest period, several meta-analyses of published studies have shown that it can be performed with equal accuracy regardless of this recommendation (Boonyasai et al., 2019; Myers et al., 2018; Pappaccogli et al., 2019). Recommended automated monitors also allow for averaging of multiple sequential readings, which literature suggests enhances accuracy, and considers the range of an individual's blood pressure response over time in the clinical setting (Boonyasai et al., 2019). These findings thus support the utility of automated monitors to counteract the need for a rest period for accurate outcomes.

Conceptual Framework and Correlation with Project Implementation

Reflecting on Roger's Diffusion of Innovation Theory and the individual level barriers identified for this clinic, including perceived utility and cost, the results of this project provide evidence that help to overcome these barriers. Both peer-reviewed literature and clinic-level data on variability in manual blood pressure measurement are provided to overcome the barrier of perceived utility. Peer-reviewed literature outlined in the Review of Evidence shows that automated blood pressure monitoring is more accurate than manual, requires less skill to perform, can be performed unattended, takes less time to perform, is supported by national and international guidelines, and eliminates the effects of white coat and masked hypertension. The project results provide evidence of variability in manual blood pressure readings at this clinic on the same patient at the same visit. A cost analysis shows that the average cost of a General Electric Dinamap brand vital signs monitor, which is frequently used in both primary and acute care settings, is $1,079 (Medical Price Online, 2023). There are five CMAs at this clinic, which translates to a total cost of $5,395, although all CMAs may not be scheduled simultaneously, in which case fewer monitors would be needed. Additional costs may include service packages for maintaining equipment.

Translational Framework and Correlation with Project Implementation

The Johns Hopkins Evidence-Based Practice Model was used to guide translation of evidence into practice for this project. In the Inquiry step, the clinic brought forth a practice question on whether automated blood pressure monitoring was superior to manual monitoring in primary care practice. The Inquiry stage involved the three PET steps: Practice Question, Evidence, and Translation (Dang & Dearholt, 2018). The Practice Question (step 1) was formulated, the team of stakeholders was put together to collect evidence, including the DNP student, the medical director, the practice manager, and the CMAs; the Evidence was collected (step 2), including the literature review and the clinic level blood pressure data; and finally the project has entered the Translation step (step 3). In this step the fit and feasibility of automated blood pressure monitoring will be evaluated for this clinic after presentation of findings to the stakeholder team. If the evidence is compelling to them, then a plan for adoption of automated monitoring will be made, resources secured, and outcomes evaluated and disseminated. This will lead to adoption of Best Practices and Practice Improvements as per the Johns Hopkins Model (Dang & Dearholt, 2018).

Relevance and Recommendations for Primary Care Practice

Thirty-nine percent of healthcare practices continue to rely on manual blood pressure measurement, despite a wealth of peer-reviewed literature and expert panel consensus briefings in favor of automated monitoring (Gulati et al., 2021). This project can serve as a framework for practices to assist in their decision-making processes, through analysis of their own practices and synthesis of current literature related to optimized diagnosis and management of patients with hypertension.

Limitations

While it was anticipated that systolic blood pressure would trend downward on the second reading, the amount of time between readings varied greatly from four to 53 minutes, with an average of 48 minutes, which renders it difficult to correlate amount of time with a potential decrease in systolic blood pressure. It was also not anticipated that CMAs would receive an in-service training on how to properly perform a manual BP reading, which may have had an impact on potential variability in readings. Finally, it was originally conceived that the primary care provider would be taking the second BP after the CMA alerted them to a high initial reading, which would have provided data on variability between different types of health care professionals.

Recommendations for Future Study

A side-by-side comparison of automated versus manual blood pressure readings on the same patient at the same visit would provide more direct evidence on potential differences between the two modalities and would be a favorable addition to future projects. Additional recommendations include controlling for time between readings for consistency; and ensuring that different types of health care professionals, or at minimum different individuals, obtain the two readings, which would help exhibit variance in BP readings that occurs between individuals.

Conclusion

Hypertension is one of the most common diseases impacting adults worldwide, the control of which could drastically reduce morbidity and mortality from heart disease, kidney disease, and stroke. It is a primary focus for healthcare advocacy, and yet most individuals with the disease are not being optimally treated, which could be directly linked to inaccurate measurement of their blood pressure on clinical encounters where decisions are made. These snapshots of a patient’s health are often the only information providers receive that guide medical management of the disease. Accurate blood pressure measurement in the clinical setting is thus imperative for proper treatment. Evidence-based practice favors the superiority of automated blood pressure measurement, making it critical to disseminate this knowledge to primary care providers and practices, and to replicate projects such as this one that help to influence adoption of best-practices in healthcare settings. This project will be disseminated at the project site, and its member organization, through brief presentation; professional peers at University of North Carolina Greensboro, through poster presentation; future healthcare organization employment sites, through peer discussion and presentation; and professional conferences, such as the North Carolina Nurses Association. Sustainability of the project at the project site is favorable, considering that automated measurement is relatively inexpensive, offers consistency, saves time, allows unattended measurement, and requires little training to perform accurately.

Summary

In summary, evidence clearly supports the use of automated blood pressure monitoring over manual for the diagnosis and management of hypertension. The results of this project support the variability in manual measurement over time, and the need for a rest period for accurate readings, a requirement that has been found unnecessary for automated measurement. The hypertension epidemic will not be adequately addressed without the use of the most accurate blood pressure measurement modality, and therefore it is critical for primary care practices and providers to be aware of evidence-based practice recommendations for automated blood pressure monitoring.

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Appendix A: Data Collection Form

Repeated Manual Blood Pressure Data Collection Form
DNP Project: Kara Fore-Flores

Instructions: *Patients selected for a repeat blood pressure should be adults, older than 40 years, preferably diverse in age, gender, and race. They can have any medical condition(s). Please do* ***not*** *place any identifying information for the patient on this form (ie: name, DOB, SSN, physical description, contact information, MRN).*

Anonymous Sequential Numeric Identifier: (*Forms will be assigned the numbers 1-30*)

Demographics:

Age: ____________

Biological Sex *(Gender assigned at birth)*:

○ M
○ F

Race/Ethnicity:

○ Hispanic
○ Black
○ White
○ Asian
○ Other

Has this patient been diagnosed with Hypertension?

○ Yes
○ No

Manual Blood Pressure #1: _______________________

Time Recorded: _________________________

Type of Staff Member: *(Please select one and do* ***not*** *identify yourself)*

○ Certified Medical Assistant
○ Licensed Practical Nurse
○ Registered Nurse
○ Physician
○ Nurse Practitioner
○ Physician's Assistant

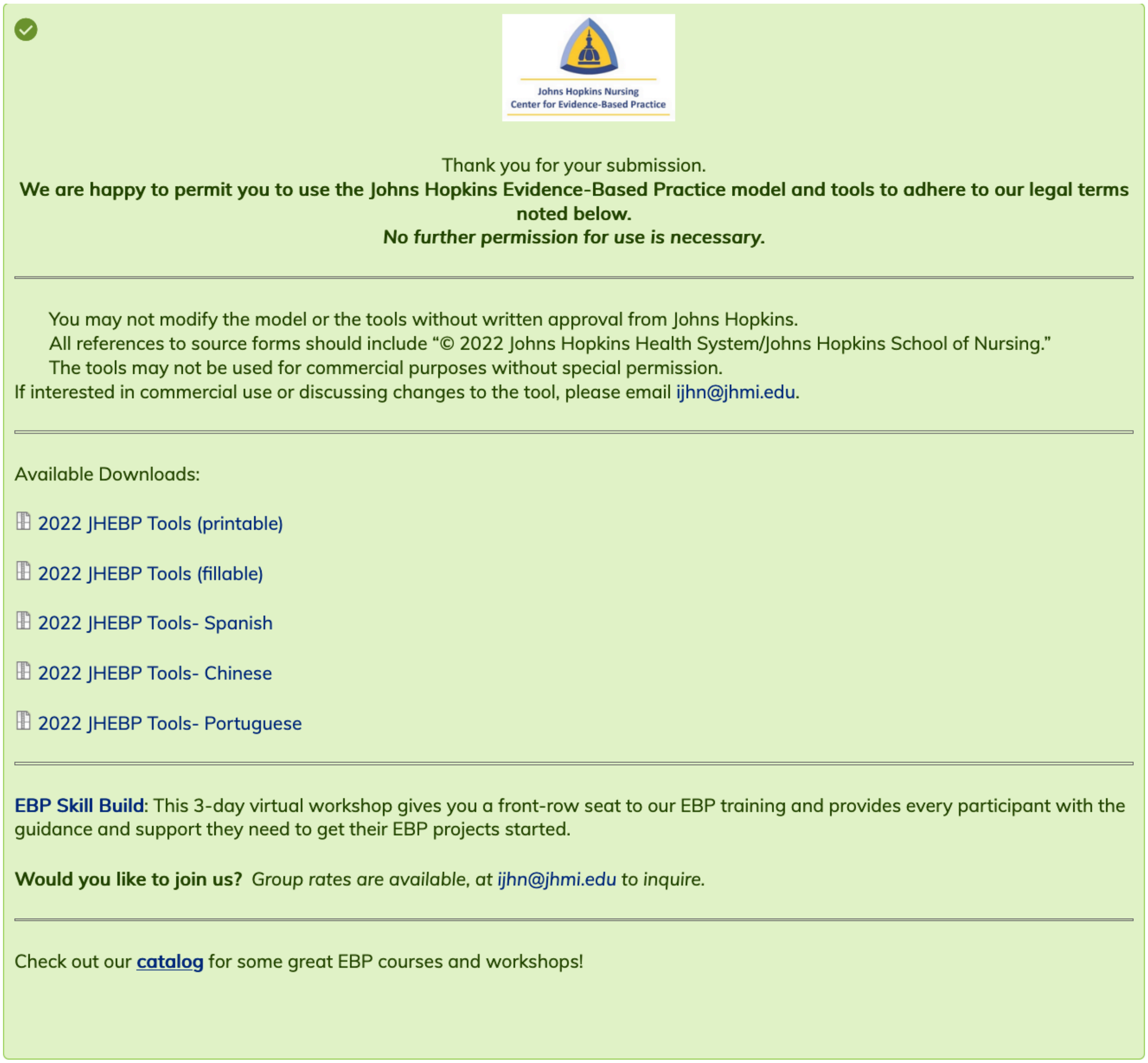
Manual Blood Pressure #2: ______________________

Time Recorded: ________________________

Type of Staff Member: *(Please select one and do* ***not*** *identify yourself)*

○ Certified Medical Assistant
○ Licensed Practical Nurse
○ Registered Nurse
○ Physician
○ Nurse Practitioner
○ Physician's Assistant

Appendix B: Johns Hopkins EBP Model and Tools Permission



Thank you for your submission.

We are happy to permit you to use the Johns Hopkins Evidence-Based Practice model and tools to adhere to our legal terms noted below.

No further permission for use is necessary.

You may not modify the model or the tools without written approval from Johns Hopkins.
All references to source forms should include "© 2022 Johns Hopkins Health System/Johns Hopkins School of Nursing."
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Available Downloads:

2022 JHEBP Tools (printable)

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