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Automated Office Blood Pressure (AOBP) Monitoring for Diagnosis of Hypertension

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PROPOSAL ABSTRACT/IMPACT STATEMENT

PROPOSAL ABSTRACT

Phase II Site(s): Keesler Medical Center, Keesler AFB, Mississippi

Project Title: Automated Office Blood Pressure Monitoring for the Diagnosis of Hypertension

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Background: White coat hypertension (WCHT) can be detected in up to 23% of patients diagnosed with essential hypertension (HTN). American Heart Association (AHA) guidelines state that elevated blood pressure readings should be confirmed with an ambulatory blood pressure monitor (ABPM) or home blood pressure monitoring (HBPM). The Keesler AFB Military Treatment Facility (MTF) is unable to issue ABPMs for patient use, and inconsistent HBPM has occurred, leading to under or over-diagnosis of HTN. Evidence based practice (EBP) shows that automated office blood pressure (AOBP) can effectively distinguish WCHT from HTN and correlate to results of an ABPM.

Clinical Question: Would the implementation of an AOBP system lower the number of patients with ICD-10 diagnoses of R03.0 "Elevated blood pressure without diagnosis of hypertension" and differentiate WCHT from HTN?

Project Design: This project was conducted in the Family Health Clinic (FHC). The Iowa Model of EMP was used as the organizing framework. A three-month retrospective review of encounters with the diagnosis code "R03.0" were reviewed to establish a baseline number of patients with an indeterminable elevated BP. Clinic providers and staff were then educated on the use of the AOBP system. The AOBP system was implemented for a three-month period. A review of the number of R03.0 coded encounters during this implementation was then conducted. These results were compared to the baseline data collected.

Analysis of the Results: 15 patients were enrolled in the implementation. 33% were diagnosed with HTN. A statistically significant difference was found between pre and post implementation values of R03.0 coded encounters, showing the AOBP differentiated between WCHT and HTN.

Implications for Practice: The incorporation of the AOBP system into the FHC for use of BP analysis in patients presenting with elevated BP, reduced the number of R03.0 diagnoses and identified HTN, leading to earlier HTN treatment.

APPROVED:

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31 Mar 2021

(Date)

Form Version: 26 Aug 2017

AOBP Monitoring for Diagnosis of Hypertension

Hypertension (HTN) is a complex medical diagnosis that has the potential to cause target organ damage, morbidity, and mortality. Approximately 95 percent of all HTN diagnoses are labeled as primary, or essential, HTN and have no known cause (Buttaro, Trybulski, Bailey, & Sandberg-Cook, 2017). According to the Centers for Disease Control (CDC) (2016), the total associated costs for treatment of HTN in the United States reached \$48.6 billion. Costs included in this figure are healthcare services, medications, and missed days of work (CDC, 2016). The economic impact combined with the nationwide morbidity and mortality resulting from HTN warrants attention (CDC, 2016). White coat hypertension (WCHT) is a syndrome where the patient's blood pressure is elevated while in clinic but falls within guidelines when assessed outside of the clinic (AHA, 2019). Of patients diagnosed with HTN, nearly 23 percent of cases can be attributed to WCHT and lead to unnecessary treatment (Omboni, et al, 2016). Given this information, the focus of this project was to introduce the use of Automated Office Blood Pressure (AOBP) measurements into practice to aid with accurately diagnosing HTN, thus differentiating it from WCHT. The aim of this project was to integrate AOBP measurements in the primary care clinic for patients that presented for their appointment with elevated blood pressures in the absence of a prior HTN diagnosis. The goal of this project was to establish an alternative, accurate, and cost-effective method for the 81st Medical Group (MDG) to differentiate between essential HTN and WCHT.

Significance of the Problem

According to the CDC (2016), an estimated 75 million American adults have high blood pressure, and another 1-in-3 American adults have prehypertension. This was a primary or contributing cause of death for more than 410,000 Americans in 2014, which equates to more

than 1,100 deaths each day (CDC, 2016). 81st MDG leadership identified an increased number of WCHT diagnoses. Current American Heart Association (AHA) guidelines state that elevated blood pressure readings in the clinic should be confirmed by a 24-hour ambulatory blood pressure monitor (ABPM) or home blood pressure monitor (HBPM) before the diagnosis of HTN can be established (AHA, 2015). However, the 81st MDG was unable to issue ABPMs for patient use due to budget constraints. Their process for further evaluating elevated blood pressure readings varied significantly from no monitoring at all, to having the patient maintain a 5-day or 10-day HBPM log. These methods can be inconsistent and unreliable for various reasons. Examples include: patients not returning to the clinic with their blood pressure logs for follow-up visits or patients may lack equipment at home to monitor their BP. The 81st MDG leadership was seeking an effective solution for improved diagnostic blood pressure readings. It was proposed that having a consistent, automated, and reliable method of obtaining patient blood pressures in the clinic would enhance the ability of healthcare providers to distinguish between clinical HTN and WCHT.

Military Nursing Significance

Mission readiness is at the forefront of military medicine and the importance of diagnosing and efficiently treating the active-duty population is vital to operations, manpower, and unit integrity. Across the Department of Defense (DoD) and more specifically, the Military Health System (MHS), the theme of trying to eliminate unnecessary costs is quite common. Within the MHS, having the ability to streamline the diagnosis of HTN by using an alternative, efficient, and cost-effective means would garner significant support. With this intervention in place, there is potential to improve standardization, minimize incorrect blood pressure measurements, and avoid over or under treatment of HTN (Cheng, Bhalla, & Chang, 2019). This,

in turn, would save the DoD money by preventing unnecessary prescriptions and follow-up visits. Furthermore, correctly diagnosing an active duty patient will allow for the correct medical management to be provided earlier in the disease process. This could allow for a patient to be world-wide qualified for deployment quicker, as their BP could be stabilized earlier in the HTN process. The data provided through this project could contribute to providing more accurate diagnoses of essential HTN and could help to sustain a medically ready active-duty population in the future.

Clinical Question

Would the implementation of an AOBP system lower the number of patients with the International Classification of Disease (ICD-10) diagnosis of R03.0 “Elevated blood pressure without diagnosis of hypertension” and differentiate WCHT from HTN?

Literature Review of Solutions

The PICO question utilized to search the literature was: In adult patients visiting the Family Health Clinic (FHC) (P) would the use of an AOBP monitoring system (I) in comparison to standard blood pressure measurements during the clinic visit or HBPM (C) reduce the number of R03.0 diagnoses and differentiate WCHT from HTN (O)? A literature review was conducted using the databases of PubMed and CINAHL. Phrases included in the search criteria included research articles based on "automated office blood pressure", "white coat hypertension", and "primary care". Search filter limitations were placed for the past 10-years and clinical trials for higher levels of evidence. After evaluating all related articles following removal of duplicates, clinical settings not pertaining to FHC, differing population groups such as pediatrics and geriatrics, and non-clinical trials, the total articles found for inclusion to our project were six. Pediatrics and geriatric populations were excluded as they were outside our population of interest

and presented with more comorbidities than HTN alone. From the literature reviewed, there was evidence to show that the incorporation of an AOBP monitor can differentiate WCHT from clinical HTN as it matches closely to results obtained by the AHA gold standard of ABPM (Cheng, Bella, and Chan, 2019) and (Myers, 2011). To maximize the effect of AOBP monitoring, it was set to take patient blood pressures in intervals for at least 10-minutes in a quiet room without provider presence (Myers, 2011). The use of AOBP monitoring differentiated WCHT from clinical HTN in a drop from 55%-18% of patients utilizing the cut off of > 20 mmHg systolic and > 10 mmHg diastolic (Myers, 2009). For pre-existing hypertensive patients, Beckett & Goodwin (2005) identified a correlation of 135/85 most associated with a ABPM mean of 140/90.

Focus Area

The focus area for the project was to implement AOBP monitoring with the intent to create an effective screening method and obtain a more accurate blood pressure measurement within the outpatient, primary care clinic setting. Research articles were analyzed covering AOBP monitoring and provided evidence in support of our goal to diagnose HTN and differentiate from WCHT. The primary aim was to compare the previous data on the number of R03.0 ICD-10 diagnoses made prior to initiation of the AOBP system to the number of R03.0 diagnoses after project completion. The project aimed to reduce the overall number of R03.0 diagnoses with a feasible and sustainable solution.

Organizing Framework

The Iowa Model of evidence-based practice (EBP) to promote quality care was used to improve the quality of care in the clinical setting. This model focused on a conceptual framework to ensure change was sustainable and allowed clinical personnel to question whether care could

be improved using research findings (Titler et al., 2001). This model was selected because it focused on organization and collaboration with other providers and encouraged the use of EBP research to initiate change. Furthermore, it provided an organized conceptual framework to guide the implementation of the project (White, Dudley-Brown, & Terhaar, 2016). During implementation of the project, the Iowa Model of EBP was used to promote quality care algorithms to guide the project design. The steps used in this model required an identification of the problem and determination of whether it was a knowledge or problem focused trigger, determination of whether the problem was a priority for the organization, and formulation of a team. The second part of this model required the team to assemble, critique, and synthesize research for use in practice, and determine if a change was appropriate for adoption into practice (Steelman, 2016).

This stepwise approach used in the Iowa Model of EBP to promote quality care helped guide the project design, research solutions, and change implementation. Determining the priority of the organization by speaking with 81st MDG leadership was one of many examples of how the Iowa Model of EBP was adapted to promote quality care. Critiquing and synthesizing research and receiving acceptance from the clinical team at the 81st MDG were also essential steps that were adopted from the Iowa Model.

Project Design

General Approach

This process improvement (PI), EBP project focused on the education and implementation of AOBP measurements in the outpatient clinical setting to diagnose essential HTN and differentiate it from WCHT. A retrospective electronic health record (EHR) review was conducted that identified patients with the R03.0 ICD-10 code, based on HBPM and clinic

blood pressure readings, to formulate a better understanding of the prevalence of this issue. Next, an educational in-service on the proper use of AOBP machines was conducted for FHC providers, nurses, and technicians. Following the in-service, the team implemented the use of AOBP machines on the previously specified patient population that presented to the clinic with a blood pressure > 140/90, in accordance with the Eight Joint National Committee (JNC-8) recommendations for treatment. An Armed Forces Health Longitudinal Technology Application (ALHTA) current procedural terminology (CPT) code, 200F, was designated to chart when AOBP was utilized. Data was collected for three months on the number of R03.0 diagnoses and the number of times that the AOBP was utilized. After the implementation time frame, encounters with the R03.0 code were reviewed to re-assess the prevalence of the diagnosis within the FHC.

Initial implementation of this project was to be established in the active duty Warrior Clinic for best military operational significance. However, due to the effects of the Covid-19 pandemic, the Warrior Clinic could not support the team's project implementation. The team was based in the FHC as directed by the 81st MDG leadership. Other barriers that the team encountered included: limited in person visits due to the Covid-19 pandemic, patient participation, extended appointment times due to utilizing the AOBP, provider bias on using the AOBP over HBPM, and the use of only one AOBP machine. The team's Phase 2 site director (P2SD) acquired one AOBP machine that was designated for project use.

Setting and Population

Keesler AFB is located in Biloxi, Mississippi. It is home to the 81st Training Wing, 2nd Air Force, and the 403rd Air Force Reserve Wing (Keesler AFB, 2019). The base serves as an education center to more than 160 courses that trains members in all branches of service and

approximately 30,000 students annually (Keesler AFB, 2019). The project took place at the 81st MDG's FHC. The staff members included primary care managers, nurses, and medical technicians, along with administrative staff and leadership (J. Varney, personal communication, October 27, 2019). The 81st MDG serves 25,000 enrollees annually (Keesler AFB, 2019). The FHC is designed to see retirees and adult family members as patients. The intervention focused on adult patients greater than the age of 18. The project team worked with clinic providers, nurses, and technicians, to identify patients that qualified for the project. The ideal candidates were those with suspected WCHT, in an effort to differentiate it from essential HTN, by utilizing the AOBP machine in the FHC.

Procedural Steps

This project utilized the implementation of AOBP and the evaluation of provider knowledge on its use in the primary care setting. Exclusion criteria were created based on provider feedback to eliminate potential causes for falsely elevated blood pressure. These steps outlined the planning, implementation, and evaluation of the project.

First, following the Iowa Model of EBP (Titler et al., 2001), the problem of WCHT was identified through key stakeholders at the 81st MDG. With the increasing number of beneficiaries empaneled to the Military Treatment Facility (MTF), identifying elevated blood pressure as WCHT versus clinical HTN was a priority focus for 81st MDG leadership. Improving accuracy of diagnosis in these patients served as the overarching goal as it would improve clinical management, alleviate unnecessary prescriptions, and decrease costs. With the identified problem selected, the project team was formed. A literature review was conducted yielding evidence in the use of AOBP systems that correlated to systolic and diastolic readings produced by 24-hour ABPMs. Evidence was also considered to determine the ideal setting

AOBP should be utilized in, what qualified as elevated blood pressure on AOBP readings, and how long the patient would need to be monitored by the machine.

Next, the results of the literature review were communicated to the P2SD and one AOBP machine was purchased. Important team members were then identified in collaboration with the P2SD, to include FHC leadership, providers, nurses, and clinic technicians. Training on the AOBP was provided to all clinic personnel. This in-service covered the significance of the AOBP assessment, its close correlation to 24-hour ABPM readings, the inclusion and exclusion criteria for AOBP assessment candidates, informing and educating patients about the assessment, and translating the results into clinical management.

A retrospective data review for ICD-10 diagnosis code R03.0 was conducted next. Institutional Review Board (IRB) approval was obtained in order to collect data on patients previously visiting the clinic with the ICD-10 R03.0 diagnosis. No personally identifiable information (PII) was collected. Following the retrospective review, the implementation of the AOBP in the FHC was initiated. Each patient signed a created HIPPA form IAW IRB policy (Appendix E). Providers and technicians who performed initial vital sign assessments on patients were instructed that for those patients presenting with a blood pressure > 140/90, an AOBP screening should be performed. This parameter was set in accordance with (IAW) the JNC-8 guidelines. Additionally, providers were able to write an order for an AOBP screening based on their clinical assessment of the patient.

To conduct the AOBP assessment, those patients meeting inclusion criteria were seated in a designated room by clinic staff and the AOBP cuff was attached to the patient's left arm. The staff member then powered on the AOBP machine and informed the patient that they would be leaving the room, but would return in approximately 10-minutes, once the assessment was

complete. The AOBP machine was pre-programmed to then take three serial blood pressure readings over a 10-minute time frame. Upon completion of the serial readings, the AOBP machine calculated the patient's mean systolic and diastolic blood pressures based on the collected data. Patients with no prior history of HTN that had an elevated blood pressure on initial check-in had an AOBP assessment performed at the conclusion of their visit. Exclusion criteria included having a previous diagnosis of HTN, a current prescription for HTN medications, severe acute pain, or encountering a recent stressful event or injury. Providers closed their patient encounters with the diagnosis code of "Z71.1, no diagnosis", prior to the initiation of the AOBP. If the patient's blood pressure was elevated according to JNC-8 guidelines, the patient was diagnosed with code "I10, Essential Hypertension". If the patient's blood pressure was not elevated based on JNC-8 guidelines, the patient was given an "R03.0" diagnosis. The procedure code, "200F", was used to designate that the AOBP monitor was utilized. After collecting results, a telephone consult was placed to the originating provider discussing the readings from the AOBP so a plan of care could be generated.

Data collection was completed utilizing a chi-square statistical measure to show the number of R03.0 diagnoses prior to project implementation in comparison to the number of R03.0 diagnoses after implementation. The number of times the AOBP was utilized was assessed by utilizing the previously mentioned diagnosis code.

Due to clinic staffing constraints, the team created a rotating schedule that designated one project team member, to include the P2SD, as the daily AOBP *champion*. This *champion* assumed the responsibility of ensuring that AOBP patients were properly screened in an accurate and timely fashion. This also alleviated the potential for clinic workflow disruptions and

minimized any inconsistencies with the AOBP assessment. A nurse or provider *champion* could be trained on how to use the AOBP system to ensure future sustainment in the FHC.

Data Analysis Plan

Data was analyzed based on independent and dependent variables established in the data plan. The independent variable identified is the initiation of the AOBP monitoring system, following in-service training for all providers, nurses, and clinic support staff. This in-service training provided general knowledge on the use of the AOBP machine, when to use it, and how to document HTN versus normotensive readings. This was a process measure. The independent variable will be documented as “before” and “after” training.

The dependent variable was the outcome measurement that looked at the number of R03.0 ICD-10 diagnoses in the three-month period before initiation of AOBP and the three-month period after initiation. The R03.0 ICD-10 code was utilized when a patient’s blood pressure was elevated, but the provider was unsure if the patient had HTN. Having an elevated blood pressure without the diagnosis of HTN is characteristic of WCHT. Through the initiation of the AOBP system it eliminated those patients that fell into the unclassified blood pressure category and diagnosed them as either having HTN or a normal blood pressure. Parametric statistics were implemented to evaluate these variables.

JNC-8 guidelines were used for the diagnosis of HTN. The JNC-8 guidelines defined HTN as a blood pressure $> 140/90$. The literature showed that the use of an AOBP has a high correlation to an ABPM, which is recommended by the AHA for diagnosis of HTN (Cheng et al, 2018). The AOBP was utilized for 10-minutes based on the literature by Myers et al. (2011) showing that this time period provided an accurate depiction of the patient’s blood pressure.

Potential Barriers

Potential barriers that were identified during the implementation phase of this project included patient participation, provider buy-in, lack of properly identifying patient candidates, and lack of having more than one AOBP machine. During the project implementation, patients with elevated BP were screened on the AOBP system. This created longer appointment times for the patient and had the potential to decrease patient participation. To optimize patient participation, a thorough explanation of the procedure and its importance were explained. Provider buy-in biases were minimized through in-service education and by assigning unit *champions* to assist with the implementation of AOBP assessments during the PI process and after leaving the 81st MDG. Refresher in-service training was conducted regularly to remind the providers that the PI project was ongoing and a schedule showing the daily project point of contact was posted on the clinic huddle board.

There was only one AOBP machine in the FHC at the 81st MDG. This created a continual barrier due to the lack of availability of additional machines if multiple patients required screening at the same time. Each AOBP assessment takes approximately 10-minutes to complete (Myers, 2011). If there is no AOBP machine available when a qualifying patient is in the clinic, it created appointment delays and potentially led to decreased customer satisfaction. To alleviate this problem, the suggestion of acquiring additional AOBP machines was made. Each AOBP machine costs \$650 (J. Varney, personal communication, February 12, 2020). Additional funding was not available for the purchase of a second machine during project implementation.

Sustainment and Dissemination Plan

The Iowa Model of EBP to promote quality care identified the importance of the organization's buy-in. Receiving acceptance from the 81st MDG leadership was vital to implementing the PI project. Upon completion of the EBP, FHC providers were briefed on the findings. Additionally, staff received refresher training on how to conduct an AOBP assessment and were educated on the HTN qualification guidelines. The trained clinical staff were provided a copy of the procedural steps for reference. A qualifying patient with an elevated blood pressure or suspected WCHT diagnosis during their appointment screening would then undergo an AOBP assessment and be educated on the reason, purpose, and outcome of the project.

A key step in sustaining the EBP is appointing primary and secondary *champions* to ensure that training is conducted regularly and that guidelines are followed. Additionally, they will be responsible for ensuring that the AOBP machine and designated assessment room are maintained. The FHC Flight Commander and Medical Director can facilitate this designation and ensure proper accountability.

HIPAA and Ethical Considerations

Potential HIPAA and ethical concerns focused on maintaining patient privacy and avoiding risk for patient harm. During the retrospective data collection, integrity of PII and protected health information (PHI) was upheld by only utilizing ICD-10 codes and blood pressure readings in AHLTA to track relevant data and prevent the breach of patient identification. The 81st MDG requirements were adhered to and approval was gained from the Institutional Review Board (IRB). It is also important to note that the focus of the EBP project was PI and not research. Additionally, each patient signed a HIPPA form discussing their participation in the project (Appendix E).

Project Results

The retrospective review of I10 and R03.0 diagnosis codes yielded a total of 752 patients diagnosed with HTN (I10) and 101 patients diagnosed with elevated BP without HTN (R03.0) for the three months prior to project implementation. The AOBP was implemented in the FHC for the months of January-March of 2021. Every adult patient over the age of 18 who presented with elevated blood pressure, based on JNC-8 guidelines, were screened with the exclusion criteria created by the DNP students and the providers within the FHC. During the two and one-half month implementation, a total of 15 patients met exclusion guidelines and agreed to participate in the PI project. The post data review showed a total of (556) I10 diagnoses and (42) R03.0 diagnoses during the period of project implementation.

With the help of Keesler's Clinical Research Laboratory, the results were analyzed using the SPSS v21 statistical analysis system. The recommended initial sample size was 97 patients. Although there were only 15 patients enrolled, the Chi-Square test was used to compare pre-intervention I10/R03.0 diagnosis codes to post-intervention I10/R03.0 codes. The Fisher's Exact Test was used to yield a statistically significant result that the incorporation of the AOBP measurement reduced the number of R03.0 diagnoses in the FHC during a three-month period. This result produced a p value of < 0.5 which allowed the team to accept the null hypothesis and show that the implementation was successful.

Analysis of the Results

Out of the 15 patients that had their blood pressure analyzed, five patients had an elevated reading of $> 140/90$ or $> 150/90$, based on JNC-8 guidelines. These patients were given a diagnosis code of "I10: Essential Hypertension". The remaining 10 patients' blood pressure readings were $< 140/90$, which did not meet the definition of HTN according to JNC-8

guidelines and were therefore assigned the diagnosis code of “R03.0: Elevated Blood Pressure without the diagnosis of Hypertension”. Every patient then had a telephone consultation initiated to the originating provider with the results of their AOBP reading and updated diagnosis code. The provider then made a decision on whether to start antihypertensive medications. In total, the AOBP enrolled patients had a total of 33.3% diagnoses of Essential Hypertension, while the remaining 66.6% of patients remained not diagnosed with HTN.

The difference in the pre-implementation R03.0 diagnoses and post-implementation R03.0 diagnoses was statistically significant. This signifies that the implementation of the AOBP was successful in identifying Essential Hypertension in patients presenting with elevated blood pressure in clinic. Based on literature, the AOBP is a recommended method for identifying elevated blood pressure and based on PI project implementation this proved that it can be implemented in the FHC setting to identify patients early on in the disease process. From start to finish the AOBP assessment only takes 10-minutes. This negates the prolonged 24-hour ABPM system and the HBPM screening method. These patients can get earlier treatment which, in turn, can lead to successful treatment of HTN.

10 of the 15 patients enrolled in the study received the diagnosis of R03.0 based on their AOBP measurements. They did not meet HTN criteria based on JNC-8 guidelines. This falsely elevated blood pressure could be associated with WCHT, rushing to get into the clinic, or underlying stress factors. The exclusion criteria attempted to eliminate potential causes of falsely elevated blood pressures prior to patient screening, so these patients likely have WCHT, which according to literature review, is prevalent in the adult population. With the AOBP reading not meeting JNC-8 HTN guidelines it could safely be assumed that they are not hypertensive at the visit and should continue with annual blood pressure screening during future wellness visits.

Organizational Impact

This project enhanced the knowledge of FHC staff members and provided a sustainable behavior for measuring blood pressures in an outpatient clinic setting. Additionally, the project created a streamlined process for diagnosing HTN and provided a means to eliminate unnecessary costs associated with chronic disease complications.

Future Directions for Research and Practice

The project's success encourages future research to identify other healthcare procedures that lack a streamlined approach to monitoring and evaluating chronic disease. Future practice integration includes implementing a standard practice for monitoring high blood pressure readings across the Defense Health Agency (DHA). This action would meet the Military Health System's (MHS) Quadruple Aim for HTN through better care, better health, decreased costs, and increased readiness.

Conclusion

The focus of the PI project was to introduce the use of AOBP measurements into practice to aid with accurately diagnosing HTN, differentiating it from WCHT. During the project implementation the team was able to produce statistically significant results, as evidenced by the difference between pre-implementation R03.0 diagnoses and post-intervention R03.0 diagnoses. Additionally, the clinical question was answered by showing that the implementation of an AOBP system lowered the number of patients with the R03.0 diagnosis. The initiation of unnecessary prescriptions and treatment due to the misdiagnosis of HTN has had negative nationwide economic implications (CDC, 2016). In the US military, HTN misdiagnosis can also have substantial career and mission readiness implications. With this PI project, the objective was met by establishing an alternative, accurate, and cost-effective method for the 81st MDG to

differentiate between essential HTN and WCHT. The evidence that the project provided can be utilized to promote the institution of this process into practice at the local and DoD level.

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Appendix A



Completion Date 26-Aug-2018
Expiration Date 25-Aug-2021
Record ID 28311995

This is to certify that:

Cassie Foss

Has completed the following CITI Program course:

OUSD P&R Human Research (Curriculum Group)
Biomedical Investigators and Research Study Team (Course Learner Group)
1 - Basic Course (Stage)

Not valid for renewal of certification through CME. Do not use for TransCelerate mutual recognition (see Completion Report).

Under requirements set by:

Office of the Under Secretary of Defense (Personnel and Readiness)



Verify at www.citiprogram.org/verify/?w0daa2bcf-c40c-499f-b89c-f55fbfe95c91-28311995



Completion Date 28-Aug-2018
Expiration Date 27-Aug-2021
Record ID 28308210

This is to certify that:

Precious Arnette

Has completed the following CITI Program course:

Responsible Conduct of Research (RCR) (Curriculum Group)
Responsible Conduct of Research (RCR) (Course Learner Group)
1 - Basic Course (Stage)

Not valid for renewal of certification through CME. Do not use for TransCelerate mutual recognition (see Completion Report).

Under requirements set by:

Office of the Under Secretary of Defense (Personnel and Readiness)



Verify at www.citiprogram.org/verify/?w3df9026e-3047-43be-a71d-d19373ad037f-28308210



Completion Date 25-Aug-2018
Expiration Date 24-Aug-2021
Record ID 28309208

This is to certify that:

Craig Schadewald

Has completed the following CITI Program course:

OUSD P&R Human Research (Curriculum Group)
Biomedical Investigators and Research Study Team (Course Learner Group)
1 - Basic Course (Stage)

Not valid for renewal of certification through CME. Do not use for TransCelerate mutual recognition (see Completion Report).

Under requirements set by:

Office of the Under Secretary of Defense (Personnel and Readiness)



Verify at www.citiprogram.org/verify/?wa0864309-ca6b-4c5d-9c40-bc7b6a5911d8-28309208



Completion Date 29-Aug-2018
Expiration Date 28-Aug-2021
Record ID 28321767

This is to certify that:

Theodore Szerszenski

Has completed the following CITI Program course:

Responsible Conduct of Research (RCR) (Curriculum Group)
Responsible Conduct of Research (RCR) (Course Learner Group)
1 - Basic Course (Stage)

Not valid for renewal of certification through CME. Do not use for TransCelerate mutual recognition (see Completion Report).

Under requirements set by:

Office of the Under Secretary of Defense (Personnel and Readiness)



Verify at www.citiprogram.org/verify/?w857f4e7b-2610-48f2-87f9-6c2fdfa73ca1-28321767

Appendix B

**USUHS FORM 3202N
DANIEL K. INOUE GRADUATE SCHOOL OF NURSING
EVIDENCE-BASED PRACTICE/PERFORMANCE IMPROVEMENT PROPOSAL**

VPR Date Stamp

Project Number: _____ (VPR will assign)

Project Title: Automated Office Blood Pressure Monitoring for the Diagnosis of Hypertension

SECTION A: STUDENT POC INFORMATION	
1. Name (Last, First, MI): <i>Foss, Cassie M.</i>	Student E-mail: _____
2. Home Address: _____	
SECTION B: COMMITTEE CHAIR / SENIOR MENTOR INFORMATION	
3. Name (Last, First, MI): <i>Williamson, John</i>	
4. Telephone: _____	E-mail: _____
5. USUHS Building/ Room No.: <i>BLDG E / Room 1053</i>	
SECTION C: PROJECT INFORMATION	
6. Attach the Abstract for the proposal, including the following sections: Site Location of the Project, Title, Authors, Background or Problem/Issue, Clinical Question/Purpose, Project Design, Anticipated Organizational Impact/Implications for Practice and also include the Proposed Timeline. Single space the abstract and use Times New Roman font, size 12.	
7. Is this proposal related to an active research project of the Chair/Senior Mentor identified in Section B? <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No If yes, complete below; if no, proceed to Part 8. Project Number: <i>n/a</i> Project Title: <i>n/a</i> Project Start Date: _____ Project End Date: _____	
8. Anticipated period of performance: Project Start Date: <i>8/1/2019</i> Project End Date: <i>2/26/2021</i>	
9. Performance Site(s): <i>Keesler AFB, Mississippi</i>	
10. Does this project involve any classified information? (Contact the USUHS Security Office for guidance) <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	
11. Do you have a funding source for this project? <input type="checkbox"/> Yes <input type="checkbox"/> No <input checked="" type="checkbox"/> NA If yes, specify the funding agency and the amount provided: <i>n/a</i>	
SECTION D: SIGNATURES	
The following signatures attest to the validity of the above information:	
<div style="display: flex; justify-content: space-between;"> <div style="width: 80%;"> <p>Cassie Foss _____</p> <p>Student (Project Point of Contact for the Group) (Signature and Date)</p> <p>_____</p> <p>Chair/Program Director (Signature and Date)</p> <p>_____</p> <p>DNP Project Director or PhD Director (Signature and Date)</p> <p>_____</p> <p>Associate Dean for Research, GSN (Signature and Date)</p> <p>_____</p> </div> <div style="width: 15%; font-size: small;"> <p>Digitally signed by WILLIAMSON, JOHN M 1115357170 DN: cn=US, ou=U.S. Government, ou=O&D, ou=PKI, ou=USAF, cn=WILLIAMSON, JOHN M 1115357170 Date: 2020.04.13 13:02:31 -0400</p> </div> </div>	<p>_____</p> <p>Chair/Senior Mentor (Signature and Date)</p> <p>_____</p> <p>Chair/Program Director (Signature and Date)</p> <p>_____</p> <p>Associate Dean for Academic Affairs, GSN (Signature and Date)</p> <p>_____</p> <p>Dean, DKU Graduate School of Nursing (Signature and Date)</p>
In light of the above signatures, the project is approved.	
<p>_____</p> <p>USUHS Vice President for Research</p>	<p>_____</p> <p>Date</p>

Appendix C



DEPARTMENT OF THE AIR FORCE
59TH MEDICAL WING (AETC)
JOINT BASE SAN ANTONIO - LACKLAND
TEXAS

October 01, 2020

FINAL DETERMINATION – NOT RESEARCH

Determination Date: 28 Sep 20

Project Lead: Cassie Foss/USAF - Keesler Air Force Base

Reference Number: FWH20200204N

Project Title: Automated Office Blood Pressure Monitoring for Diagnosis of Hypertension

You may begin your project, as you would any other clinical or operational activity, with the approval and sponsorship of your leadership.

Your activity was determined on 28 Sep 20 to be considered **not research** as defined by DoD regulation 32 CFR 219 and FDA regulation 21 CFR 56. Continued IRB oversight for this activity is not required. The proposed activity is not funded by DHHS/DoD as research; is not a systematic investigation to test a hypothesis and permit conclusions to be drawn; is not designed to develop or contribute to generalizable knowledge; and the purpose is not to investigate the safety or effectiveness of a drug, medical device or biologic.

Since the IRB does not have regulatory oversight for your study, it is the investigator's responsibility to validate the study's scientific merit and research design and to ensure the conduct of the study is upheld by the highest ethical standards, as required by the Wing. Should you require assistance in reviewing the scientific merit and research design of your study, please contact the Protocol Office. Protection of subjects' rights safety and welfare and responsibility for protecting PHI/PII and research data now fall on the investigator and their commander.

In accord with DoDI 6000.08 any intramural funding of this study as research or as a clinical investigation may continue to be received or sought regardless of this IRB determination.

Your study has received a one-time research determination. If the goals and/or activities of the project change during the course of the project, or if new activities are proposed that would constitute human subjects research, re-contact the Protocol Office, so that a regulatory expert may determine whether or not the revised plan involves human subject research activities.



Earl Grant, Jr., PhD
Designated Exempt Reviewer

Appendix D

PAO Clearance



**DEPARTMENT OF THE AIR FORCE
HEADQUARTERS 81ST TRAINING GROUP (AETC)**

23 APR 2021

MEMORANDUM FOR UNIFORMED SERVICES UNIVERSITY OF THE HEALTH SCIENCES

FROM: 81 TRW/PA

SUBJECT: Security and policy review for DNP project

1. I have conducted a security and policy review of documents submitted by Maj. Cassie M. Foss for a Doctor of Nursing Practice Project. Other students who contributed to this group project are Precious Arnette, Craig Schadewald, and Theodore Szaerszenski III. These students have approval for dissemination of final manuscript, oral and poster presentation and approval to place in USU Archives.

2. Direct any questions to myself, MSgt Eric Burks, at eric.burks.1@us.af.mil.



ERIC M. BURKS, MSgt, USAF
Superintendent, 81st Training Wing Public Affairs

Appendix E

Principal Investigator (PI) Name and Rank: Maj Cassie Foss, Maj Theodore Szerszenski, Capt Precious Arnette, Capt Craig Schadewald
Corps and Service/Organization: USAF Nurse Corp
Title of Study: Automated Office Blood Pressure Monitoring for the Diagnosis of Hypertension

I. Purpose of this Document

An Authorization is your signed permission to use or disclose your health information. The Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule, as implemented by the Department of Defense (DoD), permits the Military Health System (MHS) to use or disclose your health information with a valid Authorization. The MHS is defined as all DoD health plans and DoD health care providers that are organized under the management authority of, or in the case of covered individual providers, assigned to or employed by, the Defense Health Agency (DHA), the Army, the Navy, or the Air Force. A valid Authorization must include the core elements and required statements as contained in this document.

Please read the information below and ask questions about anything you do not understand before deciding to give permission for the use and disclosure of your health information.

II. Authorization

The following describes the purposes of the requested use and disclosure of your health information:

This quality improvement based project will utilize your health data to determine if the automated office blood pressure machine (AOBM) was utilized and if it made a diagnosis in hypertension. Your data will be utilized to compare the number of patient diagnosed with “elevated blood pressure without hypertension diagnosis” before the implementation of the AOBM, in comparison to after the AOBM use. The information that will be saved includes your original blood pressure that was collected in office prior to AOBM reading, your AOBM reading, and your diagnosis code in ALTHA. No additional health information will be stored.

A. What health information will be used or disclosed about you?

The information that will be saved includes your original blood pressure that was collected in office prior to automated blood pressure machine (AOBM) reading, your AOBM reading, and your diagnosis code in ALTHA. No additional health information will be stored.

B. Who will be authorized to use or disclose (release) your health information?

Keesler AFB MTF will be permitted to use this health information for this quality improvement project

C. Who may receive your health information?

Those who may receive this health information include evidence based practice project collaborators, project chair, and MTF leadership.

D. What if you decide not to sign this Authorization?

The MHS **will not** condition (withhold or refuse) treatment that is not part of this study, payment, enrollment, or eligibility for benefits on whether you sign this Authorization.

E. Is your health information requested for future research studies?

No, your health information *is not* requested for future research studies.

F. Can you access your health information during the study?

You may have access to your health information at any time, unless your identifiers are permanently removed from the data.

G. Can you revoke this Authorization?

- You may change your mind and revoke (take back) your Authorization at any time. However, if you revoke this Authorization, any person listed above may still use or disclose any already obtained health information as necessary to maintain the integrity or reliability of this study.
- If you revoke this Authorization, you may no longer be allowed to participate in this study.
- If you want to revoke your Authorization, you must contact: Maj Jennifer Varney, 228-376-3870

H. Does this Authorization expire?

Yes, it expires at the end of the study

I. What else may you want to consider?

- No publication or public presentation about the research described above will reveal your identity without another signed Authorization from you.
- If all information that does or can identify you is removed from your health information, the remaining de-identified information will no longer be subject to this Authorization and may be used or disclosed for other purposes.
- In the event your health information is disclosed to an organization that is not covered by HIPAA, the privacy of your health information cannot be guaranteed.

Signature of Research Participant or Personal Representative:

Your signature acknowledges that:

- You authorize the MHS to use and disclose your health information for the research purposes stated above.
- You have read (or someone has read to you) the information in this Authorization.
- You have been given a chance to ask questions, and all of your questions have been answered to your satisfaction.

Participant Signature

Date

Participant Printed Name

If the personal representative signs on a participant's behalf, then the personal representative must provide verification of their authority under applicable state law.

Personal Representative Signature

Date

Personal Representative Printed Name
Representative's

Description of the Personal
Authority

