Hypertension Education for Nurses to Improve Protocol Compliance Utilizing Shared Decision-Making Framework

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Abstract

According to the United States Surgeon General's (SG) call to action to control hypertension (HTN), about 108 million adults are diagnosed with HTN (2020). The SG report states that "nearly one in two adults have hypertension, and only about one in four people have it under control," placing individuals at a higher risk for heart disease and stroke. This DNP project promoted nursing autonomy and authority through SDM and expanded the nurses' role in team-based care (TBC) to improve patient outcomes through better control of blood pressure for patients diagnosed with HTN by improving compliance with the nursing HTN protocol over four weeks. The project intervention consisted of a PowerPoint presentation promoting SDM, nursing autonomy, TBC, developing a high-functioning team, pre-and post-test, and chart audits. A total of eight primary care nurses participated in the intervention, with 100% of the pre-and post-tests returned and 20 preintervention and 16 post-intervention chart audits completed. The project used quantitative data to determine if there was a gain in knowledge and improvement in compliance with the HTN nursing protocol post-intervention. A paired sample t-test was used to compare the pre-and post-test mean, which revealed a p-value of .0005, indicating a statistically significant improvement in knowledge from the pre-test and post-test. The chart audits showed improved compliance with the HTN nursing protocol from 49% pre-intervention to 96% post-intervention. The implication for nursing practice was increased knowledge regarding the nurses' role in SDM, the impact of SDM on nursing autonomy and TBC, and improved compliance with the HTN nursing protocol. The implication for the organization was the development of a high-functioning interdisciplinary team approach to care utilizing all team members' knowledge, skills, and experiences and the potential for improved patient outcomes. Although the initial outcome data of the quality improvement project showed positive results, further evaluation of the effectiveness of the intervention is needed to validate the results and continue to enhance the understanding of the importance of nurses' participation in SDM, the nurses' role in TBC, and the impact on patient outcomes and nurses' functioning autonomously.

Keywords: hypertension (HTN), shared decision-making (SDM), autonomy, team-based care (TBC)

Problem Identification

In 2019, half a million deaths in the United States were attributed to hypertension (HTN) as the primary diagnosis (Facts about, 2021). According to the United States (US.) Surgeon General's (SG) call to action to control HTN, about 108 million adults are diagnosed with HTN (2020). The data in the US SG report states, "nearly one in two adults have HTN, and only about one in four people with HTN have it under control," placing individuals at a higher risk for heart disease and stroke, "the first and fifth leading causes of death in the United States" (SG, 2020, p. 2). Heart disease and stroke are among the Healthy People 2030 objectives, and sights HTN as a significant health indicator for heart disease and stroke and cost the US \$131 to 198 billion each year (Healthy People, 2020). Healthy People 2030 (2020) reports that 47.8% of adults diagnosed with HTN have it under control, with a goal to increase that percentage to 60.8% by 2030 (p. HDS-05).

American College of Cardiology and American Heart Association (ACC/AHA), CDC, Healthy People 2030, and the US Surgeon General has published guidelines for the detection and care of HTN. Every guideline is designed around the concept of team-based care (TBC), where collaboration, accountability, knowledge, shared decision-making (SDM), and ownership of each team member's roles and responsibilities are combined with working towards a common goal to provide patient center care. The published guidelines delineate the nurse's role as assessment, monitoring, medication management (with some variation in medication recommendations responsibility), education, support, and consultation with other services. Although the nurse's role may vary slightly in the guidelines, the overall theme is allowing each team member autonomy to share in the decision-making process (Whelton et al., 2018; CDC, 2020; Healthy People, 2020).

West Texas Veterans Healthcare System (WTVAHCS) is located in rural West Texas and

is the organization chosen for this DNP project. The organization is an ambulatory care system that serves 20,000 male and female Veterans with six community-based outpatient clinics (CBOC) spread over 33 rural and highly rural counties covering 55,000 square miles. The nursing staff at WTVAHCS is multigenerational and has varying education levels, with more than 50% possessing an Associate Degree in Nursing (ADN). This DNP project aims to improve nurses' compliance with the HTN nursing protocol through education and the implementation of SDM in the protocol framework resulting in increased blood pressure (BP) control for patients and increased autonomy for nursing staff. Currently, WTVAHCS has 7,041 patients diagnosed with HTN, which is 35% of the enrolled population, and this 35% utilizes 25% of available appointment slots annually. Nursing documentation audits have indicated that nurses are compliant less than 50% of the time with the HTN protocol. The chart audits revealed that the nurses did not use the protocol, did not follow the guidance, or did not follow up.

After inquiring why nurses weren't compliant with the HTN protocol, the primary reason was that they believed it was the providers' responsibility to manage the care and direct the nurses' tasks. The concept of SDM, as defined in the shared governance model, will be integrated into education to address the nurses' perception of their role. The principles of SDM include partnership, equity, accountability, and ownership, allowing nurses the authority and responsibility to make decisions and be actively engaged in the care and treatment of patients diagnosed with HTN (McKnight & Moore, 2021). According to McKnight and Moore (2021), SDM "promotes positive patient outcomes and a culture of positivity, inclusion, and job satisfaction" (p. 1).

This DNP project aims to show a statistically significant improvement in nurses' compliance with the HTN protocol after completing education on applying SDM to the HTN

protocol. In addition, the project will have a meaningful impact on the care of 7,041 patients diagnosed with HTN by ensuring care coordination between the patient and the care team, a collaborative multi-disciplinary team approach, and potentially improved BP. Moreover, this project will promote the principles of SDM and encourage autonomy in nursing practice. The project will be piloted at the centrally located primary care clinic.

Project Question

To understand this DNP project proposal, it is essential to understand the problem. The format for this DNP project is PICOT (population, intervention, comparison, outcome, timeline). The PICOT for this project is:

a) Population: Ambulatory care nurses at a rural Veterans Healthcare System at the centrally located primary care clinic.

b) Intervention: Develop an educational intervention for the nurses' role in using HTN nursing protocol and shared decision-making principles

c) Compare: Current care

d) Outcome: Show a statistically significant improvement with the HTN nursing protocol as measured by chart audits.

e) Time: The time frame is four weeks

The PICOT question for this DNP project proposal is: Will education on the nurses' role in shared decision-making show a statistically significant improvement in nursing compliance with the VA HTN nursing protocol within four weeks?

The significance of this DNP project is two-fold; first, the promotion of nursing autonomy and authority through SDM and expanding the nurse's role from monitoring BP and patient education to supplementing and complimenting the medical provider's role (Henrie et al., 2019). Secondly, the effective improvement of patient outcomes and better control of BP for patients through the use of a nursing HTN protocol (Zhua et al., 2018) and ensuring care is multi-faceted, patient-centered, and tailored to meet the patient's needs

Search Methods

This literature search aims to retrieve evidence supporting professional nursing practice by encouraging autonomy and SDM, promoting professional identity, motivating nurses to work to the full extent of their practice, and being an active care team member. The vehicle for this literature search is using an SDM framework to educate nurses on using an HTN nursing protocol. The current literature does support the nursing role as an essential and integral part of the decision-making process using the TBC model of care.

This literature review utilized Touro University Nevada's electronic library, including multiple database search engines, e.g., PubMed, MEDLINE, Cochrane, CINAHL, etc. Booleans were used for search terms related to the PICOT question, "Will education on the nurses' role in shared decision-making show a statistically significant improvement in nursing compliance with the VA HTN nursing protocol within four weeks?" The initial search terms selected related to the PICOT question were "shared decision making," OR "nursing autonomy," AND "nurse interventions," AND nurses' role, AND "hypertension." An additional search was conducted using "Nursing autonomy" AND "Team-based Care," OR "TBC," AND "Hypertension," OR "HTN."

Inclusion Criteria:

Studies were included if the article was in English, the setting was primary care, ambulatory care, the target population was 18 years old and older, peer-reviewed or scholarly, focused on nurses' role or a multi-disciplinary team approach, and included SDM or implied SDM between professionals.

Exclusion Criteria:

Studies were excluded if the article contained research older than five years, was an editorial or opinion-based, focused on pediatric or pregnant populations, focused on the patient's SDM between the nurse or provider, or the article was not in English. The initial search produced 25 articles. After adjusting the search terms, a second search yielded 108,499 articles. This number was reduced to 1,612 after a quick review of titles and relevance to SDM, team-based care (TBC), nursing autonomy, nurses' role, nurse-led intervention, and hypertensive care. A second screening resulted in a potential 92 pertinent articles. Subsequently, the articles were further sorted by reviewing the abstract, introduction, and conclusion, searching for key terms, e.g., SDM, autonomy, communication, collaboration, nurse role, nurse-led intervention, teambased care (TBC), protocol, and guidelines, the reason and focus of the study, methodology, and results reducing the number of articles to 10 relevant articles.

Review of Literature

Six of the articles selected were literature reviews of randomized control trials, metaanalyses, or a systematic review of the outcomes of care interventions for patients diagnosed with chronic conditions such as HTN. Leonga et al. (2021) reviewed RCTs on the benefits of shifting tasks from providers to non-physician professionals. Van Hooft et al. (2017) performed a realist review of nurse-led interventions that support self-management for patients with chronic conditions. Derington et al. (2019) did a literature review of RCTs for the effectiveness of teambased care (TBC) in maintaining BP control related to cost. Himmelfarb et al. (2016) reviewed RCTs and meta-analyses of RCTs of team-based hypertension care involving nurses or pharmacists. Mills et al. (2018) conducted a meta-analysis comparing the effectiveness of the strategies to reduce BP in patients diagnosed with HTN. Smith et al. (2020) did a literature review of meta-analyses, systematic reviews, and RTCs comparing TBC to usual care for HTN management. Wagner et al. (2017) completed an intensive observation that identified and shared innovative staffing arrangements to improve access to care and provide high-quality team-based care using a TBC model. Kronebusch et al. (2020) conducted a quality improvement project that evaluated the effectiveness of enhancing the nurse's role in a TBC model compared to traditional care for patients with HTN. Reddy et al. (2018) completed a retrospective cohort study of Veterans Health Administration (VA)-Medicare dual-eligible Veterans and the association between TBC and continuity; Zhua et al. (2018) completed a single-blind, randomized controlled trial of a nurse-led hypertension management model.

Leonga et al. (2021) reviewed 21 relevant RCTs on task shifting from primary care providers to non-physician professionals (e.g., nurses, pharmacists, etc.). All the RCTs reviewed supported the concept of an expanded role (medication management, education, consultation with other services, e.g., nutrition, physical therapy, and follow-up) for non-physician professionals in caring for patients diagnosed with chronic conditions. Leonga et al. (2021) concluded that giving nurses the autonomy to share in decision-making and expanding the nurse's role in managing HTN care was comparable to traditional care and showed a modest improvement in BP. Additionally, expanding the nurse's role garnered other benefits to the patient and team, such as increased numbers of patients returning for follow-up, increased access to care, better management of all chronic conditions, and improved patient satisfaction (Leonga et al., 2021).

Van Hooft et al. (2017) reviewed 38 articles on nurse-led interventions that support selfmanagement for patients with chronic conditions. The review consisted of seven nurse-led interventions to determine the best approach to the goal of self-management. Van Hooft et al. (2017) concluded that nurse-led interventions in chronic disease management increased the patient's motivation and self-efficacy to meet care goals. Although this article did not discuss SDM or nursing autonomy, it implied that using an SDM framework and allowing autonomy for the nurses improves patient outcomes in managing chronic disease.

Derington et al. (2019) reviewed the current literature on the effectiveness of team-based care (TBC) in maintaining BP control related to cost. Derington et al. (2019) referred to several studies that gave positive results with the TBC model of care using nurse-led interventions, revealing that nurse-led interventions were comparable to physician-led care. Deringtion et al. (2019) did not specifically discuss the importance of nursing autonomy or SDM in the care of HTN but implied SDM and autonomy using the TBC model of care.

Himmelfarb et al. (2016) reviewed and discussed the synthesis of 52 RCTs on TBC and expanding the role of nurses or pharmacists in HTN care. Himmelfarb et al. (2016) identified the importance of expanding the nurse's role in the TBC model as the most effective strategy to improve HTN. Himmelfarb et al. (2016) concluded that the literature supported that providing the nurse the autonomy to make decisions based on the TBC model in most cases produced a significant improvement in BP with a reduction of SBP of 6.2 mm Hg and diastolic BP (DBP) of 3.1 mm Hg or p= 0.05 at 3-years; p=0.02 at 5-years (Himmelfarb et al., 2016).

The single-blind randomized controlled trial by Zhua et al. (2018) was a nurse-led HTN management model. Zhua et al. (2018) designed the nurse-led HTN management model giving the nurse the autonomy to make decisions regarding care and taking charge of the assessment of care, referral initiation, collaboration with the primary team on medication recommendations, and care delivery after being trained on HTN care. This trial supports the benefits of providing nurses the autonomy to participate in SDM for patients diagnosed with HTN after being trained or

educated by showing a significant reduction in BP in the study group.

The retrospective cohort study completed by Reddy et al. (2018) reviewed the association between TBC and continuity and examined how well the team delegated or allowed autonomy of the team members. The study concluded that patients seen by teams using the TBC model of care saw fewer hospitalizations and ED visits, improved clinical-level measures, and had a low probability of experiencing many types of high-cost health issues (Reddy et al., 2018). The study did not specifically discuss SDM or nursing autonomy but supported care delivery utilizing the TBC model of care, which emphasizes SDM and autonomy for each team member.

Mills et al. (2018) reviewed 100 articles for a meta-analysis comparing the effectiveness of strategies to reduce BP in patients diagnosed with HTN. The analysis compared traditional primary care provider care with and without TBC, home BP monitoring, health coaching, and non-physicians titrating medication. The TBC model of care with non-physicians titrating medication was shown to have the most significant reduction in BP (Mills et al., 2018). Mills et al. (2018) implied that SDM and autonomy for the team members through implementing the TBC model have a significant positive impact on patient outcomes.

Smith et al. (2020) reviewed and discussed the synthesis of 100 trials comparing TBC to traditional care for HTN management. Smith et al. (2020) concluded that the TBC model of care resulted in a more significant reduction of BP than traditional provider HTN care. Although Smith et al. (2020) did not discuss SDM or nursing autonomy in caring for patients with HTN, it supported the TBC model, where nurses participated in SDM and maintained autonomy by using algorithms or protocols in HTN management.

Wagner et al. (2017) conducted an intensive observation to identify and share innovative staffing arrangements that improve access to care and provide high-quality care by expanding

team members' roles through the TBC model. The observation team determined that the TBC model of care promoted expanding the roles of non-physician professionals and led to substantial improvements in disease control for chronic conditions such as HTN (Wagner et al., 2017). Wagner et al. (2017) did not specifically discuss SDM or nursing autonomy but implied SDM and autonomy using the TBC model and identified improved access to care with TBC.

Kronebusch et al. (2020) developed a quality improvement project that evaluated the effectiveness of enhancing the nurse's role in a TBC model compared to traditional care for patients with HTN. The nurse-led interventions consisted of evidence-based provider order sets and a nurse protocol. Kronebusch et al. (2020) concluded that allowing nurses autonomy, participation in SDM, and working to the full extent of their practice using protocols, algorithms, and provider order-sets positively impacts patients with HTN and meets their BP goals.

Although much of the literature focused on the SDM between the patient and the medical provider, there was significant evidence of the benefits of autonomy in decision-making and nurse-led interventions in the care of patients diagnosed with HTN. Multiple studies were done separately that focused on the effectiveness of the team-based care model, nursing autonomy, SDM, nurse-led interventions, and hypertensive guidelines, but there is little to no literature that includes all elements of the PICOT question. The literature implies a connection between the nurses' role in SDM and improved compliance with HTN guidelines or protocols. The implication is that providing autonomy to nurses in an SDM framework such as a TBC model of care significantly impacts patient outcomes, improves the population's health, improves access to care, decreases hospitalizations and ED visits, and reduces the cost of care.

Team-Based Care

Leonga et al. (2021) discussed TBC as related to task shifting to other team members, such

as nurses or pharmacists. Leonga et al. (2021) concluded that task shifting, such as autonomous prescribing and initiating specialty consults, is supported by evidence-based research. The TBC model of care can improve the WTVAHCS Patient Aligned Care Team (PACT) team's collaboration and assist in exchanging information and cooperation toward a common objective of improving patient outcomes experiences and providing patient-centered care. Additionally, TBC can provide the nursing staff with the authority, permission, and expectation of accountability and responsibility.

Van Hooft et al. (2017) concluded that the most successful nurse-led interventions use protocols or algorithms within a team environment. Van Hooft et al. (2017) article described a team environment as equivalent to the TBC model of care, implying support for TBC as a strategy for chronic disease management. The TBC model encourages nurses to function to the full extent of their education, certification, and experience (Van Hooft et al., 2017), which can improve job satisfaction, retention, and professional accountability in WTVAHCS' outpatient service.

Himmelfarb et al. (2016) determined that expanding the roles of nurses and pharmacists using the TBC model of care was the most effective strategy to improve HTN. TBC, including nurse-led interventions, has significantly contributed to patients receiving high-quality care (Himmelfarb et al., 2016). The TBC model of care can enable the PACT nurses to create a culture of collaboration and professional respect.

Cost Savings

Derington et al. (2019) found that implementing the TBC model of care directly impacted the reduction in healthcare costs by decreasing complications related to HTN. Derington et al. (2019) discovered that implementing recommended guidelines (e.g., TBC) directly impacts cost savings per person, averaging \$1,696 annually. With any healthcare facility, the cost is a priority, and strengthening the TBC model of care may provide the WTVAHCS with a model of care that reduces hospitalization, ED visits, and complications due to chronic disease and ultimately reducing cost.

According to Himmelfarb et al. (2016), the TBC model of care promotes cost reductions and controls spending through a team approach to care. Himmelfarb et al. (2016) noted that if the TBC model of care is implemented, each patient can save \$525, totaling \$18.8 billion over ten years. The WTVAHCS serves a large geriatric population with higher healthcare costs related to chronic conditions; using the TBC model of care can reduce costs by improving the population's health.

Smith et al. (2020) discovered that TBC models for care for HTN had been clinically and cost-effective. TBC resulted in cost savings relative to traditional care in most studies analyzing the management of HTN and the impact of the TBC model (Smith et al., 2020). Even though there was some variability in cost savings, TBC showed some cost savings in most situations (Smith et al., 2020). Strengthening the TBC model of care is one strategy the WTVAHCS nursing leadership is promoting to provide high-quality care with the additional benefit of reducing cost.

Protocols/algorithms/guidelines

Derington et al. (2019) reviewed the effectiveness of BP control in the TBC model of care. Derington et al. (2019) discovered that the Department of Veterans Affairs has successfully achieved BP (BP) control rates of 80% using a standardized protocol. Derington et al. (2019) recommended that health systems prioritize the use of protocols within the TBC model of care with the long-term goal of improving patient outcomes and satisfaction with HTN care. According to the WTVAHCS nursing leadership, nursing has protocols and algorithms for treating HTN but has been reluctant to utilize the protocols fully. Providing education and training on properly using the protocols can improve the quality of care and allow the nurses the autonomy to provide patient-centered care.

Himmelfarb et al. (2016) concluded that nurses gained the skills to assess patients' health status, adjust medications, and address barriers to HTN care using evidence-based protocols and algorithms to guide practice. Expanding the role of nurses through protocols and algorithms resulted in increased team engagement, improved patient outcomes, and improved job satisfaction (Himmelfarb et al., 2016). Staying current and continually advancing nursing knowledge, education, and skills is the responsibility of every nurse. The WTVAHCS nursing leadership is committed to improving nursing, and implementing protocols and algorithms is one strategy for advancing nursing practice that can be used.

Smith et al. (2020) concluded that nurse-led protocols encouraged autonomy, promoted SDM within TBC, and showed significant improvement in BP management. Additionally, incorporating non-physician providers using protocols into the health care team to manage HTN has been shown to be more effective than traditional care and has been a recommended practice strategy for reaching BP goals (Smith et al., 2020). The WTVAHCS nursing leadership intends to increase nurses' involvement in treating patients diagnosed with HTN using an SDM framework and allowing nursing autonomy through protocols.

Nurse-led intervention

Leonga et al. (2021) found that patients receiving care through nurse-led interventions have better outcomes, lower healthcare risks, and reduced hospitalization and ED visits. Evidence suggests that nurses should play a far more significant role in supporting patient care through the use of nurse-led interventions (Leonga et al., 2021). Nurse-led interventions are a reliable tool that allows nurse-driven care (Leonga et al., 2021) and can benefit WTVAHCS by improving access to care, promoting patient-centered care, reducing healthcare costs, increasing nursing involvement in SDM, and encouraging autonomy.

Zhua et al. (2018) believed that nurse-led HTN intervention allows nurses the autonomy to make decisions regarding the care of hypertensive patients, including medication management and referrals to other services. The nurse-led intervention was consistently more successful than traditional care at reducing BP and effectively managing HTN (Zhua et al., 2018). Implementing nurse-led interventions such as Zhua's et al. (2018) HTN care model can significantly impact the delivery of quality care and improve the WTVAHCS' population health.

Reddy et al. (2018) found that nurse-led interventions enhanced adherence to treatment regimens such as medication management. Reddy et al. (2018) determined that nurse-led interventions added to already proven methods of care delivery, combined capabilities, strengthened the TBC care model, and positively impacted chronic conditions. Reddy et al. (2018) literature review supports the need to implement nurse-led interventions for chronic disease management. Currently, WTVAHCS nurses do not use the available nurse-led interventions or do not complete the intervention resulting in a missed opportunity to provide the best care possible. This DNP project will promote the use of nurse-led interventions within the PACT and support nursing autonomy and participation in SDM.

Expanded roles

Leonga et al. (2021) found that evidence suggests that nurses should undertake a substantially expanded role to support patient care in response to the changing healthcare demands. Expanding the roles of nurses has been promoted as one of the strategies for improving care quality and meeting national health goals (Leonga et al., 2021). The nursing leadership at WTVAHCS has recognized that as healthcare demands increase, it is essential for nurses to develop their skills and knowledge to share in the care of patients. This DNP project aims to expand the nurse's role by educating about how an SDM framework can promote autonomy within the HTN protocol.

Van Hooft et al. (2017) discussed a realist review of nurse-led interventions supporting the care of chronic conditions. Van Hooft et al. (2017) addressed the need to expand the role of nurses to meet the needs of the increased healthcare demands. WTVAHCS can benefit from nurses taking on more responsibilities for a broader spectrum of patients in ambulatory settings and working to the full extent of their practice. The expanded role can include new duties for population health, care coordination, SDM, and interdisciplinary collaboration.

Reddy et al. (2018) focused on expanding the roles of the care team. Reddy et al. (2018) observed that the role of nurses in the VHA TBC model was already expanded as a care manager, although nurses hesitate to function at the top of their practice at WTVAHCS. The DNP project can reinforce the nurse's role in collaboration and SDM and provide them with the tools to work autonomously within the TBC model of care.

Summary

Healthcare hasn't always been approached as a team. Patients were cared for by a single doctor who attended to all the patient's needs. As healthcare evolves and incorporates new requirements, mandates, and expectations with new technologies into wellness and sickness and complicated aging management plans, the lone provider who relies on limited resources to deliver the healthcare needed to the patients may put the patient at risk is now considered as undesirable in health care (Truglio-Londrigan, & Slye, 2018).

The DNP lead reviewed scholarly peer-reviewed literature that evaluated the nurse's role in caring for patients with chronic conditions using an SDM framework that allows nursing autonomy. Although each article's approach to the discussion varied, there was one overarching theme. The TBC model of care was touted as the preferred approach to high-quality care delivery for chronic conditions throughout the literature over traditional care.

It was evident that TBC allowed for the division of labor and delineation of members' roles, responsibilities, and accountability and promoted SDM, the autonomy of each team member, communication, and collaboration. Additional themes identified were either a result of TBC or integrated into the TBC model of care, the use of protocols/algorithms /guidelines, and expanding the nurse's role in the care delivery of chronic conditions.

An ongoing theme in the literature was using protocols/algorithms/guidelines within the TBC model. Each article discussed TBC as a cooperative strategy in which team members share tasks to provide high-quality and efficient patient care. The evidence promoted the inclusion of protocols/algorithms/guidelines into TBC to maximize SDM, autonomy, and flexibility for team members and promote TBC's overall functionality. Additionally, the literature supported the use of protocols/algorithms/guidelines in establishing a culture of communication and collaboration encouraging all team members to work to the top of their practice.

The final theme throughout the literature was expanding the nurse's role within the TBC model of care. The literature discussed that no single team member could do every task required when caring for patients with the increasing complexity of the healthcare system. With the increase in mandates, regulatory requirements, and accelerating costs, the literature supported optimizing the team's knowledge, skills, and abilities by expanding each team member's role within their discipline. Furthermore, members should have enough autonomy to avoid overlap in functions, improving efficiency, accuracy, and timeliness of care. The literature discussed expanding the nurse's role through evidence-based tools such as standing order sets,

protocols/algorithms/guidelines, and participation in SDM within the TBC model of care.

Project Rational

This DNP project aims to promote nursing autonomy and authority through education on the SDM framework using the HTN nursing protocol to assist nursing in understanding how SDM impacts and increases autonomy in nursing practice. The objectives for this project are:

- Educate nurses on the benefits of SDM and how it can promote autonomy. The education will be tracked with Microsoft TEAMS meeting transcription, which records the training and accounts for attendance during the four weeks of project implementation.
- Expand the nurse's role within the TBC model of care by promoting nursing autonomy. Nurses' autonomous use of the HTN nursing protocol will show a statistically significant improvement measured using chart audits within four weeks.
- Increase in understanding of SDM as evidenced by a statistically significant improvement in the pre-and post-test after completing the nursing SDM education.

The culmination of these objectives can drive the expansion of the nurses' role to supplement and complement the medical practitioner's role and ensure that care is multi-faceted, patient-centered, and personalized to meet the patient's needs and improve patient outcomes.

After meeting with the WTVAHCS nursing leadership and discussing gaps in nursing practice, the leaders expressed that the most glaring gap in nursing practice at WTVAHCS is that nurses believe it is the providers' responsibility to manage the care of patients and provide direction to the nurses. This level of disengagement can have a negative impact on patient outcomes. Promoting and expecting nurses to use an SDM framework to practice autonomously is the vehicle through which nurses apply their expertise to improve patient outcomes and drive quality. Nurses who can apply their clinical and organizational skills through independent practice can increase care quality (Echebiri et al., 2020). Capitalizing on all available resources is crucial in a value-based system because healthcare is under growing pressure to achieve improved performance with limited resources. Nurses are a valuable resource as the largest discipline in the healthcare workforce. Promoting autonomous nursing practice maximizes the worth of this critical human resource for patients, providers, and nurses, whereas neglecting to do so can leave gaps in patient care, reduces its value, and erodes the advantages knowledgeable nurses bring by contributing to better patient outcomes.

Project Framework

The framework for this rapid cycle quality improvement project is the Plan-Do-Study-Act (PDSA) model (Appendix A). PDSA is a four-step process that guides the change process by separating the steps into specific tasks, evaluating the outcome, improving on it, and retesting the improvement (AHRQ, 2020). The PDSA model asks three questions, what change is trying to be accomplished; how will the change be measured; and what changes can be made to accomplish the desired improvement (AHRQ, 2020)

The theory used in the project's development was Kanter's structural empowerment theory (1977, 1993), which emphasizes organizational systems rather than individual characteristics (Valdez et al., 2019). Kanter's theory of structural empowerment has been widely applied to the profession of nursing and is the concept used to develop this DNP project (DiNapoli et al., 2015). Kanter believed that by sharing authority and empowering people, a leader's power would increase, resulting in improved organizational performance (Echebiri et al., 2020). Furthermore, Kanter believed that individual skill sets would grow with the right tools, information, and support, allowing for better decision-making while performing at the top of their profession (Echebiri et al., 2020). According to Valdez et al. (2019), Kanter identified two organizational

structures, formal and informal power. Formal power is associated with high-profile jobs that require a focus on independent decision-making (Valdez et al., 2019). Informal power is associated with building ties and alliances with peers and colleagues (Valdez et al., 2019). Kanter's theory included the following four conditions in addition to formal and informal power that must be met for empowerment to occur (Echebiri et al., 2020):

Opportunity for Progress

Opportunity for progress refers to advancing and growing within an organization, broadening one's knowledge, and abilities, and furthering their education (Echebiri et al., 2020). Kanter believed that opportunity significantly impacts employee satisfaction and productivity (DiNapoli et al., 2015).

Access to information

Access to information refers to possessing the formal and informal knowledge required to succeed in the workplace, including technical knowledge, the expertise required to accomplish the job, and an understanding of organizational policies and decisions (DiNapoli et al., 2015). Employees gain a feeling of purpose and meaning when they have access to information, which improves their capacity to make judgments and influence decisions that support organizational goals (DiNapoli et al., 2015).

Access to support

Access to support refers to feedback and guidance from supervisors, peers, and subordinates (DiNapoli et al., 2015). Support can be emotional support, mentoring, coaching, or hands-on help (DiNapoli et al., 2015). Kanter asserted that staff who believe they are supported reflect a greater interest in the organization and are more productive than those who do not perceive they have access to support (DiNapoli et al., 2015).

Access to resources

Access to resources refers to an individual's ability to obtain the materials, money, supplies, time, and equipment needed to achieve personal and organizational objectives and goals (DiNapoli et al., 2015). Employees must have access to resources to succeed in their job duties (DiNapoli et al., 2015). Additionally, access to resources is linked to productivity (DiNapoli et al., 2015).

Ensuring these conditions are implemented can result in greater job satisfaction, commitment, trust, and a reduction in job burnout (Valdez et al., 2019). Kanter's hypothesis has been shown to have a measurable impact on employee empowerment, job satisfaction, organizational morale, and success, particularly in healthcare (Valdez et al., 2019). It has also been noticed that when empowerment is present, there is a reduction in work pressure, increased peer cohesion, SDM, employee autonomy, and improved retention (Monje Amor et al., 2021).

Kanter's structural empowerment theory describes constructs theoretically consistent with the nursing care process and can be logically extended to nurse-patient interactions, the healthcare team, and patient outcomes (Valdez et al., 2019). Empowered nurses report higher job satisfaction, loyalty, confidence, and a considerable reduction in work-related stress (Gottlieb et al., 2021). Nurses feel more autonomous when nursing leaders create an environment that supports and encourages them to exercise control over their practice (Gottieb et al., 2021). It has been proven that structural empowerment promotes autonomy, a cohesive healthcare team, SDM, work satisfaction, reduced burnout, and improved patient outcomes (Valdez et al., 2019).

The DNP-prepared nurse is focused on applying, integrating, and translating research or evidence into practice (Trautman et al., 2018). Kanter's structural empowerment theory has been emphasized as a beneficial aspect and one that is critical to an organization's success (Valdez et al., 2019). According to DiNapoli et al. (2015), Kanter demonstrated a link between self-efficacy, competence, autonomy, SDM, job satisfaction, and an impact on the organization. The major tenet of Kanter's structural empowerment for a healthcare organization to succeed is to use partnership principles (DiNapoli et al., 2015). Kanter emphasized sharing power as much as possible, cooperation and relationship-based practice, invention, and originality (DiNapoli et al., 2015). In a work environment that applies Kanter's structural empowerment theory, employees' self-efficacy, job satisfaction, competency, and patient outcomes benefit (Trautman et al., 2018). At WTVAHCS, nurses believe it is the providers' responsibility to manage the care and direct the nurses' tasks resulting in disengagement in patient care and nurses not functioning at the full scope of their practice. Empowering nurses aligns with the aim of this DNP project of promoting nursing autonomy and authority. Transforming Kanter's structural empowerment theory into the WTVAHCS nursing work environment provides a mechanism to emphasize partnership, the TBC model of care, interprofessional collaboration, SDM, autonomy, nurses working to their full scope of practice, promoting patient-centered care, and improving patient care outcomes. Empowering nurses can influence attitudes and behaviors, promote a feeling of competence, increase emotional respect and trust, and encourage autonomy, SDM, self-efficacy, and a sense of job meaningfulness (Gottlieb et al., 2021).

Project Context

Direct population

WTVAHCS nursing staff is multigenerational and has varying education levels, with about 50% possessing an Associate Degree in Nursing (ADN). The direct population identified for this DNP project is eight RNs assigned to the primary care clinic (PCC). The inclusion criteria are all RNs providing or overseeing care in the chosen PCC. The exclusion criteria are any RNs providing care outside the chosen PCC. This DNP project aims to improve nurses' compliance with the HTN nursing protocol through education on the impact of SDM on nursing autonomy using a protocol framework. The justification for selecting this population is to support professional nursing practice by encouraging autonomy and SDM, promoting professional identity, motivating nurses to work to the full extent of their practice, and participating as an active care team member.

Indirect population

The indirect population is Veterans between 18 to 101 years old diagnosed with HTN. The PCC has 2,151 patients diagnosed with HTN, which is 47% of the enrolled population (4,500), and this 47% utilizes 30% of available appointment slots annually. The inclusion criteria for the DNP project will be patients enrolled in the chosen PCC diagnosed with HTN. The exclusion criteria are patients not enrolled in the chosen PCC and patients who are not diagnosed with HTN. **Setting**

The DNP project setting is part of America's largest integrated healthcare system, which provides care for nine million Veterans at 1,293 healthcare facilities (Veterans Health, 2022). The DNP project setting is located in the WTVAHCS parent facility in a highly rural area of Texas. WTVAHCS is an ambulatory care system that serves 20,000 male and female Veterans in six community-based outpatient clinics (CBOC) spread over 33 rural and highly rural counties covering 55,000 square miles. The project setting within WTVAHCS chosen for the DNP project is a PCC with an enrolled population of 4,500 Veterans between 18 and 101 years old. There are four PC medical providers (e.g., MD, NP, PA), one Associate Chief Nurse – Outpatient (ACN – OP) that oversees one Nurse Manager (NM), six Registered Nurses (RN), three Licensed Vocational Nurses (LVN), and a variety of other healthcare disciplines (e.g., pharmacists, mental health providers, and social workers) assigned to the PCC. The team uses an electronic medical record for all patient documentation (Computerized Patient Record System [CPRS]); this is the documentation system used for this DNP project to collect data and monitor the HTN nursing protocol's usage, including population information and chart audits.

Internal stakeholders

The internal stakeholders related to this DNP project are the overall WTVAHCS facility (macro-level), PCC (meso-level), nurses (micro-level), and providers (micro-level). According to Moran et al. (2020), internal stakeholders in the healthcare setting are primarily part of the organization and are comprised of diverse personnel, such as various healthcare professionals, administrators, and others who play a role in clinical and non-clinical responsibilities (p. 135). In this DNP project, the internal stakeholders are professional staff providing patient care in the primary care clinic (e.g., frontline Register Nurses (RN) and medical providers) as well as the ACN-OP, PCC NM, System Redesign Coordinator (SRC), and the executive team (e.g., Director, Chief of Staff, and Associate Director). As the focus of this DNP project, the RNs are major internal stakeholders and play a critical role in the project's success. They can rally support and promote buy-in or put-up barriers for successful implementation and sustainability.

The PCC NM's role is to assist RNs with understanding the problem, purpose, implications, and impact of the DNP project on their nursing practice. The PCC NM has sufficient authority to drive the recommended change related to the DNP project. The ACN-OP has the authority, expertise, and leadership within the organization to provide support and guidance for a successful implementation and promotion of staff buy-in.

The SRC's role is as an improvement advisor. The SRC has the expertise in quality improvement methods to act as a resource and advisor to guide the DNP project. The executive

team possesses the ultimate power and leadership skills within the organization and has the authority to provide needed resources and remove barriers.

External stakeholders

According to Reavy (2016), external stakeholders can be interested in the project's success but have an indirect effect (p. 69). The external stakeholders for this DNP project include patients and families or significant others. External stakeholders play an important role in change implementation by providing feedback throughout the project implementation process (Reavy, 2016). Patients are the ultimate users of healthcare services, and their support is vital to the project's success. WTVAHCS leadership fully supports the DNP project, has agreed to provide resources, and access to the facility employees and data, and established an affiliation agreement with Touro University Nevada.

Interventions

The planned intervention for this DNP quality improvement project will be completed over four weeks. To meet the objective of educating nurses on the benefits of SDM and how it promotes autonomy, an educational PowerPoint (Appendix B) will be presented to the ambulatory care nurses. The presentation identified strategies for participation in SDM and how nurses can function autonomously within the TBC model to expand the nurse role within the TBC model of care. The HTN nursing protocol will be an example of how nurses function autonomously and increase their understanding of their role in SDM and its impact on nursing practice. The PowerPoint presentation will increase the nurses' understanding of SDM, promote nurses functioning autonomously and improve the nurses' compliance with the HTN nursing protocol.

The PowerPoint will be presented over a one to two-hour session and educate the PCC nurses on how SDM and autonomy support professional nursing practice, promote professional

identity, motivate nurses to work to the full extent of their scope of practice, and be an active team member. The PowerPoint presentation (Appendix B) includes a definition of SDM, as Moss et al. (2016) described. The discussion on SDM will include a video by Dr. Joy Doll on collaboration in health care and its impact on care (https://youtu.be/qOV-5h0FpAo) (Appendix C). Resources from the Centers for Disease Control and Prevention on interprofessional collaboration will be identified for future use (Interprofessional Collaboration | Transitions to Professional Nursing Practice (lumenlearning.com/suny-delhi-professionalnursing /chapter/interprofessionalcollaboration/) (Appendix D). The American Nurses Credentialing Center 2020 magnet mission and vision statement's definition of nursing autonomy will be included along with Oshodilet al. (2019) description of nursing autonomy. Examples of how nurses practice SDM and function autonomously every day (e.g., giving PRN medications) will be part of the discussion. The presentation will introduce TBC as a care delivery model where patient care needs are addressed as a coordinated, collaborative effort among multiple healthcare providers and across settings of care (Smith et al., 2018; ANA, 2016). The roles and responsibilities of the TBC members will be discussed, along with how communication within the TBC model impacts patient care (Smith et al., 2018; ANA, 2016). The "Formula 1 Pitstop 1950 vs. 2013"

(https://www.youtube.com/watch?v=EPKRAFWscfE) (Appendix E) will illustrate the difference between a low-performing team working individualistically versus a high-performing team functioning as one within the TBC model of care.

The presentation will identify strategies for building a high-functioning team through SDM, autonomy, and TBC, as Huber and Joseph (2021) and Mitchell et al. (2012) describe. The discussion will include the following strategies, the team's shared goals, clear roles, creating mutual trust within the team, effective communication, and measurable processes to ensure

positive outcomes (Hube & Joseph, 2021; Mitchell et al., 2012). Finally, a review of the VA HTN nursing protocol (Appendix F) and the VA HTN clinical practice guideline (https://www.healthquality.va.gov) (Appendix G) will be included in the discussion on how the nursing protocols allow nurses to participate in SDM and function autonomously.

A 15-question test (Appendix H) will be administered before and after the completion of the PowerPoint presentation to measure if there was a gain in the nurses' knowledge. Additionally, a chart audit (Appendix I) will be performed weekly over the remaining implementation period to determine the nurses' compliance with the HTN nursing protocol. The audit results will be shared with the nursing staff as a group and individually in a question-andanswer format. During weeks two through five, the DNP Leader will be available to the PCC nurses for one-on-one and group sessions, questions and concerns, and continued guidance related to SDM, nursing autonomy, and the HTN nursing protocol.

Tools

The tools for the DNP project are the PowerPoint presentation (Appendix B) to educate the nurses on SDM, nursing autonomy, TBC, and the HTN nursing protocol. A 15-question preand post-test (Appendix H) will be administered to determine if there was an increase in knowledge after the PowerPoint presentation. A video (Appendix C) by Dr. Joy Doll will be shared to illustrate a collaborative team (Collaboration in Health Care: The Journey of an Accidental Expert?) along with a video (Appendix E) to demonstrate a high-performing team (Formula 1 Pit Stop 1950 vs. 2013). VA HTN nursing protocol (Appendix F) and the VA HTN Clinical Practice Guideline (CPG) (Appendix G) will be reviewed in the PowerPoint presentation as examples of nurses working autonomously. A chart audit (Appendix I) using the ICD 10 code 110-16 to pull medical records will be completed to determine if there was a positive change in the nurses' compliance with the HTN nursing protocol. Lastly, the nurses will be given resources on the Centers for Disease Control and Prevention (CDC) website to review for future use (Appendix D).

Current literature on SDM and nursing autonomy were used to create the PowerPoint and pre-and post-test for this DNP quality improvement project. The VA HTN nursing protocol and CPG are tools created by the organization for use in patient care and do not require permission for use. The video by Dr. Joy Doll, "Collaboration in Health Care: The Journey of an Accidental Expert?" is available on Tedx Talk and is an open-source video (Appendix J). The video "Formula 1 Pit Stop 1950 vs. 2013" is available for use under the Fair Use Law (Appendix K). The DNP Lead worked with the organization's subject matter experts (SME) in nursing education (Director for Nursing Education), lean six sigma (Systems Redesign Coordinator), and the Project Mentor to develop the PowerPoint presentation and pre-and post-test. The DNP Lead met with each SME separately and as a group to review the following criteria for the intervention:

- Review the purpose and problem for the DNP project
- Review the target participants
- Review the DNP project objectives and expected outcome
- Validate the literature used for the PowerPoint presentation and test
- Review the timeline
- Review the mechanism used to present the PowerPoint (Microsoft TEAMS)
- How the intervention was being coordinated
- Validate the tools used for the intervention

The Content Validity Index (CVI) rating tool was sent to the Project Team and the Project

Mentor to measure the pre-and post-test construct to support the test's validity. All references

used to develop the education PowerPoint presentation and tools were noted in the PowerPoint presentation. Additionally, the pictures on the slides were part of the PowerPoint library and did not require permission for use; the Centers for Disease Control and Prevention provided free resources; all videos used were accessible as open-source use or Fair Use Law and did not require permission for use. Lastly, the audit tool is the tool created by the organization for nursing documentation reviews and does not require permission for use.

Data Collection

The plan for data collection for this DNP quality improvement project has two components. The first component is the pre-and post-test (Appendix H) to determine if there is a change in knowledge and understanding before and after the PowerPoint presentation (Appendix B) intended to educate the PCC nurses on the benefits of SDM and how it can promote autonomy in team-based care. The second component is the pre-and post-intervention chart audit to determine if the nurses are functioning autonomously and showing improvement in compliance with the HTN nursing protocol.

The process for the pre-test will be to send the pre-test to the primary care clinic administrative assistant (AS) to distribute to each nurse before the PowerPoint presentation. The nurses will complete the pre-test anonymously and return it to the AS, who will submit it to the DNP Lead. After the PowerPoint presentation, the DNP Lead will distribute the post-test to the nurses to complete anonymously. A pre-and post-test analysis using a paired t-test will be conducted to determine if there is an improvement in knowledge before and after the intervention. The analysis can suggest whether the intervention was successful and if the nurses learned the content of the presented material.

The second data collection component will be done using descriptive analysis of the chart

audit (Appendix I) during weeks two through five. Each week 10% (or all the charts if less than 10) of the nursing visits with the ICD code I10-16 will be pulled for each PCC nurse. The chart audit will consist of the elements of the HTN protocol (Appendix F) as identified in the chart audit tool. The results of each chart audit will be shared with the PCC nurses and nursing leadership each week and at the conclusion of the project. All data will be kept in a password-protected folder on a secure desktop accessible using a Personal Identity Verification (PIV) card with a password and will be destroyed at the conclusion of the project using a double delete method.

Ethics and Confidentiality

The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research produced the Belmont Report in 1979, which serves as the ethical underpinning for federal legislation protecting human research participants (US Department of HHS, 2016). The Commission set forth the following principles, respect for persons, beneficence, and justice for research studies involving human subjects (US Department of HHS, 2016).

Any activity that risks psychological or physical harm to participants should consider ethical implications, including a QI project (US Department of HHS, 2016). It is important to distinguish if the project is a research study or a QI project so that the appropriate steps can be taken to protect human subjects or participants. The DNP Leader submitted a project cover sheet tool (Appendix L) along with the organization's Institution Review Board determination tool (Appendix M) to the Performance Improvement Committee for review for this DNP project. The committee determined that this was a QI project and not a research study involving human subjects and did not have the potential to cause psychological or physical harm to the participants. The DNP Lead determined that although the QI project did not involve human subjects, there would be a consideration for the nurses' privacy through anonymity. The pre-and post-test will not include the names of the participants on the test. The patients' privacy will be respected during the chart audits by not collecting demographic information.

The benefits of this QI project for nurses are that they will be given the authority to function autonomously to the full scope of their practice, participate in SDM for optimal patient care, and expand their role in TBC. These benefits to nurses will transfer to patients by increasing the number of patients returning for follow-up, increasing access to care, better management of all chronic conditions, promoting patient-centered care, reducing healthcare costs, and increasing and improving patient satisfaction (Leonga et al., 2021).

The most significant risk for the QI project is not psychological or physical harm but an attitude of resistance from the nurses not wanting to participate in the education and/or are not interested in making changes to their practice. This attitude could result in remaining status quo in the current practice and non-compliant with the new intervention. The participants were recruited through the ACN – OP and PCC NM. The ACN – OP and the PCC NM agreed to make it mandatory for the PCC nurses to participate as part of their ongoing requirements for professional education. The ACN – OP, and NM expressed that the PCC nurses could benefit from this DNP intervention by improving their nursing practice. For this DNP project, there will be no gifts or monetary compensation for participation.

Analysis

The measure used for this QI project will be the paired sample t-test using the SPSS software for the pre-and post-test. The pre-and post-test scores were analyzed using the paired sample t-test with an alpha level of 0.05. The paired sample t-test analyzes the difference between two variables or groups on the same subject at separate times (e.g., pre-and post-intervention) (Pallant, 2020). The assumption when using a paired t-test is that the differences between the pairs

(the pre/post-test) are normally distributed, which can be shown using a histogram (Pallant, 2020). The paired t-test assumes that the differences between the two test scores are normal but not that the observations within each group are normal (Pallant, 2020). The assumption is that the paired t-test will determine if the mean of the pre-test scores is significantly different from the mean of the post-test scores, indicating if the intervention improved the nurses' knowledge related to SDM, nursing autonomy, and TBC (Pallant, 2020). The hypothesis for this intervention is that the PowerPoint presentation will increase the nurses' knowledge and understanding of SDM, nurses functioning autonomously, and improve the nurses' compliance with the nursing HTN protocol.

The second item to be measured is the pre-and post-chart audits using descriptive statistics. The pre-and post-chart audits' elements were analyzed and compared to determine if the nurses completed all components of the nursing HTN protocol. The analysis will indicate if the intervention successfully promoted nurses functioning autonomously, at the full scope of their practice, and expanded their role in TBC by improving compliance with the nursing HTN protocol. This measure assumes that the PCC nurses will continue to comply with the nursing HTN protocol, function autonomously, and participate in SDM within the TBC model after the intervention.

Results

The data analysis will determine whether the aim of the DNP project was met and if the null hypothesis is accepted or rejected. The sample size for the DNP project intervention consisted of eight PCC nurses. The steps of the intervention entailed a pre-test, a PowerPoint presentation, a post-test, and pre-and post-chart audits over four weeks. The data from the pre-and post-test will indicate whether there was an increase in the nurses' knowledge of SDM, autonomy, and TBC, as evidenced by a statistically significant improvement in the tests before and after the PowerPoint

presentation. The chart audits will determine if there is an improvement in compliance with the HTN protocol using an average percentage.

Prior to the PowerPoint presentation, pre-tests were presented and completed by eight PCC nurses. After the presentation, eight post-tests were submitted. The pre-and post-test data analysis was calculated using a paired sample t-test (Appendix N). The paired sample t-test results indicated a p-value = .005 showing highly statistically significant results. The null hypothesis was rejected, indicating the difference in the pre-and post-test was not caused by chance and denoting a gain in knowledge after the PowerPoint intervention.

Each nurse answered the pre-and post-test independently of the other nurses, the differences between the tests followed a normal distribution, and there were no extreme outliers in the differences in the eight tests. The paired sample t-test for the pre-and post-test showed no violations of the assumptions implying the t-test was reliable.

The chart audits were conducted using an audit tool (Appendix N) and calculated as an average percentage to determine if there was an improvement in compliance with the utilization of the HTN nursing protocol. The first week of chart audits included four medical records and showed the nurses were compliant with the nursing HTN protocol, with an average of 91% compliance. Week two chart audits included three medical records and showed an average of 95% compliance. Weeks three and four included five and four medical records, respectively, and showed an average of 100% compliance with an overall average of 96% compliance. The results show a significant improvement from the pre-intervention chart audit results of overall average compliance of 49%.

Table 1

Pre-Intervention Chart Audit Results

35



Note: Shows average compliance with the HTN Nursing protocol pre-intervention = 49%

Table 2



Post-Intervention Chart Audit Results

Note: Shows average compliance with the HTN Nursing protocol post-intervention = 96%

The four-week timeline (Appendix O) for this DNP project started on July 06, 2022,
concluded on August 03, 2022, and stayed on track with no modifications required to the timeline. **Summary**

The critical findings for this DNP project were that promoting SDM and nursing autonomy assisted nursing in understanding their role in TBC and allowed them to expand their role in care through the use of available tools (e.g., protocols, Clinical practice guidelines, and State Nursing Practice Act). Additionally, the chart audits answered the PICOT question, showing a significant improvement in compliance with the HTN nursing protocol after completing the educational seminar. This DNP project had the full cooperation of the organizational and nursing leadership. The leadership assisted with removing barriers such as gaining access to patient medical records and scheduling time for staff to participate in the intervention, and ensuring all resources were available. The project strengths were as follows:

- There was active participation, communication, cooperation, and collaboration between nursing and organizational leadership and the DNP leader during the development and implementation of the DNP project.
- The DNP project (intervention) was well received by nursing and organizational leadership and the PCC Nurses.
- There was a 100% response for pre/post-test
- The timeline was well organized
- Multiple PCC nurses requested information regarding the difference between the scope of practice vs. delegation of authority.
- The PCC nurses showed interest in the DNP project, as evidenced by four nurses requesting one-on-one mentoring and coaching regarding SDM, autonomy, and TBC.

The weaknesses are as follows:

- There was a small sample size of eight nurses, which can reduce the project's impact because of low statistical power.
- There was a small sample size of 20 and 16 medical records, respectively, for the pre-and post-chart audits, reducing the likelihood of reproducing the same results on a larger scale.

Interpretation

The published literature on the impact of SDM, TBC, nursing autonomy, and expanding the nurses' role in care through nurse-led interventions such as protocols and algorithms aligned with the results of the DNP project. The literature supported nurses' participation in SDM as a member of the TBC model to promote nursing autonomy to improve patient outcomes. Several authors reported that allowing nurses to participate in SDM and the authority to function autonomously using nurse-led interventions are comparable to traditional physician-only care and, in most situations, improved patient outcomes (Leonga et al., 2021; Derington et al., 2019).

The DNP project data results aligned with the published literature's conclusions that SDM, nursing autonomy, and TBC improved the care of patients diagnosed with HTN and patient outcomes. The PowerPoint presentation met the objective of educating the PCC nurses on the benefits of SDM and how it can promote autonomy. The paired sample t-test indicated an increase in knowledge after the intervention, as evidenced by the pre-and post-test results meeting the objective of increasing the nurses' understanding of SDM. Additionally, there was an improvement in compliance with the nursing HTN protocol, as evidenced by the pre-and post-intervention chart audit results meeting the objective of expanding the nurse's role within the TBC model of care by promoting nursing autonomy.

The contextual elements of this DNP project were leadership, organizational culture, teamwork, communication, resources, evaluation, monitoring, feedback, and champions. Each

contextual element was interrelated and worked synergistically to influence the implementation of the DNP project. Organizational and nursing leadership enhanced and supported the implementation of the intervention by providing resources, encouraging teamwork, ensuring communication, providing feedback, and assisting in selecting a PCC champion.

The anticipated outcomes aligned with the observation during the development and implementation of the project. Nurses actively participated in the DNP project intervention, asked questions, and requested one-on-one mentoring and coaching on SDM, autonomy, TBC, and scope of practice versus delegation of authority post-intervention. Leadership and PCC nurses supported the intervention to change the organizational culture and improve the nurses' understanding of TBC, SDM, autonomy, communication, and compliance with the HTN nursing protocol. The outcomes showed a statistically significant improvement in knowledge from the pre-test and post-test (p= .0005) (Appendix H and N) and compliance with the HTN nursing protocol (49% to 93%).

Although this DNP quality improvement project could not immediately determine any cost savings related to the intervention, the literature identified a relationship between SDM, nurse-led interventions, and TBC and a reduction in the cost of care. Two articles that highlighted the cost benefits of SDM, nurse-led intervention, and TBC are Derington et al., 2019, and Reddy et al., 2018. Derington et al. (2019) reviewed RCTs for the effectiveness of team-based care (TBC) in maintaining BP control related to cost, which revealed that nurse-led interventions, such as HTN nursing protocols, were comparable to physician-led care at a significantly lower cost.

Reddy et al. (2018) completed a retrospective cohort study of Veterans Health Administration (VA)-Medicare dual-eligible Veterans and the association between TBC and continuity. The study concluded that patients seen by teams using the TBC model of care saw fewer hospitalizations, and ED visits, improved clinical-level measures, and had a low probability of experiencing many types of high-cost health issues reducing the overall cost of care.

There were no trade-offs in the development and implementation of this DNP project. The project aimed to improve the nurses' understanding of SDM, autonomy, TBC, and compliance with the HTN nursing protocol was successful.

Limitations

The limitation of this DNP project was related to the small sample size. The project's sample size consisted of eight primary care registered nurses, and the chart audits included 20 pre-intervention and 16 post-intervention medical records. This project was a rapid cycle quality improvement project, which typically has a small sample size and requires frequent data collection to test the project concept, demonstrate the improvement's feasibility, and refine the strategy for change (Etchells et al., 2016). The limitation of a smaller sample size is an increased margin for error, making it difficult to determine if the data analysis outcome is factual, resulting in the null hypothesis being wrongly accepted and showing no difference in the project outcome (Etz & Arroyo, 2015). Working closely with nursing and organizational leadership and the PCC nursing champion on the design and implementation minimized and corrected any possible errors. Although not an actual limitation overcoming the organization's submissive culture and improving the nurses' understanding and ownership of their role in SDM, functioning autonomously, and becoming an active healthcare team member was a challenge. The nursing and organizational leader minimized this challenge by supporting the intervention and encouraging the nurses to participate with an open mind.

Conclusion

This DNP project focused on expanding the nurse's role by promoting SDM, nursing autonomy,

and TBC to improve nursing compliance with the HTN nursing protocol. After the intervention (PowerPoint presentation, pre-and post-test, and chart audits), the pair sample t-test of the preand post-test showed a p-value of .0005, indicating a statistically significant improvement in the nurses' knowledge of SDM, nursing autonomy, and TBC, the impact of SDM on nursing autonomy and strategies to create a TBC environment and availability of tools to expand the nurses' role. Additionally, the chart audits data showed improved nursing compliance with the HTN protocol from average compliance of 49% to 96%. The DNP project implication for nursing practice was an increased knowledge regarding the nurse's role in SDM, the impact of SDM on nursing autonomy and TBC, improved compliance with the HTN nursing protocol, and the potential for improved patient outcomes. Additionally, the intervention guided the PCC nurses' use of available tools for participation in SDM and functioning autonomously. The implication for the organization was the development of a high-functioning interdisciplinary team approach to care utilizing all team members' knowledge, skills, and experiences. Lastly, the organizational and nursing leadership requested permission to add the PowerPoint presentation to nursing orientation and expand the DNP project to all nurses in primary care clinics within the organization. The next steps will be to provide the PowerPoint and pre-and post-test to the nursing leadership to implement the intervention across the organization.

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Appendix A

PDSA



Appendix B

- A definition of shared decision-making (Moss et al., 2016).
 - A process that involves a collective, collaborative effort between various professional healthcare providers working to provide patients, families, caregivers, and communities when considering and communicating each other's unique perspectives in delivering the highest quality of care.
 - Video, "Collaboration in Health Care: The Journey of an Accidental Expert?" <u>https://youtu.be/qOV-5h0FpAo</u> by Dr. Joy Doll.
 - Identify resources from the Centers for Disease Control and Prevention on interprofessional collaboration; <u>Interprofessional Collaboration | Transitions to</u> <u>Professional Nursing Practice (lumenlearning.com/suny-delhi-professionalnursing</u> /chapter/interprofessional-collaboration/).
- A definition of nursing autonomy (ANCC, 2020; Oshodi1et al., 2019).
 - Autonomy is the ability of the nurse to assess and perform nursing actions for patient care based on competence, professional expertise, and knowledge.
 Autonomy provides nurses the authority to make decisions and the freedom to act in accordance with one's professional knowledge base.
 - Ownership, Strength, Relationships, Motivation.
- An introduction to team-based care (Smith, et al., 2018; ANA, 2016).
 - Team-based care is a delivery model where patient care needs are addressed as coordinated, collaborative efforts among multiple health care providers and across settings of care.
 - Roles and responsibilities of team members

- Impact of interprofessional communication
- A video depicting a high-functioning team, "Formula 1 Pit Stop 1950 vs. 2013."
 - https://www.youtube.com/watch?v=EPKRAFWscfE
- Strategies for building a high-functioning team through SDM, autonomy, and TBC (Huber, D. & Joseph, L., 2021; Mitchell et al., 2012).
 - Shared goals
 - Clear roles
 - Mutual trust
 - Effective communication
 - Measurable processes and outcomes
- Example of how nurses work autonomously
- A review of the VA HTN nursing protocol and the VA HTN clinical practice guideline (https://www.healthquality.va.gov) with a discussion of how nursing protocols allow nurses to function autonomously.







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Appendix C



(https://youtu.be/qOV-5h0FpAo)

Interprofessional Collaboration

Healthcare has faced a vast number of challenges in delivery of quality care over the past 50 years. The population is older, more diverse, medically complex with a higher prevalence of chronic disease requiring multiple specialty providers, a greater reliance on technology and innovation, and uncoordinated delivery systems. Healthcare has also shifted towards delivering care to individuals with vast healthcare disparities (Institute of Medicine [IOM], 2003a). Collaborative practice can improve the delivery of care through a concerted effort from all members of the healthcare team and leaders through the organization.

In response to these challenges, collaborative practice environments are indispensable to improving safety and patient care indicators. Collaborative practice has been found to reduce the rate of complications and errors, reduce length of stay, and lower mortality rates. Collaboration also leads to reduce conflict among staff and reduced turnover. Additionally, collaborative practice strengthens health systems, improves family health, improves infectious disease, assists with humanitarian efforts, and improved response to epidemics and noncommunicable disease (World Health Organization [WHO], 2010).

Collaboration has become an essential component to implementing health promotion and disease prevention/management (Humphreys et al., 2012; Odum & Whaley-Connell, 2012). Due to the high rates of medical errors over the past several decades, interprofessional Collaboration has emerged as a pragmatic intervention step that can reduce errors and improve care (Interprofessional Education Collaborative [IPEC], 2016)

Nurses and others healthcare professionals need to work together in order to address challenges that impede progress on improving safety and quality care. The IOM (2015) states, "No single profession, working alone, can meet the complex needs of patients and communities. Nurses should continue to develop skills and competencies in leadership and innovation and collaborate with other professionals in health care delivery and health system redesign" (p. 3).

Common Concept Definitions

• Elements of Collaboration

"Participants from different cultures, high level of interaction, mutual authority, sharing of resources" (Green & Johnson, 2015, p. 5)

• Interprofessional collaborative practice (IPCP)

"When multiple health workers from different professional backgrounds work together

with patients, families, and communities to deliver the highest quality of care" (Green & Johnson, 2015; WHO, 2010).

• Interdisciplinary Collaboration (IDC)

A team of healthcare practitioners who make a joint, consensus decision about patient care facilitated by regular, face-to-face meetings (Ivey, Brown, Teske, & Silverman, 1988).

Note: The difference between IPCP and IDC is the former can be applied to multiple categories of "patients" (individual patient and/or family, groups, and communities) whereas the latter is applied exclusively to the patient and/or family.

Interprofessional teamwork

"The levels of cooperation, coordination and collaboration characterizing the relationships between professions in delivering patient-centered care" (IPEC, 2016, p. 8).

• Interprofessional team-based care

"Care delivered by intentionally created usually relatively small work groups in health care who are recognized by others as well as by themselves as having a collective identity and shared responsibility for a patient or group of patients (e.g., rapid response team, palliative care team, primary care team, and operating room team)" (IPEC, 2016, p. 8).

• Interprofessional competencies in health care "Integrated enactment of knowledge, skills, values, and attitudes that define working together across the professions, with other health care workers, and with patients, along with families and communities, as appropriate to improve health outcomes in specific care contexts" (IPEC, 2016, p. 8).



The Institute of Medicine (IOM, 2011) released a landmark report called, *The Future of Nursing: Leading Change, Advancing Health.* The report addressed the critical role of nurses in the delivery of healthcare and made three core recommendations: transforming nursing education, practice, and leadership. The report states nurses must become leaders at every level of the healthcare system in order to participate in

ongoing healthcare reform. Leadership is key to becoming a full partner on the healthcare team, and to advocate for policy changes that assist with improving delivery of healthcare.

Additionally, the report found nurses are the best source of information about the patient, family, and communities though are largely excluded from decision-making. Nurses are left with carrying out orders that may or may not be safe, quality patient-centered care. In order to be part of the decision-making process, the report suggests nurses lead through engaging all members of the healthcare team through interprofessional Collaboration and mutual respect. The report offers two recommendations in the area of interprofessional Collaboration:

Recommendation 2

Expand Opportunities for Nurses to Lead and Diffuse Collaborative Improvement Efforts

Recommendation 7

Prepare and Enable Nurses to Lead Change to Advance Health (IOM, 2011)

The IOM (2015) has followed up on these recommendations and has concluded nursing has made progress with providing quality, patient-centered, accessible, and affordable care, though continued efforts to meet the following recommendations are ongoing:

- Removing barriers to practice and care
- Transforming education
- Collaborating and leading
- Promoting diversity
- Improving data (IOM, 2015)

Benefits of Collaborative Practice

Today's complex healthcare environment has made it difficult for patients to access care, especially those with chronic disease who need access to a variety of specialty services. Patients need assistance with following prescribed orders and follow up appointments with multiple providers. Interprofessional Collaboration has improved access to care, safety, chronic disease outcomes, and use of specialty care (Lemieux-Charles & McGuire, 2006; WHO, 2010).

Interprofessional Collaboration offers nurses the opportunity to lead and influence change at multiple levels of care (national, regional, local patient settings). Nurses can have a voice in political activism through professional organizations or through academic/practice partnerships (Moss, Seifert, & O'Sullivan, 2016). Collaboration offers nurses the opportunity to serve on boards of directors, government committees, or

advisory boards. Through collaboration efforts, nurses can fulfill their role in a variety of ways, with the overarching goal of redesigning the healthcare delivery system.

Through interprofessional Collaboration, healthcare organizations can improve safety and quality through committee membership. Nurses can participate in committees that are unit- or organization-wide. Committees are formed based on improving safety and quality by using outcome data, such as preventing hospital-acquired infections, falls, and increased patient satisfaction. Additionally, committees may focus on the health and well-being of staff, to reduce nurse turnover and burnout. Participating in committees benefits everyone, from the patient to the entire organization.



By joining committees, nurses have the opportunity to speak up and share their knowledge and expertise with the interprofessional team, management, and other stakeholders inside and outside of the organization. Interprofessional Communication gives nurses a voice, allows them to become intimately involved in the decision-making process and creating solutions. Since nurses implement many of the solutions, nurses must share their insight to ensure the solution has a patient-centered approach. Interprofessional Communication is the main way nurses can advocate for and uphold patient rights.

No committees at your workplace? Create one! Locate a problem area in your workplace or unit, research solutions, and present a plan to your manager. Chairing a committee is a good way to network with other professionals and it's an important part of your professional development as a professional nurse.

Littlechild and Smith (2013) cite a wide range of healthcare benefits from interprofessional Collaboration, including improved efficiency, higher levels of team responsiveness, creative skill sets, and the implementation of innovative holistic services. Several additional benefits of interprofessional Collaboration as follows:

- Opportunity to learn new ways of thinking
- Network with professionals from different organizations
- Gain new knowledge, wisdom from others
- Access to additional resources previously unavailable
- Potential to develop new skill sets
- Increased productivity due to shared responsibility
- Access to funding, sharing of costs (research)

• Pooling of knowledge for solving large, complex problems (as cited in Green & Johnson, 2015)

Collaboration has enabled large-scale international organizations like the WHO to achieve more than previously thought possible because of the strength and support of individual members working collectively for a common goal (Green & Johnson, 2015). Collaborations with large groups of professionals and international organizations (such as the WHO) occur throughout all areas of healthcare education, research, and practice. All three domains are connected; research informs education, which informs clinical practice and education. The table below shares some exemplars of successful interprofessional Collaboration in healthcare.

Name	Purpose		Website
The Cochrane Collaboration	"Cochrane is a global independent network of health practitioners, researchers, patient advocates and others, responding to the challenge of making the vast amounts of evidence generated through research useful for informing decisions about health."	Evidence	www.cochrane.org
U.S. Preventive Services Task Force	" the U.S. Preventive Services Task Force is an independent, volunteer panel of national experts in prevention and evidence-based medicine. The Task Force works to improve the health of all Americans by making evidence-based recommendations about clinical preventive services such as screenings, counseling services, and preventive medications."	Public Health	<u>www.uspreventive</u> servicestaskforce.org
Global Alliance for Musculoskeletal Health " a national and international patient, professional, scientific organisations around the world . focused on health policy and evidence, with a mandate to develop strategies and set the agenda, aimed at improving quality of life for individuals around the world by implementing effective prevention and treatment through its unified voice and global reach"		Clinical Practice	<u>https://gmusc.com</u>

Table 1: Exemplars of Successful Interprofessional Collaboration in Healthcare

The following TEDx Talks video discusses the role of collaborative practice in healthcare:

video of collaborative practice in healthcare

(TEDx Talks, 2018)

Joy Doll, the speaker in the video above, discusses six lessons (below) she learned through developing a collaborative practice initiative for a healthcare organization. Joy found these lessons were vital to successful, productive teamwork:

- 1. Grit: willingness to take on challenges
- 2. Don't listen to "NO"
- 3. "Ego-up", engage in meaningful activities that lead towards the goal
- 4. Psychological safety: speak up with confidence, without consequences
- 5. Define your culture:
 - everyone teaches, everyone learns
 - assume positive intent of others
- 6. know yourself through self-assessment, reflection (i.e. strengths/weaknesses)

Joy reflects on the LEGO movie where leadership and Collaboration are weaved into the storyline. To watch the LEGO movie, go to <u>this website</u>.

Cost of Reduced Collaboration

The lack of interprofessional Collaboration prevents nurses from working to the full extent of their training and education. In order to improve practice, and assist with improving the delivery of healthcare, all nurses must be vested in improving and reducing the barriers of interprofessional Collaboration (Moss et al., 2016).

Foundational Documents of Professional Practice

Interprofessional or interdisciplinary Collaboration is an indispensable part of nursing practice. The American Nurses Association (as cited in ANA, 2021) defines Collaboration as "working cooperatively with others, especially in joint intellectual efforts, in a way that includes collegial action and respectful dialogue" (p. 110).

Scope and Standards of Practice

As discussed in Week 1, the Scope and Standards of Practice, developed by the ANA (2021), serves as a template for professional nursing practice for all registered nurses. Standard 11, Collaboration, states, "The registered nurse collaborates with the healthcare consumer and other key stakeholders" (ANA, 2021, p. 95). The following is a snapshot of some of the competencies of the Collaboration standard:

- Values the expertise and contribution of other professionals and key stakeholders.
- Partners with the healthcare consumer and key stakeholders to advocate for and effect change, leading to positive outcomes and quality care.
- Uses effective group dynamics and strategies to enhance performance of the interprofessional team.
- Promotes engagement through consensus building and conflict management
- Partners with all stakeholders to create, implement, and evaluate plans (ANA, 2021, p. 96).

Nursing's Scope of Practice is dynamic and is responsive to the changing needs of individuals and society as a whole. The nursing profession relies on all healthcare professionals to be actively involved in healthcare planning and decision-making; thus Collaboration is at the core of all short- and long-term goals (ANA, 2015b). Healthcare professionals are expected to collaborate in the following ways:

- Sharing knowledge, techniques, and ideas about how to deliver and evaluate quality and outcomes in healthcare
- Sharing some functions/duties with others, and having a common focus on the overarching goal
- Recognizing the expertise of others within and outside the profession, referring patients to other providers as appropriate (ANA, 2015b)

The Code of Ethics

As discussed in Week 1, the Code of Ethics is an expression of the values, duties, and commitments of registered nurses. Provision 8 states, "The nurse collaborates with other health professionals and the public to protect human rights, promote health diplomacy, and reduce health disparities" (ANA, 2015a, p. 129). Provision 8 includes two interpretative statements:

8.2: Collaboration for Health Human Rights, and Health Diplomacy

 Nurses are committed to advancing health, welfare, and safety to all people, to individuals and globally. Some examples include world hunger, poverty or environmental pollution, and violation of human rights. Access and availability to quality healthcare services requires interdisciplinary planning and Collaboration with partners, whether locally, state-wide, nationally, or globally (ANA, 2015a, p. 203).

8.3: Obligation to Advance Health and Human Rights and Reduce Disparities

• Through Collaboration with community organizations, nurses can work individually or collectively, to assist with educating the public on current or future health threats. Nurses have a responsibility to work collaboratively

with community agencies to assist the public with facilitating informed choice and identify situations that may contribute to illness, injury or disease. Lastly, the nurse needs to support initiatives that address barriers to healthcare, including the needs of the culturally diverse populations (ANA, 2015a, p. 204)

Provision 2 states, "The nurse's primary commitment is to the patient, whether an individual, family, group, community or population" (ANA, 2015a, p. 25). Interpretive statement 2.3, titled Collaboration, explains shared goal making is a concerted effort of individuals and groups. The complexity of the healthcare system requires nurses to work closely with the interdisciplinary team for safe, quality delivery of care.

Provision of safe, quality care at the community, national, and international levels can be accomplished through creation of community partnerships, political activism and substantial Collaboration with all stakeholders. It is the nurse's ethical responsibility to consider Collaboration in all aspects of nursing practice. Safe, quality care cannot be performed by one person, but together, with others, goals can be achieved. It is through Communication and Collaboration that nurses are able to provide the best possible care to their patients.

Nursing's Social Policy Statement

As discussed in Week 1, nursing's social policy statement describes the value of the nursing profession within society, defines the concept of nursing, reviews the standards of practice, and regulation of nursing practice. The nursing practice is inherently connected to society, thus requiring a social contract between society and the profession (ANA, 2015b).

Collaborative efforts with other healthcare professionals are rooted in establishing effective trusting relationships, leading to partnerships where individuals begin to value each other's differences, similarities, experience, and knowledge.

The Essentials

Transforming practice to collaborative care environments required transformation of nursing education, as stated in the IOM (2011) report. The Essentials provide a framework for competencies within undergraduate nursing education (American Association of Colleges of Nursing [AACN], 2008).

Communication and Collaboration among healthcare professionals are critical to delivering high quality and safe patient care (AACN, 2008, p.3). Collaboration is based on the complementary interaction of the team member's roles. Understanding roles and perspectives are vital to Collaboration.

Interprofessional Collaborative Practice Organizations

Interprofessional Education Collaborative

The IPEC (2016) was created in 2009 to develop core competencies for interprofessional collaborative practice. The original IPEC report was developed 2011, since revised in 2016, was developed through the initiative of six healthcare disciplines with the intent of defining core interprofessional competencies for their professions. The professions included dentistry, nursing, medicine, osteopathic medicine, pharmacy, and public health. After the release of the first IEC report, support from additional health professions and educational organizations ensued. The four core competencies for interprofessional collaborative practice are as follows:

Competency 1: Values/Ethics for Interprofessional Practice

• Work with individuals of other professions to maintain a climate of mutual respect and shared values.

Competency 2: Roles/Responsibilities

• Use the knowledge of one's own role and those of other professions to appropriately assess and address the health care needs of patients and to promote and advance the health of populations.

Competency 3: Interprofessional Communication

• Communicate with patients, families, communities, and professionals in health and other fields in a responsive and responsible manner that supports a team approach to the promotion and maintenance of health and the prevention and treatment of disease.

Competency 4: Teams and Teamwork

 Apply relationship-building values and the principles of team dynamics to perform effectively in different team roles to plan, deliver, and evaluate patient/population-centered care and population health programs and policies that are safe, timely, efficient, effective, and equitable (IPEC, 2016, p. 10)

While standardized forms of communications improve Communication, integrating the constructs of teamwork, Collaboration, and the awareness of each team member's roles is crucial to the success of interprofessional Communication (IPEC, 2016).

Interprofessional Professionalism Collaborative

The Interprofessional Professionalism Collaborative (IPC, n.d.) was created to develop tools used by healthcare education organizations to assist with developing

interprofessional professionalism behaviors within academic curriculum. In addition, researchers us the tools developed by the IPC to advance interprofessional professionalism, a required element of interprofessional collaborative practice. The definition of interprofessional professionalism is as follows:

Consistent demonstration of core values evidenced by professionals working together, aspiring to and wisely applying principles of, altruism and caring, excellence, ethics, respect, Communication, accountability to achieve optimal health and wellness in individuals and communities (Frost et al., 2019; Stern, 2006, p. 15).

The IPC (n.d.) has identified six core interprofessional behaviors:

- 1. Communication
 - Impart or interchange of thoughts, opinions or information by speech, writing, or signs; "the means through which professional behavior is enacted." (Stern 2006)

2. Respect

• "Demonstrate regard for another person with esteem, deference and dignity . . . personal commitment to honor other peoples' choices and rights regarding themselves . . . includes a sensitivity and responsiveness to a person's culture, gender, age and disabilities . . . the essence of humanism . . . signals the recognition of the worth of the individual human being and his or her belief and value system." (Stern, 2006)

3. Altruism and Caring

 Overt behavior that reflects concern, empathy, and consideration for the needs, values, welfare, and well-being of others and assumes the responsibility of placing the needs of the patients or client ahead of the professional interest (IPC, n.d., para. 4).

4. Excellence

• Adherence to, exceeds, or adapts best practices to provide the highest quality care (IPC, n.d., para. 5).

5. Ethics

 Consideration of a social, religious, or civil code of behavior in the moral fitness of a decision of course of action, especially those of a particular group, profession, or individual, as these apply to everyday delivery of care (IPC, n.d., para.6).

6. Accountability

 Accept the responsibility for the diverse roles, obligations, and actions, including self-regulations and other behaviors that positively influence patient and client outcomes, the profession, and the health needs of society (IPC, n.d., para. 7). Nurses are engaged and motivated to provide the best possible care for their patients. Nurses use their knowledge and expertise to design patient-centered goals. In order to realize these goals, nurses must be leaders throughout the healthcare system, and engage others to participate and be vested in full Collaboration with the patient's best interest in mind. Sherman (2015) states the following behaviors helps nurses influence others to foster interprofessional Collaboration:

- Establish your voice: effective communication and listening skills, address concerns, be perceived as trustworthy
- Expand networks: develop relationships with others to form a joint vision
- Shared accountability: leads to a sense of community, joint decisionmaking
- Empower others: encourage others to speak up and act



WHO: Interprofessional Education & Collaborative Practice

WHO (2010) has created strategies to improve interprofessional education and collaborative practice to improve health outcomes globally. To make this initiative achievable, WHO has outlined a series of action items policymakers can use to improve their local healthcare systems.

WHO (2010) explains that the overall well-being of a country is centered on maternal and child health. Each day, 1500 women die from complications during pregnancy or childbirth worldwide. Healthcare workers who work together to identify the key strengths of each team member and use those strengths to improve the care of complex health issues, can improve these alarmingly high death rates. Maternal and child health is just one of many complex health problems within society that can be improved through collaborative work environments.

Acute care hospitals conduct morning meetings or interprofessional rounds to discuss care practices, plans, discharge. Nurses are uniquely positioned at the center of the interprofessional team to monitor information exchange between nursing, medicine,

	Strategy	Promoting Behaviors	Barriers	The 14 C's of Teamwork
т	Team	 good selection of team members good team leaders maturity and flexibility of team members 	 poor selection of the disciplines and team members poor process of team functioning 	Coordination of effortsConflict management
E	Enthusiasm	 personal commitment of team members 	 lack of proper measures to evaluate success of interdisciplinary work lack of guidelines for multiple authorship in research publications 	Commitment
A	Accessibility	 physical proximity of team members Internet and email as a supporting platform 	 language problems 	 Cohesiveness Collaboration
М	Motivation	 incentives 	 insufficient time for the project insufficient funding for the project 	Contribution
w	Workplace	 institutional support and changes in the workplace 	 institutional constraints 	Corporate support

ο	Objectives	 a common goal and shared vision 	discipline conflicts	Confronts problems directly
R	Role	 clarity and rotation of roles 	 team conflicts 	 Cooperation Consensus decision- making Consistency
к	Kinship	 communication among team members constructive comments among team members 	 lack of Communication between disciplines unequal power among disciplines 	 Communication Caring Chemistry (personality, "good fit")

(Choi and Pak, 2007)

Table 2: Promotors, Barriers, and Approaches for Interdisciplinary Teamwork

Dietary, social work, unlicensed staff, and others. Team collaboration will be most effective when trained team members are fully vested in the organization and are experienced in working as a cohesive team

Developing core competencies is an expectation of all nurses. Seeking out professional development opportunities is an obligation as stated in the Code of Ethics. Provision 5, interpretative statement 5.2 states, the nurse has the responsibility for professional growth and maintenance of competence (ANA, 2010a, p. 159).

Barriers and Promoters to Collaboration

Collaboration among healthcare professionals requires leadership and planning, common goals, and a "teamwork" atmosphere. The literature discussed below reviews an assortment of promoters (actions that enhance Collaboration and teamwork) and barriers that impact the success of Collaboration. The main take aways include a commitment to work together for a common goal, use of effective communication and collaboration skills, and the initiative to identify and resolve team conflicts.

Choi and Pak (2007) conducted a literature review to determine the promotors, barriers, and approaches to enhance interdisciplinary teamwork. The researchers discovered eight major concepts of teamwork and formulated them within the acronym "TEAMWORK."

See Table 2 for the promoters, barriers, and approaches for each concept are aligned to the acronym, including the "14 C's" for teamwork approaches.

Similar to some of the above points, WHO (2010) has identified the following mechanisms that impact collaborative practice, including:

- Management support: need to identify and support change champions
- Initiative to change the culture of an organization, and oneself
- Individual's attitude towards Collaboration

Hierarchical Team Structure

Lancaster, Kolakowsky-Hayner, Kovacich, and Greer-Williams (2015) found a lack of Collaboration among physicians, nurses, and unlicensed personnel (UAP) due to hierarchical team structures. While some physicians acknowledged nurses' knowledge and expertise, the study revealed hierarchical, subservient relationships. Nurses and UAPs did not have meaningful discussions about patient needs or care, and physicians viewed themselves as the main decision-maker.

The hierarchical structure of healthcare teams must be addressed in order to improve Collaboration and Communication among the team members. If unresolved, hierarchy will lead to tension, misunderstandings, and conflicts, burdening the healthcare system with consistent poor outcomes and fragmentation of care.

See more information about hierarchy in the previous chapter on Communication

Nursing leadership has a responsibility to create environments where Collaboration can transpire on a daily basis, with full, open participation from all members of the interprofessional team. Awareness of the barriers to Collaboration, such as unequal power among disciplines (hierarchy), language conflicts, or lack of a "good fit" among team members gives rise to educational opportunities for the organization and/or

nursing units. Nurses at all levels of care in the organization are responsible for addressing their personal educational gaps and encourage the team to seek out competency training.

Awareness of team members' roles assists with having accurate expectations of each other. Since nurses spend the greatest amount of time with patients, they are uniquely positioned to share an abundant amount of important information about the patient, thus, an assertive, effective communication style is warranted during collaborative meetings. Eliminating the hierarchy barriers is key to ensuring nurses have the confidence to speak up without fear of being reprimanded by physicians. advocating for patient needs, ensuring safe, quality care is provided requires an environment where information is shared freely, and everyone's voice is heard.

Tools and Frameworks to Improve Interprofessional Collaboration

Morgan, Pullon, and McKinlay (2015) conducted a review of the literature examining the elements of interprofessional Collaboration in primary care settings. The overarching element to achieving and sustaining effective interprofessional Collaboration was the opportunity to share frequent, informal Communication among team members. Continuous sharing of information led to an interprofessional collaborative practice, where knowledge is shared and created among the team members, leading to development of shared goals and joint decision-making. Two key facilitators to interprofessional Collaboration are the availability of a joint meeting time to communicate and having adequate physical space.

See the previous chapter on Communication for information on TeamSTEPPS[®], an evidence-based tool designed to improve patient safety and quality though improved Communication and Collaboration.

In Week 4, Leadership in Nursing, discussion about the Healthy Work Environment Model (HWEM), created by the American Association of Critical Care Nurses (AACN, 2016), incorporates *True Collaboration* as one of the six core standards. The *True Collaboration* standard states nurses must be relentless in pursuing Collaboration.

See Week 4 for more information about AACNs Healthy Work Environment Model

Successful Collaboration is highly valued and a necessity in today's healthcare environment. Experts suggest the daunting process of building a culture of Collaboration within an organization is well worth the effort and an indispensable part of success (Adler, Heckscher, & Prusak, 2011).

Appendix E



(https://www.youtube.com/watch?v=EPKRAFWscfE)

Appendix F

					LVN/	TIAD
Guideline	Criteria	Protocol Order	Frequency	RN	LPN	UAP
Hypertension (HTN)	(Essential) HTN is	Inclusions: Patients 18-75 years old				
Patient with	defined as systolic	with diagnosis of HTN.				
established diagnosis	blood pressure equal to					
<u>ONLY</u>	or greater than 140	Exclusions: Patient treated for a known				
	mmHg or diastolic	urgent care or emergency room visit, or				
	blood pressure equal to	hospitalization in the past 30 days.				
<u>RN</u> may release	or greater than 90	Patients enrolled in dialysis or				
routine labs & routine	mmHg on at least 2	palliative/hospice care.				
in-house consults for	subsequent occasions					
replacement DME/	or taking anti-HTN					
Supplies and	meds w/goal of					
continuation of care	maintaining a normal					
LVN *HOLD FOR	blood pressure.					
SIGNATURE	Receiving medication					
	specifically for HTN.					
	e.g., diuretic, ACE-I, or					
	ARB					
	Do Not duplicate order,					
	e.g., patients with co-					
	morbidities (DM/HTN)					
Hypertension (HTN)	Diagnosis of HTN	Chem-8	Annually	Х	X*	
"Established	-		-			
diagnosis"	Receiving medication	*HOLD FOR SIGNATURE				
	specifically for HTN.					
	e.g., diuretic, ACE-I, or	-Place a note in CPRS include all				
	ARB	nursing actions				
Hypertension (HTN)	Diagnosis of HTN	Prosthetics Consult				
"Established						

diagnosis"	+Blood Pressure Cuff	One-time order or if	Х	$+X^*$	X**
		lost or damaged			

Continue:	Diagnosis of HTN	+HTN Education – Health Promotion	+Patients may self-	+X	$+X^*$	+X**
		Disease Prevention for Pt. Education	<i>refer</i> for any of these			
Hypertension (HTN)	Medication		services – Call			
"Established	Management Criteria:	+Medication Management – add	service to confirm	+X	$+X^*$	$+X^{**}$
diagnosis"	New DM diagnosis	pharmacist to note as cosigner	availability for			
	HgA1C > 9%		patient			
NOTE: UAP must	Uncontrolled HTN	+Nutrition Consult		+X	$+X^*$	$+X^{}$
notify RN or PCP of	Uncontrolled					
need for a consult	hypercholesterolemia	+MOVE Consult		+X	$+X^*$	$+X^{**}$
	Nutrition Criteria:					
+NOTE: provide	BMI >25 with co-	*HOLD FOR SIGNATURE				
education & training	morbidities (DM, HTN,					
	CAD);	-Place a note in CPRS include all				
	BMI >30	nursing actions.				
	Increased risk for DM					
	(FBG 101-125), new					
	DM, or A1C >8.5%					
	LDL >100 with					
	2 or more risk factors					
	Chronic Kidney Disease					
	(eGFR <50)					
	HTN/CHF					
	Pregnancy					
	MOVE Criteria:					
	BMI > 30 or BMI > 25					
	with comorbidities					
	Contraindications					
	Pregnant and					
					LVN/	
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Guideline	Criteria	Protocol Order	Frequency	RN	LPN	UAP
Continue:	lactating		+Patients may			
	female, active		self-refer			
Hypertension (HTN)	cancer, or life-					
"Established diagnosis"	threatening					
	issues.			X+	X+	X+
		+Provide the CDC guide to stop smoking:				
	Reduce	Tobacco/E-cig/Dip etc. user				
	Nicotine					
	Exposure	https://www.cdc.gov/tobacco/campaign/tips/quit-				
	_	smoking/guide/				
		-Place a note in CPRS include all nursing actions				

Appendix G

W. - Health Care - Wr/DoD Clinical Practice Guidelines - Clinical Practice Guidelines - Chronic Disease (in Primary Care) Guidelines - Diagnosis and Nanagement of Hypertension (HTN) in Primary Care (2020)

VA/DoD Clinical Practice Guidelines

W000 Gineal Predice

Guidelines

W4/DoD Clinical Fractice Guidelines Home

- Putter Guidence
- Cardelines

+ Chronic Disease in Primary Care

Actima

Chronic Kichey Disease (CKD) Chronic Obstructive Puntonary Disease Distretes Melitius (DM)

Dyslpidems (LIPIDS)

Hip & Knee Ostecarthritis (OA)

Hypertension (HTN)

A20/Annext

Menagement of Adult Overweight and Obesity

Mental Health

- + Military Related
- + Pain
- + Rehsbritation

+ Womens Health

• More fired in Care

QUICK LINKS

Diagnosis and Management of Hypertension (HTN) in Primary Care (2020)

WADdb Clinkal Pacifice Oxide Ine Diagnosis and Management of Hypertension in the Primary Care Setting



The guideline describes the critical decision points in the Diagnosis and Management of Hypertension in Primary Care and provides clear and comprehensive evidence based recommendations incorporating current information and practices for practitioners throughout the DoD and VA Health Care systems. The guideline is intended to improve patient outcomes and local management of patients with hypertension.

Disclaimer: This Clinical Practice Guideline is intended for use only as a tool to assist a clinician/healthcare professional and should not be used to replace clinical judgment.

About the CPG

The guideline is formatted as two clinical algorithms and 78 evidence-based recommendations.

- Module A:
- Screening and Diagnosis
- Module B
 Ireatment
- The and the fits

Questions about the HTN Cuideline

Guideline Lunks	Patient Provider Tools	Related Guidelines		
HINT of Godelme (2020) 📆	HIN Patient Sammary (2020)	Dystpidemia (CP005)		
HTN Cinicise Summery (2024) 📆	High Blood Plassure Brochura	Octoberes Methos (CM)		
HTN Pocket Card (2020) 📷	024200			
Video Links	Webmars	Podcasts		
Horre Blood Pressure Monitoring	Updated WVDOD Clinical Practice	HTN/DASH Elici Podcast Spreaker		
Measuring Blood Pressure in the Olinic	Hyperlension in Primary Care	2020 Hypertension Clinical Practice		
too Finandatana	Webmer (2020)	Guidalina Lipdates Spraaker		

Refired CPG's can be found on our archive page

return to top a



VAD ₆ D CLINICAL PRACTICE GUIDELINES					an l			Varch 2020	
Sidebar 6: Optimize Treatment	Guidance Conducting Office	DASH Diet Protocol			Select Antihypertensive Therapy ^a				
Aussistements	Blood Pressure Neasurement Nutrient Records		Recommend	ied intaka		Spiect	Usual Desage	Correcto	
 Consider analysing for interfering substances (some prescription profession) MSI 74 detailed constrained in and 	Property people the prioriti	Smorad St 65 of total caloriau		wine.		Ned cation*	Range	- WITTING	
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 Optimize treatment (lefer to Appendix F, Table F-1 in the full CPG) 	reading	Calcoled ate	55% of term	color as:	Diantics	Hydradt lorgth agite	$Z_{i}^{\alpha}=M^{\alpha}\eta_{i}^{\alpha}cal_{i}^{\alpha}$	- Wonitor Ki- Jevels	
 Add another agent from a different case. 	When all the occupy and should be include both include the second of a Ensure that the patient has emplied higher blacker	Detary fiber	30 gram	siter				· Avoic in pregnancy	
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 Canader spectary consultation for patients with resident (11%) Canader exvintementions to enterior management of HTM and interove 	Kiting on an examining table does not tabili these orbite	Chalestano	180 mg	at a	Auth	Caropo	17-+anglein	 Wontor K+ and 	
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Appendix H

Pre/Post-Hypertension Education for Nurses to Improve Protocol Compliance Utilizing Shared Decision-Making Framework

1. Shared decision-making (SDM) in healthcare is a process that involves a collective effort between various professional healthcare providers working to provide patients, families, caregivers, and communities when considering and communicating each other's unique perspectives in delivering the highest quality of care. T F

2. Nursing Autonomy is the ability of the nurse to (select all that are correct)

a. Assess and perform nursing actions for patient care based on competence, professional expertise, and knowledge.

b. Allow nurses the authority to make decisions and the freedom to act in accordance with one's professional knowledge base.

c. An idea that nurses should have control over their nursing practice and should be able to make decisions that fall within their scope of practice, training, and expertise.

d. All of the above are correct

3. A delivery model where patient care needs are addressed as coordinated efforts among multiple health care providers and across settings of care is?

a. Assisted living care model

b. A paternalism model of care that is designed to tell patients what their care needs are, what is important, and what needs to be addressed

c. A team-based care delivery model where patient needs are addressed as a coordinated, collaborative effort among multiple health care providers and across settings of care.

d. A care model that only includes the nurse and provider in the decision-making process

4. SDM is a key component of patient-centered healthcare and is a collaborative practice that happens when the interdisciplinary team works together. T F

5. What are the components of autonomy?

a. Ownership, strength, relationships, motivation

b. Do no harm, independence, licensure

c. Interdependence, optimism, good attitude

d. None of the above

6. SDM impacts nursing autonomy by:

a. Promoting nurses to work to the full extent of their practice and achieve more effective control over nursing practice

b. Restricting nurses' involvement in the development of the patient's care plan

c. Providing guidance in emergency situations only

d. Limiting communication between the healthcare team

7. The following are examples of tools nurses can use to function autonomously T F

Clinical Practice Guidelines Algorithms State Nurse Practice Act Protocols

8. Nurse are not allowed to make autonomous decisions in their everyday practice T F

9. According to the American Nurses Association, the State Nurse Practice Act provides guidance to RNs on their scope of practice and standards of practice. T F

10. An example of how protocols assist the RN in functioning autonomously is by?

a. Providing step-by-step instructions

b. Superseding nursing judgment and critical thinking

c. Providing written documents that delegate to the nurse the authority to perform certain medical acts and actions

d. Restricting access to the patient's medical record unless permitted by the provider

10. Communication and relationship building are foundational for the initiation of SDM T F

11. SDM can negatively impact nurses' ability to more effectively control their practice and will decrease job satisfaction $T extbf{F}$

12. The following are strategies that can assist with building a high-functioning team T F Shared goals Clear roles Mutual trust Effective communication Measurable processes and outcomes

13. Which of the below is an example of nursing shared decision-making and nursing autonomy?

a. Giving PRN pain meds and adjusting a patient's treatment plan

b. Asking the provider if it's appropriate to check vital signs when there are concerns about the patient's status

c. Limiting the number of tasks you delegate to LVN/LPNs or CNAs

d. Waiting for the provider to give instructions in an emergency situation, e.g., when to start providing CPR.

14. What tools are available for nurses to participate in SDM and work autonomously at your present organization?

a. There are no tools available to assist nurses with SDM and to work autonomously

b. There is a limited number of tools available to assist nurses with SDM and to work autonomously

c. Clinical practice guidelines with algorithms embedded; State Nurse Practice Act; and local nursing protocols

d. Nurses do not need any tools to assist them in SDM and working autonomously

15. Protocols are written documents mutually agreed upon and signed by a nurse and a licensed physician, by which the physician delegates to that nurse the authority to perform certain medical acts and actions. T F

Appendix I

HYPERTENSION NURSING PROTOCOL 04/30-2021

		HYPERTENSI	ON NURSING	PROTOCOL C	HART AUDIT		
Pt ID							
DX (ICD 10							
I10-16)							
Meets							
inclusion							
criteria							
Review of							
medications							
Rx (diuretic,							
ACE-I, or							
ARB)							
specifically							
for HTN							
Annual Labs							
current							
within last							
12 months							
Last provider							
visit within							
12 months							
Current							
Weight							
Current B/P							
Blood							
pressure cuff							
order placed							
Discussed							

HTN					
education					
and available					
resources					
Discussed					
med					
management					
and available					
resources					
Discussed					
nutrition and					
available					
resources					
(MOVE!)					
Discussed					
nicotine –					
stop smoking					
if applicable					
Consults per-					
protocol					
order and					
release					
Comments					

Appendix J



Appendix K

Fair Use Law

U.S. Copyright Office (n.d.). More information on fair use. <u>https://www.copright.gov/fair-use/more-info.html</u>

Fair use is a legal doctrine that promotes freedom of expression by permitting the unlicensed use of copyright-protected works in certain circumstances. <u>Section 107 of the Copyright</u> <u>Act</u> provides the statutory framework for determining whether something is a fair use and identifies certain types of uses—such as criticism, comment, news reporting, teaching, scholarship, and research—as examples of activities that may qualify as fair use. Section 107 calls for consideration of the following four factors in evaluating a question of fair use:

- Purpose and character of the use, including whether the use is of a commercial nature or is for nonprofit educational purposes: Courts look at how the party claiming fair use is using the copyrighted work, and are more likely to find that nonprofit educational and noncommercial uses are fair. This does not mean, however, that all nonprofit education and noncommercial uses are fair, and all commercial uses are not fair; instead, courts will balance the purpose and character of the use against the other factors below. Additionally, "transformative" uses are more likely to be considered fair. Transformative uses are those that add something new, with a further purpose or different character, and do not substitute for the original use of the work.
- *Nature of the copyrighted work*: This factor analyzes the degree to which the work that was used relates to copyright's purpose of encouraging creative expression. Thus, using a more creative or imaginative work (such as a novel, movie, or song) is less likely to support a claim of a fair use than using a factual work (such as a technical article or news item). In addition, use of an unpublished work is less likely to be considered fair.
- Amount and substantiality of the portion used in relation to the copyrighted work as a whole: Under this factor, courts look at both the quantity and quality of the copyrighted material that was used. If the use includes a large portion of the copyrighted work, fair use is less likely to be found; if the use employs only a small amount of copyrighted material, fair use is more likely. That said, some courts have found use of an entire work to be fair under certain circumstances. And in other contexts, using even a small amount of a copyrighted work was determined not to be fair because the selection was an important part—or the "heart"—of the work.
- *Effect of the use upon the potential market for or value of the copyrighted work*: Here, courts review whether, and to what extent, the unlicensed use harms the existing or future market for the copyright owner's original work. In assessing this factor, courts consider whether the use is hurting the current market for the original work (for example, by displacing sales of the original) and/or whether the use could cause substantial harm if it were to become widespread.

In addition to the above, other factors may also be considered by a court in weighing a fair

use question, depending upon the circumstances. Courts evaluate fair use claims on a caseby-case basis, and the outcome of any given case depends on a fact-specific inquiry. This means that there is no formula to ensure that a predetermined percentage or amount of a work—or specific number of words, lines, pages, copies—may be used without permission.

Appendix L

Veterans Affairs Project Cover Sheet

Last edited by: Rebekah Friday Last edited on: May 13, 2022 IRBNet Number – 000-000-000 Project Title – Hypertension Education for Nurses to Improve Protocol Compliance Utilizing Shared Decision-Making Framework

1. Introduction

Welcome to the Department of Veterans Affairs - Project Cover Sheet.

Questions with an asterisk (*) must be answered. Incomplete submissions will be returned unreviewed. You have the option to save the application as you progress and complete it at a later time.

Please keep the information in this form accurate and up-to-date. If any future changes to this project affect information in this form, please revise the appropriate sections and submit the form.

(No Response)

2. Project Summary:

This project aims to improve nurses' compliance with the hypertension (HTN) nursing protocol through education and the implementation of shared decision-making (SDM in the protocol framework resulting in increased blood pressure (BP) control for patients and increased autonomy for nursing staff.

The project setting is the PPC at WTVAHCS with an enrolled population of 2,151. There are three PC physicians, one Associate Chief Nurse that oversees one Nurse Manager, three RNs, three LVNs, and a variety of other healthcare disciplines (e.g., pharmacists, mental health providers, and social workers) assigned to the PCC.

The identified population for the project is the eight nurses as described above. The QI project will exclude nurses not assigned to the PCC.

The internal stakeholders related to this project are the overall WTVAHCS facility (macro-level), PCC (meso-level), nurses (micro-level), and providers (micro-level).

The external stakeholders for this DNP project include patients and families or significant others.

The PICOT question is: Will education on the nurses' role in shared decision-making show a statistically significant improvement in nursing compliance with the VA HTN nursing protocol within four weeks?

• The objectives for this project are:

• Educate nurses on the benefits of SDM and how it can promote nursing autonomy. The education will be presented using a prepared PPT with pre/post-test presented via TEAMS and attendance will be tracked with Microsoft TEAMS meeting transcription, which records the training and accounts for attendance during the four weeks of project implementation.

• Expand the nurse's role within the Team-based care (TBC) model of care by promoting nursing autonomy. Nurses' autonomous use of the HTN nursing protocol will increase as measured by chart audits within four weeks. There will be a chart audit for ICD 10 codes I10-I16 – Hypertensive disease.

• Increase in understanding of SDM as evidenced by a change in the pre-and post-test after completing the nursing SDM education.

• Intervention:

To meet the objective of educating nurses on the benefits of SDM and how it promotes autonomy, an educational PowerPoint will be presented to the ambulatory care nurses. To expand the nurse's role within the TBC model of care, the presentation will identify strategies for participation in SDM and how nurses can function autonomously within the TBC model. The HTN nursing protocol will be an example of how nurses function autonomously and increase the nurses' understanding of their role in SDM and the impact on nursing practice. The PowerPoint presentation will increase the nurses' understanding of SDM, promote nurses functioning autonomously and improve the nurses' compliance with the HTN nursing protocol. The pre and post-test will measure whether the nurse gains knowledge after the PPT presentation

- The tools for the DNP project are:
- PowerPoint presentation on SDM, autonomy, and TBC (Appendix B)
- HTN nursing protocol (Appendix F).
- VA Clinical Practice Guideline. (<u>https://www.healthquality.va.gov</u>) (<u>Appendix G</u>)
- 15-question Pre, and post-test (Appendix H).
- Video, "Collaboration in Health Care: The Journey of an Accidental Expert?" (<u>https://youtu.be/qOV-5h0FpAo</u>) (Appendix C).

Video, "Formula 1 Pit Stop 1950 vs. 2013."

(https://www.youtube.com/watch?v=EPKRAFWscfE) (Appendix E)

- Chart audit tool (Appendix I).
- Centers for Disease Control and Prevention (CDC) website to review for future use. (Interprofessional Collaboration | Transitions to Professional Nursing Practice (lumenlearning.com/suny-delhi-professionalnursing /chapter/interprofessional-

<u>collaboration/)</u> (Appendix D).

3. Significance

What is the significance and/or value of this research to Veterans or the VHA?

The significance of this project is the promotion of nursing autonomy and authority through SDM and expanding the nurse's role from monitoring BP and patient education to supplementing and complementing the medical provider's role (Henrie et al., 2019). The effective improvement of patient outcomes and better control of BP for patients through the use of a nursing HTN protocol (Zhua et al., 2018) and ensuring care is multi-faceted, patient-centered, and tailored to meet the patient's needs

PAGE: Study Funded Is this study funded? (Radio Buttons) a. No

a. No

4. PAGE: Funding Information – This PAGE will only appear if "Study Funded: YES" is selected. This PAGE will repeat for each Funding Source to be entered. N/A

a. Funding Source Code

- (Drop-down Menu)
- i. [0000] None
- ii. [9002] BLR&D Research Advisory Group (CC 103)
- iii. [9009] BLR&D Other Designated Research (CC 109) iv. [9024] Health Services R&D (Prog 824)
- v. [9003] BLR&D Merit Review (CC 103)
- vi. [9010] BLR&D Research Career Scientist (CC 110)
- vii. [9025] Cooperative Studies (Prog 825)
- viii. [9006] BLR&D Special Research Initiatives (CC 106) ix. [9022] Rehabilitation R&D (Prog 822)
- x. [9026] Million Veteran Program (Prog 826-CC160)
- xi. [9008] BLR&D Career Development (CC 108)
- xii. [9023] Agent Orange & Related Herbicides
- xiii. [9050] Clinical Science R&D xiv. [9103] National Cancer Institute
- xv. [9117] Natl Inst of Environmental Health Science
- xvi. [9129] Natl Inst on Arthritis, Musculoskeletal & Skin Disease
- xvii. [9105] National Eye Institute
- xviii. [9119] Natl Inst of General Medical Sciences
- xix. [9131] Natl Inst on Deafness & Other Communication Diseases
- xx. [9107] National Heart, Lung & Blood Inst
- xxi. [9121] Natl Inst of Neurological Disorders & Stroke
- xxii. [9133] Natl Inst on Drug Abuse

xxiii. [9109] Natl Inst of Allergy & Infectious Disease xxiv. [9122] Natl Human Genome

Research Institute xxv. [9135] Natl Inst on Mental Health

- xxvi. [9111] Natl Inst of Child Health & Human Dev
- xxvii. [9123] National Institute of Nursing Research
- xxviii.[9137] Natl Center for Research Resources
- xxix. [9113] Natl Inst of Dental and Craniofacial Research
- xxx. [9125] National Institute on Aging
- xxxi. [9138] Natl Inst of Biomedical Imaging and Bioengineering
- xxxii. [9115] Natl Inst of Diabetes, Digest. & Kidney
- xxxiii.[9127] Natl Inst on Alcohol Abuse & Alcoholism xxxiv. [9143] Natl Inst of Health
- (Inst not listed) xxxv. [9202] Centers for Disease Control
- xxxvi. [9213] Environmental Protection Agency
- xxxvii. [9225] National Library of Medicine
- xxxviii. [9203] Dept of Defense
- xxxix.[9215] Food and Drug Administration
- xl. [9227] National Science Foundation
- xli. [9205] Dept of Education
- xlii. [9217] Health Resources & Svcs Admin
- xliii. [9229] Rehabilitation Services Admin xliv. [9207] Dept of Energy

xlv. [9219] Natl Inst of Occupational Safety xlvi. [9235] U.S. Public Health Service xlvii. [9209] Dept of Health & Human Services xlviii. [9221] Natl Aeronautics & Space Admin xlix. [9237] Natl Inst of Disability Rehab. Research [9211] Dept of Labor 1. [9223] Agency for Health Care Policy Research li. lii. [9299] Other Federal Government Agency liii. [9301] Affiliated University liv. [9307] State Government [9360] VA Medical Care Supported Mgmt. Studies lv. [9303] Private Donor lvi. lvii. [9309] Foreign Government lviii. [9305] Local Government lix. [9311] SWOG lx. [9399] Other Government or Academic [9701] A.H. Robins lxi. lxii. [9723] Cytogen lxiii. [9752] Lorex lxiv. [9779] Rhone-Poulenc Rorer lxv. [9703] Abbott lxvi. [9725] Du Pont lxvii. [9754] Marion-Merrell Dow lxviii. [9781] Ross lxix. [9705] Adria lxx. [9729] E.R. Squibb 1xxi. [9756] Mc Neil lxxii. [9782] R.W. Johnson Pharm 1xxiii. [9706] Aventis Pharmaceuticals 1xxiv. [9731] Eli Lilly 1xxv. [9758] Mead Johnson lxxvi. [9783] Sandoz 1xxvii.[9707] Alpha Therapeutic [9732] Fujisawa lxxix. [9760] Merck & Co. lxxx. [9784] Schering lxxviii. lxxxi. [9708] American Cyanamid lxxxii.[9733] G.D. Searle [9762] Merrell-Dow lxxxiv. [9785] SmithKline Beecham lxxxiii. lxxxv.[9709] Ayerst [9734] G.H. Besselaar lxxxvi. [9764] Miles lxxxvii. lxxxviii. [9787] Sanofi-Aventis lxxxix. [9710] Amgen xc. [9736] Genentech xci. [9765] Novartis xcii. [9789] Stuart xciii. [9711] Beecham xciv. [9738] Glaxo xcv. [9766] Proctor & Gamble xcvi. [9790] Takeda xcvii. [9712] Berlex xcviii.[9740] Hoechst-Roussel xcix. [9768] Organon [9791] Syntex ci. [9713] Boehringer Ingelheim cii. [9742] Hoffman-La Roche c. ciii. [9770] Ortho civ. [9792] TAP Pharm cv. [9715] Boots cvi. [9744] Hybritech cvii. [9773] Parke-Davis

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- cviii. [9793] Upjohn
- cix. [9717] Bristol-Meyers Squibb
- cx. [9745] Immunomedics
- cxi. [9775] Pfizer
- cxii. [9795] Warner-Chilcott
- cxiii. [9719] Burroughs Wellcome cxiv. [9746] Janssen
- cxv. [9776] Purdue Frederick
- cxvi. [9797] Wyeth-Ayerst
- cxvii. [9720] Centocor
- cxviii. [9748] Knoll cxix. [9777] Roberts Pharm cxx. [9798] Zeneca
- cxxi. [9721] Ciba-Geigy
- cxxii. [9750] Lederle
- cxxiii.[9778] Roche
- cxxiv. [9799] Other Private Proprietary Company
- cxxv. [9803] Alzheimer's Dis & Related Dis Assoc
- cxxvi. [9823] Arthritis Foundation
- cxxvii. [9863] National Dairy Council
- cxxviii. [9805] American Cancer Society
- cxxix. [9827] Council for Tobacco Research cxxx. [9867] Natl Foundation Ileitis & Colitis
- cxxxi. [9809] American Diabetes Association
- cxxxii. [9831] Cystic Fibrosis Foundation
- cxxxiii. [9871] National Kidney Foundation cxxxiv. [9811]
- American Fed for Aging Research cxxxv. [9833] Deafness Research
- Foundation
- cxxxvi. [9875] National Multiple Sclerosis Society
- cxxxvii. [9812] American Foundation for AIDS Research
- cxxxviii. [9837] Dermatology Foundation cxxxix. [9879] Paralyzed Veterans of
- America cxl. [9813] American Heart Association
- cxli. [9839] Disabled American Veterans
- cxlii. [9883] Robert Wood Johnson Foundation
- cxliii. [9815] American Kidney Foundation cxliv. [9843] Epilepsy Foundation of America
- cxlv. [9885] Scleroderma Foundation
- cxlvi. [9817] American Legion
- cxlvii.[9847] Juvenile Diabetes Foundation
- cxlviii. [9887] Smokeless Tobacco Research Council
- cxlix. [9819] American Lung Association
- cl. [9851] Lupus Foundation of America
- cli. [9891] Spinal Cord Society
- clii. [9821] American Narcolepsy Association
- cliii. [9855] March of Dimes
- cliv. [9895] VA Private Research Corporation clv. [9822] Amer Parkinson Disease Assoc
- clvi. [9859] Muscular Dystrophy Association
- clvii. [9899] Other Voluntary Agency/Foundation
- b. Funding Source Code Other
- If the specific Source Code is not listed or if Other is selected, please name the funding source.
- N/A

Merit Award c. Is this a Merit Award? (Radio Buttons)

- Yes i.
- ii. No

d. Administrative Code N/A

(Drop-down Select)

- [00] Funded with other than research dollars (e.g., medical dollars, QUERI) i.
- [01] No funding ii.
- [02] VA Funds iv. [03] VA Reimbursed from another Federal Agency iii.
- [04] VA Direct Grant v.
- [05] VA General Post Funds vi.
- [06] VA Private Research Corporation vii.
- viii. [07] Affiliated University
- ix. [08] Other
- [09] Med Care-Supported Studies x.
- xi. [10] CRADA Partner
- Service ID N/A e.

This number is specific to the individual PI per award. Please enter N/A if no service ID is associated with this funding.

(Plain Text Response)

f. Award Number - N/A (eRA Commons award number. Starts with RX, BX, CX, HX) (Plain Text Response)

Funding Start Date - N/A g. (Calendar Tool)

Funding End Date - N/A h. (Calendar Tool)

PAGE: Contracts/ Agreements - N/A 5. Will any contracts or agreements be required to be executed specific to the project? NO

Do not answer yes if there is an agreement such as an institutional agreement for IRB or IACUC reliance. These are not necessarily project specific.

(Radio Buttons)

Yes a.

b. NO

Unsure (please check the Agreements Algorithm on the ORD webpage - if still c. unsure, please contact your research office)

6. PAGE: Contracts/ Agreements Information - This PAGE will only apply if "Contracts/ Agreements: YES" is selected. N/A

Please select all that apply.

(Checkboxes)

Cooperative Research and Development Agreement (CRADA) a.

- b. Data Use/Sharing Agreement (DUA/DSA)
- c. Material Transfer Agreement (MTA)
- d. Clinical Sharing Agreement
- e. Contract
- f. Business Associates Agreement
- g. Unsure
- 7. PAGE: VA Project Lead/ Principal Investigator (if research)
- a. Name (as it appears in Outlook for VA email) Rebekah F. Friday

b. Highest Degree(Drop-down Menu)i. MDii. DO

- iii. DDS iv. DMD
- v. PhD
- vi. DNP
- vii. PsyD
- viii. RN ix. PT/DPT
- x. OT
- xi. PharmD
- xii. CSW
- xiii. MSW xiv. DSW xv. MPH
- xvi. DrPH xvii. ScD
- xviii. Bachelor's Other
- xix. Master's MSN
- Other
- xx. Doctorate Other xxi. Other

c. Phone 432-263-6371

d. Alt. Phone - This response is optional. (Plain Text Response)

e. VA Email rebekah.Friday@va.gov

f. VA Appointment

- (Drop-down Menu)
- i. WOC
- ii. IPA
- iii. Full-time
- iv. iv. Part-time
- v. Contractor
- vi. Fee-basis

g. Part-time 8ths - This response is optional.

If this individual is part-time, 8ths: (Plain Text Response)

h. COI Disclosures?

Have all VA study personnel serving in an investigator role submitted an OGE-450 Alt VA for review by the COI Administrator? N/A

Note: Bio sketches and COI acknowledgments (from COI administrator) or COI resolution plans (from OGC-Ethics) are required only for study team members serving in an investigator role. **N/A**

i. Yes. Findings by the COI Administrator/OGC-Ethics of all study team personnel serving in an investigator role are attached. **N/A**

ii. Yes. However, COI review is pending on one or all. Acknowledgments (by COI Administrator) or resolution plans (from OGC-Ethics) will be forwarded upon completion of review.

8. Additional Project Personnel – This PAGE will repeat for each Additional Personnel entered. This PAGE is optional.

a. Name (as it appears in Outlook for VA email) Leslie R. White

b. Highest Degree

(Drop-down Menu)

- i. MD
- ii. DO
- iii. DDS
- iv. DMD v. PhD
- vi. DNP
- vii. PsyD
- viii. RN ix. PT/DPT x. OT
- xi. PharmD
- xii. CSW
- xiii. MSW xiv. DSW xv. MPH
- xvi. **DrPH**
- xvii. ScD
- xviii. Bachelor's -Other xix. Master's Other
- xx. Doctorate Other
- xxi. Other
- c. Project Roles
- (Drop-down Menu)
- i. Co-PI
- ii. Other Investigator (Co-I/Sub-I)
- iii. Study Coordinator iv. Project Staff (Statistician, Research Pharmacist, etc.) v.

Medical Monitor

vi. Other – Project Mentor

d. VA Appointment -**Title 38**

e. WOC

ii. IPA

iii. **Full-time**

- iv. Part-time
- v. Contractor
- vi. Fee-basis

If you selected "Other," please record the Project Role below.

a. Name (as it appears in Outlook for VA email) **Tracey Johnson-Glover**

Highest Degree b. (Drop-down Menu) MD v. vi. DO DDS vii. viii. DMD v. PhD ix. DNP x. PsyD RN ix. PT/DPT x. OT xi. xiv. PharmD **CSW** XV. xvi. xvii. MSW xiv. DSW xv. MPH DrPH xix. ScD XX. Bachelor's -Other xix. Master's - Other xxi. xxii. Doctorate - Other

xxiii. Other

c. Project Roles – Other – This RESPONSE is optional. **Project Team**

d. VA Email tracey1.johnsonglover@touro.edu

e. VA Appointment N/A

- f. WOC
- v. IPA
- vi. Full-time iv. Part-time
- vii. Contractor
- viii. Fee-basis

g. Part-time 8ths - This response is optional.

If this individual is part-time, 8ths:

(Plain Text Response)

a. Name (as it appears in Outlook for VA email) **Catie Chung**

Highest Degree b. (Drop-down Menu) ix. MD DO х. DDS xi. DMD v. PhD xii. DNP xii. xiii. PsyD RN ix. PT/DPT x. OT xiv. xviii. PharmD xix. CSW XX. MSW xiv. DSW xv. MPH xxi. xxii. **DrPH** xxiii. ScD xxiv. Bachelor's -Other xix. Master's - Other xxiv. Doctorate - Other

xxv. Other

c. Project Roles – Other – This RESPONSE is optional. Academy Mentor

- d. WOC N/A
- vii. IPA
- viii. Full-time
- ix. Part-time
- ix. Contractor
- x. Fee-basis

e. VA Email Cchung6@touro.edu

f. VA Appointment N/A

g. Part-time 8ths - This response is optional. If this individual is part-time, 8ths: (Plain Text Response)

a. Name (as it appears in Outlook for VA email) **Christine A. Everett**

b. Highest Degree
(Drop-down Menu)
xiii. MD
xiv. DO
xv. DDS
xvi. DMD v. PhD
xv. DNP
xvi. PsyD
xvii. RN ix. PT/DPT x. OT

xxii. PharmD
xxii. CSW
xxv. MSW xiv. DSW xv. MPH
xxv. DrPH
xxvi. ScD
xxvii. Bachelor's – BSN
xxviii.Other
xxix. xix. Master's - Other
xxvii. Doctorate - Other
xxvii. Other

d. Project Roles – Other – This RESPONSE is optional. **Project Champion**

e. WOC

- x. IPA
- xi. **Full-time**
- xii. Part-time
- xi. Contractor
- xii. Fee-basis

f. VA Email Christine.Everett@va.gov

g. VA Appointment

g. Part-time 8ths - This response is optional.If this individual is part-time, 8ths:(Plain Text Response)

h. COI Disclosures?

Has this VA study personnel member serving in an investigator role submitted an OGE450 Alt VA for review by the COI Administrator? **N/A**

Note: Bio sketches and COI acknowledgments (from COI administrator) or COI resolution plans (from OGC-Ethics) are required only for study team members serving in an investigator role. **N**/**A**

(Radio Buttons)

i. Yes. Findings by the COI Administrator/OGC-Ethics of all study team personnel serving in an investigator role are attached. N/A

ii. Yes. However, COI review is pending on one or all. Acknowledgments (by COI Administrator) or resolution plans (from OGC-Ethics) will be forwarded upon completion of review. N/A

iii. Not Applicable. This individual is not serving in an investigator role.

9. PAGE: Project Characteristics

What does this project involve? Check all that apply. **ALL N/A** (Checkboxes)

a. Data and/or biospecimens from living human individuals. [Upload your form 10-250 with your submission for review by the Privacy Officer] [Determination] [You indicated your project involves data and/or biospecimens from living human individuals.]

b. Data and/or biospecimens from deceased individuals [Upload your form 10-250 with your submission for review by the Privacy Officer]

c. Animals [You indicated your project involves animals and will require review by your local IACUC.]

d. VA research laboratory [You indicated that your project involves using either chemicals, biologics, viruses, or bacteria and therefore will require completion of the VHA Form 10-0398 and SRSS review.]

e. Non-VA research laboratory [You indicated that your study involves a non-VA laboratory, please attach a copy of the agreement for review or contact your research office for how to establish an agreement.]

f. Viruses, toxins, bacteria [You indicated that your project involves using either chemicals, biologics, viruses, or bacteria and therefore will require completion of the VHA Form 10-0398 and SRSS review.]

g. Recombinant DNA [You indicated that your study involves recombinant DNA.]

h. Chemicals [You indicated that your project involves using either chemicals, biologics, viruses, or bacteria and therefore will require completion of the VHA Form 10-0398 and SRSS review.]

i. Radiation or radioisotopes [You indicated that your project involves radiation or radioisotopes and therefore will require review by the radiation safety committee.]

j. Non-Veterans as research subjects [You indicated that non-veterans may be recruited as research subjects. R&D Committee approval is required to enroll non-veterans.]

k. Institutional Support (i.e., EKG, Psychiatry, Medicine, Nursing, Surgery, Pharmacy, etc.) [One Service Impact Form for each area in which Institutional Support is required.]

1. Controlled Substances [You indicated that your project involves the use of prescribed drugs or other controlled medical substances, and you will need to complete the pharmacy impact statement and the safety forms to accompany your submission.]

m. Physical Hazards (i.e., Noise, Vibration, extremes of temperature and pressure, explosive hazards, electrical hazards, mechanical hazards) [You indicated that your project involves a physical hazard and therefore will require completion of the VHA Form 10-

0398 and SRSS review.]

n. Other

10. PAGE: Project Characteristics – Other – This PAGE will only appear if "Project Characteristics: Other" is selected.

Since you indicated that the project involves characteristics that were not listed on the previous page, please explain.

(Rich Text Response)

11. PAGE: Determination Requests – This PAGE will only appear if "Project Characteristics: Data and/or Biospecimens from living/deceased human individuals" OR "Project Characteristics: Other" is selected.

Are you seeking any of the following determinations:

- Exemption
- Not Research Determination (QI, EBP)
- Non-human subject Research Determination

(Radio Buttons)

- a. Yes
- b. No

12. PAGE: Human Research Multi-Site Study – This PAGE will only appear if "Project Characteristics: N/A

Data and/or biospecimens from living human individuals" is selected. Is this a multi-site study involving human research?

Note: Human research is a systematic investigation designed to contribute to generalizable knowledge where the investigator obtains, uses, studies or analyzes information or biospecimens about living individuals either through access to their identifiable information/specimens or through interaction or intervention with the individuals.

(Radio Buttons)

a. Yes

b. No

c. Unsure (discuss with your research office)

13. PAGE: Cooperative Human Non-Exempt Study– This PAGE will only appear if "Human Research Multi-Site Study: Yes" is selected. **N/A**

Is this a Cooperative Human Non-Exempt Study (CHNE – a multisite non-exempt study engaging more than one federal institution and requiring single IRB review)?

(Radio Buttons)

a. Yes

b. No

c. Unsure - [You indicated that you are unsure if this study is a multisite study requiring single IRB review. Please clarify with your research office whether this study requires an exception to the single IRB provision before proceeding.]

14. PAGE: Single IRB Exception – This PAGE will only appear if "Cooperative Human Non-Exempt Study: Yes or Unsure" is selected. N/A

All VA Non-Exempt Human Subjects Research that has more than one institution engaged in the research must use a single IRB, unless one of the following conditions are met: N/A

• An exception to the Single IRB provision has been granted

• The project was not approved or transitioned to follow the 2018 Requirements of the Common Rule

• The VA facility is the only federal site involved in the project and no other site is receiving federal funds

If another institution already obtained an exception (either from ORD or another Federal Agency), there is no requirement to apply for one. Simply upload a copy of the exception for your institution's records. N/A

Note: If you need instructions on how your institution can request an exception, or if you are unsure if your project has already been granted an exception at another VA site, visit the ORD's webpage on single IRBs: https://www.research.va.gov/programs/orppe/single_irb.cfm

Which of the following best describes your project?

N/A

a. All the study sites are already under the oversight of a single IRB – [You indicated that your Cooperative Human Non-Exempt project is under the oversight of a single IRB].

b. We have already obtained an exception to the Single IRB provision – [You indicated that your Cooperative Human Non-Exempt project has received an exception to the Single IRB provision. Please include a copy of the exception with your submission for your institution's records.]

c. Our institution requires an exception to the Single IRB provision, and we will apply for an exception with ORD – [You indicated that your Cooperative Human Non-Exempt project requires

an exception to the Single IRB provision, and that you will apply for an exception with ORD. An exception must be granted before your project is reviewed by the IRB.]

d. **None of the above, or unsure -** [You indicated that you are unsure if your Cooperative Human Non -Exempt project requires single IRB review. Please clarify with your research office whether this study requires an exception to the single IRB provision.]

15. PAGE: No Single IRB Review or Exception Explanation – This PAGE will only appear if "Single IRB Exception: None of the above, or unsure" is selected. N/A

You indicated that your Cooperative Human Non-Exempt project may not require Single IRB review or an exception to the Single IRB provision. Please clarify with your research office on whether this study requires an exception to the Single IRB provision and explain below why the provision may not apply to your project. In your explanation, please address the following:

- When was your project first approved by an IRB?
- Is your VA facility the only federal site in the project?
- Are any other sites in the project receiving federal funds?

N/A

16. PAGE: IRB of Record Type - This PAGE will only appear if "Human Research Multi-Site Study: YES" is selected. N/A

Which of the following facility types is the IRB of record? If more than 1 IRB will review this study, please select the IRB type for the IRB reviewing your project.

N/A

- a. PI's VA Medical Center IRB
- b. Other VA Medical Center IRB
- c. VA Central IRB
- d. DOD Defense Health Agency (DHA) Medical Center
- e. DOD Defense Health Agency (DHA) Uniformed Services University
- f. DOD Army
- g. DOD Navy
- h. DOD Air Force
- i. DOD Marines
- j. NIH All of Us IRB
- k. NIH NCI IRB
- 1. Other Federal IRB
- m. Affiliate University IRB
- n. Commercial IRB
- o. Non-affiliate University IRB
- p. Other IRB

17. PAGE: IRB of Record Name - This PAGE will only appear if "Other Federal IRB" OR "Affiliate University IRB" OR "Commercial IRB" OR "Non-affiliate University IRB" OR "Other IRB" is selected What is the name of the IRB of Record? **N**/**A**

18. PAGE: Additional IRBs - This PAGE will only appear if "Human Research Multi-Site Study: YES" is selected. N/A

Will any additional IRBs (other than the IRB of record) be reviewing the study? (Radio Buttons)

- a. Yes
- b. No

19. PAGE: Additional IRB Information – This page will only appear if "Additional IRBs: YES" is selected. This PAGE will repeat for each Additional IRB. **N**/A

Please enter the name and facility type of each Additional IRB that is not the IRB of record.

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a. IRB Facility Type

(Drop-down Menu)

- i. PI's VA Medical Center IRB
- ii. Other VA Medical Center IRB
- iii. VA Central IRB iv. NCI IRB (NIH)
- v. All of Us (NIH)
- vi. Other Federal IRB (DOD/DHA, NIH, DOE, NIST, etc.)
- vii. Affiliate University IRB
- viii. Commercial IRB
- ix. Non-affiliate University IRB
- x. Other
- xi. Unknown

b. IRB Name

Hypertension Education for Nurses to Improve Protocol Compliance Utilizing Shared Decision-Making Framework

20. PAGE: Form Complete

Thank you for completing the Veterans Affairs – Project Cover Sheet.

Based on your responses, the following additional documentation must be included with this package before submission. Upload additional documentation in the Designer.

Additional required documentation: [SMART LIST]

Please click Preview to review the information you have provided in this form.

Refer to the end of the document for this checklist as you continue to prepare this submission.

Please use this checklist to ensure that you have attached all the necessary documentation for complete IRB review. (No Response)

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Appendix M

VA Central IRB Form 108

20 pages September 20, 2021



The Principal Investigator/Study Chair (PI/SC) is required to use this form to submit new research project applications to the VA Central IRB. This form is to be used when there is interaction with human subjects.

This form and all other forms that may be required as part of the PI/SC submission can be downloaded from the VA Central IRB <u>Researcher's</u> Library in VAIRRS (IRBNet).

Section 1: PI/SC Information

Project Title: Hypertension Education for Nurses to Improve Protocol Compliance Utilizing Shared Decision-Making Framework

Initial \boxtimes **Revised** \square *Revision Date*: Click or tap here to enter text.

PI/SC Facility Name: West Texas VA Health Care System

City and State: Big Spring, TX

1. Name of Principal Investigator (PI)/Study Chair (SC) : Rebekah Friday Email: rebekah.friday @va.gov Phone Number: 432-263-7361 7118
2. PI/SC Academic Degrees: MSN
PI/SC Board Certifications: NEA-BC and CNL
3. PI/SC Employment Status: (Check all that apply)
☑ VA Employee (#8ths _610) □ Other (VA WOC, IPA) Specify Appointment Type: Click or tap here to enter text.
a. For ORD-funded studies, is the PI/SC at least a 5/8ths VA employee?
\Box Yes (skip to question 4) \Box No (answer question 3b) \boxtimes Not Applicable
b. If the response to 3a is no, is a copy of the ORD funding service approval waiver included as part of this submission?
Yes \square No \square If no, indicate when submitted for approval: Click or tap here to enter text.
4. Describe the PI/SC's qualifications to act in the capacity as overall PI/SC to do the research in this project and attach a copy of his/her biosketch (Merit Review or NIH Format):
Doctor of Nursing Practice Student
5. Complete the questions below regarding the PI/SC's current research activities:
a. What current percentage of the PI/SC time is devoted to research activities?0
b. What percentage of the PI/SC's time will be devoted to this project?0
c. How many active studies is the PI/SC currently overseeing?0
d. How many of the above are multisite studies in which the PI/SC is the overall PI?0
6. Is there a Co-PI or Co-Study Chair?
Yes \Box (see additional questions below) No \boxtimes
If yes, indicate the following for each: Name: Click or tap here to enter text. Site: Click or tap here to enter text.
<u>Additional form requirement:</u> If there is a Co-PI(s) or Co-Study Chair(s), each Co-PI/SC must complete VA Central IRB Form 108a, Co-PI/SC New Project Application Supplement to be submitted as an attachment to this application. See Section 14, Contents of Application Package.

Section 2: PI/SC Study Team Information

1. Study Coordinator Contact Information (If multiple Coordinators, list each one.)						
Name of Project Coordinator: Rebekah Friday						
Phone: 432-263-7361 Email: rebekah.friday @va.gov						
Name of Project Coordinator: Click or tap here to enter text.						
Phone: Click or tap here to enter text. Email: Click or tap here to enter text. @va.gov						

2. List the PI/SC and personnel from this site and other sites who will be assisting in managing the overall study. Information on study team members from this site and other sites who are <u>only</u> involved in local site research activities should be listed on the Local Site Investigator (LSI) Application for the specific site and not on this form.

Note: Include Study Coordinators listed above but do not list CSP Coordinating Center personnel.

Project Team Member	Degrees	VA Employee Status (#/8ths, WOC, IPA)	Facility Location	Project Role	Access to Identifiable data? (Yes / No)	Obtaining Informed Consent? (Yes or No)	Date of Latest VA HSP Training (mm/yr)
Dr. Les White	PhD	610	WTVAHCS	Project Mentor	Yes	Yes	00/00
Dr. Tracey Johnson- Glover	DNP	NO	Touro University Nevada	Project Team	NO	NO	00/00
Dr. Catie Chung	PhD	NO	Touro University Nevada	Academic Mentor	NO	NO	00/00
Christine Everett	BSN	610	WTVAHCS	Project Champion	Yes	Yes	00/00
Angela Daniel	MSN	610	WTVAHCS	Team Member	Yes	Yes	00/00
Click here	Click here	Click here	Click here	Click here	Click here	Click here	Click here

Note: Additional project members may be added by inserting more rows above. If a project role has not yet been filled, indicate "TBD" (to be determined) and complete the rest of the row for that role.

3. Is there a mechanism at your site for review of Conflict of Interest (COI) disclosures?

lote: Biosketches and COI forms or determinations are required only for study team members serving in an investigator role.

□ Yes. Findings of my local COI Committee/ other local COI review are attached.

□ Yes. Local COI review is pending. Determination will be forwarded upon completion of review.
☑ Yes. But this project is a QI project and does not require COI review
4. Does this project involve a designated VA Coordinating Center(s)? Yes □ No ⊠
If Yes , please provide the name of the Coordinating Center(s) and contact information below.
Name of Coordinating Center: Click or tap here to enter text.
Contact Name (Program Manager or other POC): Click or tap here to enter text.
Phone Number: Click or tap here to enter text. Email address: Click here to enter text. @va.gov
Additional Form Requirement: Submission of a VA Central IRB Form 108b, Cooperative Studies Program (CSP) Coordinating Center PI/SC New Project Application, is required for each center if yes was checked.
Section 3: Project Overview
Note: Your protocol must also contain all information described in Sections 3 through 14 of this Application.
The VA Central IRB has an optional protocol template that can be used.
1. What organization is funding this study? (Check all that apply)
🗆 CSP 🗆 CSR&D 🗆 HSR&D 🗆 RR&D 🗆 BSLR&D 🗆 QUERI
\Box VHA Central Office \Box DoD \Box Private Nonprofit: Specify: Click here to enter text.
Commercial Sponsor: <i>Specify:</i> Click or tap here to enter text.
☑ No funding required
Funding Agency Project number: Click or tap here to enter text.
2. What are the research questions or hypotheses to be studied? The PICOT question for this DNP project proposal is: Will education on the nurses' role in shared decision-making change nursing compliance with the VA HTN nursing protocol within four weeks?
3. Describe the relevance to Veterans of studying the above questions or hypotheses and the importance of the knowledge this project is likely to generate:
1. The promotion of nursing autonomy and authority through SDM and expanding the nurse's role from monitoring BP and patient education to supplementing and complimenting the medical provider's role. 2.

The effective improvement of patient outcomes and better control of BP for patients through the use of a nursing HTN protocol and ensuring care is multi-faceted, patient-centered, and tailored to meet the patient's needs

4. What research methods will be used in the project? (Check all that apply)

	Surveys/Questionnaires		Interviews	Audio Taping	
	Behavioral Observations	\boxtimes	Chart Reviews	Video Taping	
	Focus Groups		Randomization	Double-Blind	
	Control Group		Placebo	Withhold/Delay Treatment	
	Specimen Collection		Deception	Other (Specify): Staff Education; PPT presentation; pre/post test	

	es the project involve usual care?	Yes □	No 🗵	If no, skip to question (
	es, answer the following additional qu	estions:		
	a. Who will provide the usual care, provider?	i.e., the study	v team or the par	ticipant's health care
	Click or tap here to enter text.			
	 b. Clearly differentiate what is usua performed solely for research purpo study or if it is being delivered to all 	I care and wh ses. Indicate participants:	nat procedures a if usual care is	nd/or interventions are be limited to one arm of the
	Research procedures: Click or ta	p here to ent	er text.	
6.	Usual Care: Click or tap here to e	enter text.		
	es this project involve international re	search? Ye	es □ No ⊠	
	International research does not includ le participating sites where the overall	le studies in study-wide	which VA is on PI is not a VA i	ly one (or more) of nvestigator.
7.				
	es this project involve collaborative re	esearch? Ye	es 🗆 See belo	w No 🗵
	es, delineate which research activities wi laborative research study:	Il be conducte	ed as the VA po	rtion of the overall
Note:	ck or tap here to enter text.			
	Collaborative studies do not include s aceutical companies or other for-profi	tudies cond t or non-Fed	ucted under a (eral partners.	CRADA with

Section 4: Potential Risk/Benefit Analysis

1. Indicate the potential risk level of the project: (<i>Minimal Risk is defined as "the probability</i> and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.")
oxtimes Less than Minimal $oxtimes$ Minimal $oxtimes$ Greater than Minimal
Note: The IRB will make the final risk level determination.
2. What are the potential risks or harms for participants in this project?
List in bullet or number format. None NOTE: Risks or harms can be physical, psychological, financial, social, or legal. They may involve breaches of confidentiality and privacy. Do not include the risks of usual care unless usual care is part of the research interventions being performed.

I

3. What are the anticipated benefits, if any, to participants or to society from this project?

List in bullet or number format. 1. The promotion of nursing autonomy and authority through SDM and expanding the nurse's role from monitoring BP and patient education to supplementing and complimenting the medical provider's role. 2. The effective improvement of patient outcomes and better control of BP for patients through the use of a nursing HTN protocol and ensuring care is multi-faceted, patient-centered, and tailored to meet the patient's needs

4. Briefly describe the procedures or explain why there is no need for established procedures for the orderly withdrawal or termination of participation in the project by the participants?

This is a QI project that is focused on improving nursing practice and does not include human participants using treatment

5. Will any of the following be administered to participants or will they be exposed?

Ionizing Radiation	Yes 🗆	No 🛛	\mathbf{X}
Radioactive Materials	Yes 🗆	No 🛛	\times

6. Check one of the boxes below based on your study design and provide the references from the protocol for the information in the table:

 \Box Prospective Study \Box Retrospective Study \Box Both \boxtimes Not a Study

- Note: If retrospective is checked, some of the below categories may not apply and can be marked as "Not applicable."
- 7. Complete the table below.

Safety Issues	Reference the protocol page and section.	If not referenced in the protocol, cite document type, page, and section where it is referenced.
What Safety Information is Collected	N/A	N/A
How will Safety Information be collected	N/A	N/A
Frequency of Safety Data Collection	N/A	N/A
Safety Conditions that Trigger Immediate Suspension of Research	N/A	N/A

Procedures to notify participants or PCP of findings affecting participants' health or welfare	N/A	N/A
Procedures to minimize risk	N/A	Click here to enter text.
Inclusion Criteria	Ambulatory (PACT) Nurse	N/A
Exclusion Criteria	Other nurses	N/A
8.	Will an independent Data Safety Monitoring Board (DSMB) or DMC monitor the project?	
---------------------------------------	--	
	□ Yes ⊠ No	
	If yes, provide a description of responsibilities to include frequency of meetings: Click here	
	If no , provide the protocol section and/or page where the data safety and monitoring plan is described, to include statistical tests to be used for analyzing the safety data to determine if harm is occurring.	
	N/A	
9.	If the PI/SC is not a clinician, is there an appropriately credentialed and privileged clinician who has been designated as a member of the study team to make required decisions to help protect the health of the subject, review data on adverse events, and report new findings?	
	□ Yes □ No ⊠ N/A	
10.	How will you manage information from participating sites that might be relevant to participant protection and describe how that information will be conveyed to the VA Central IRB (i.e., reports of problems, interim results)?	
	N/A	
Note Cent VA a or O Infor	e: Reference VHA Handbook 1058.01, Research Compliance Reporting Requirements, and the VA tral IRB Table of Reporting Requirements, which can be found on the VA Central IRB website, for and VA Central IRB reporting requirements for Unanticipated Problems Involving Risks to Subjects thers, Serious Adverse Events, Protocol Deviations, Apparent Serious Noncompliance, and rmation Security Incidents.	

Section 5: Human Participant Information

No sh	Note: A participant is considered <u>"enrolled" at the time the consent is signed</u> so this number should include an allowance for screen failures prior to randomization.				
1.	How many participant records will be reviewed prior to enrollment/consent occurring? 0				
2.	How many participants will be screened prior to enrollment/consent occurring? 0				
3.	 How many participants will be enrolled (total number to include randomized and screen failures after consent is obtained)? 				
	a. Will all research activity be the same at all sites? \Box Yes \Box No \boxtimes N/A				
	If no, please describe the activity that is different or limited (For example, 2 sites will analyze data only, or, 1 site will consent and enroll all participants etc.):				
	b. Are there any further screening procedures after enrollment? \Box Yes \boxtimes No				
	If yes, describe: Click or tap here to enter text.				
4.	4. Are non-Veterans at VA sites, not including VA employees, being enrolled? Note: This does not include non-Veterans enrolled at non-VA sites. □ Yes ⊠ No				

If **yes**, provide justification. Click or tap here to enter text.

5. Does this project target a specific race, gender, or ethnic group as participants?

🗆 Yes 🛛 No

If yes, indicate which group and why this group is being targeted: Click here to enter text.

6. What is the age range of participants? (Check all that apply.)

Neonates (See note below)	
Children Under 18 (See note below)	
Young Adults (18-21)	
Adults (22-65)	\boxtimes
Seniors (Over 65)	

Note: If neonates or children is checked, the approval of the Medical Center Director will be required. Only non-invasive monitoring and/or prospective observational and retrospective record review studies that are minimal risk can be conducted in VA involving neonates.

7. Does the project involve the potential enrollment of any of the following populations or categories of participants? Note: These populations must be checked "Yes" if they are not being excluded from the research.

No	a. Employees (Only if participating in their VA employee capacity)	\boxtimes	
	b. Students		
	c Individuals with impaired decision-making capacity		
	d. Pregnant women (See below)		
	e. Economically and/or educationally disadvantaged persons		
	f. Prisoners (See Below)		
	g. Illiterate, limited, or no English language proficiency		
	h. Terminally ill patients		

<u>Additional Form Requirement</u>: If prisoners, or pregnant women was checked, submission of the applicable VA Central IRB Form 110 series supplement must also be submitted (110a for Pregnant Women and 110b for Prisoners.)

Section 6: Informed Consent

1. Will the study team obtain information or biospecimens for the purpose of screening, recruiting, or determining the eligibility of prospective subjects without the informed consent of the prospective subject or the prospective subject's LAR?

Yes \Box See below. **No** \boxtimes Skip to question 2.

If yes, check one or both below boxes if they apply to this study:

Yes

 Information will be obtained through oral or written communication with the prospective subject

or the subject's Legally Authorized Representative (LAR)

□ Identifiable information or biospecimens will be obtained by accessing records or stored identifiable biospecimens.

If either or both above boxes are checked an informed consent waiver request does not have to be submitted for this activity. However, a request for a HIPAA waiver will still need to be submitted and

informed consent obtained for any research interventions after eligibility is established. If neither box
was checked, this activity will need to be included in a request for an informed consent waiver
2. Will the project involve requesting any waiver or alteration of the consent process or a waiver of documentation of consent for any part of the project?
Yes See below No Skip to question 3.
If yes, check one or more of the following boxes and submit the applicable form(s).
Waiver of informed consent for the entire study. (VA Central IRB Form 112a must be attached)
An alteration of the informed consent process. (VA Central IRB Form 112a must be attached.) <i>Note: If deception is involved this box should be checked.</i>
 Waiver of informed consent for only a specific portion(s) of the study (not including recruitment). (VA Central IRB Form 112a must be attached) Specify for what portion(s) of the study the request is being submitted.
Click or tap here to enter text.
 Waiver of documentation of informed consent. (VA Central IRB Form 112b must be attached.) Specify for what portion(s) of the study the request is being submitted:
Click or tap here to enter text.
3. Will documented informed consent be obtained from participants?
Yes \Box See below No \boxtimes Go to question 3.
If yes , will there be the use of surrogate consent? Yes \Box No \Box
NOTE: Currently, the VA Central IRB does not accept studies proposing the use of a broad consent. Please reference the VA Central IRB's template, Investigator Guidelines for Preparing <u>an Informed Consent</u> , and follow the instructions. If planning to obtain surrogate consent, check applicable state and local laws to ensure compliance with surrogate requirements.
3. Does the project propose the use of assent for participants unable to give informed consent?
N/A 🛛 Yes 🗆 See below No 🗆
If yes, describe the process for obtaining assent and the procedure followed if the participant dissents: Click or tap here to enter text.
4. Does the project involve photos, videos or voice recordings of a VA participant that are done for research purposes?

Yes \Box See below **No** \boxtimes

NOTE: If yes, this must be covered in the informed consent process and documented in the consent documents (consent form, information sheets, telephone scripts as applicable.) If these are also going to be used for treatment and included in the participant's medical record, a VHA Form 10-3203, Consent for Use of Picture and/or Voice, should also be submitted.

5. Describe the plan for training Local Site Investigators on informed consent procedures:

□ N/A (Can only be checked if a waiver of informed consent for the entire study is being sought)

Section 7: HIPAA Authorization for Project Participants

NOTE: Written HIPAA authorization signed by the individual to whom the information or record pertains is required when VA health care facilities need to utilize individually identifiable health information for a purpose other than treatment, payment, or health care operations, e.g., research. (VHA Handbook 1605.1).

1. Check all the following that apply if Protected Health Information (PHI) will be used.

If more than one box is checked, specify the part or phase of the study to which the specific checked boxes apply:



- attached to cover the entire study.
- □ A request for a HIPAA Waiver of Individual Authorization (VA Central IRB Form 103) for recruitment purposes only is attached.
- □ A request for a HIPAA Waiver of Individual Authorization (VA Central IRB Form 103) is attached to cover a portion of the study. *Specify portion of study*: Click or tap here to enter text.
- N/A QI project does not include patients participation

Additional forms requirement:

• For requesting a HIPAA waiver, submit VA Central IRB Form 103, Request for Waiver of HIPAA Authorization.

• When using a separate model HIPAA authorization form that is not combined with the informed consent, submit VA Form 10-0493, Authorization for Use & Release of Individually Identifiable Health Information for Veterans Health Administration (VHA) Research.

• In addition, as an option VA Form 10-10116, Revocation of Authorization for Use & Release of Individually Identifiable Health Information for Veterans Health Administration (VHA) Research, can also be submitted if desired.

2. Will the project require that participants authorize release of medical records or health information from non-VA sites?

Yes, See below
No

Additional form requirement: A model FL-10-212, must also be submitted.

8: Participant Recruitment Information

1. Describe the recruitment strategy for the just, fair, and equitable recruitment and selection of subjects, and reference recruitment procedures as cited in the protocol to include the following:

Describe **step-by-step** how recruitment will take place, i.e., obtaining names from CPRS or other databases, use of recruitment letters, referrals, posters, phone calls etc., to include any screening procedures prior to enrollment. **Number steps or use bullets.**

The project is education for ambulatory (PACT) nurses and does not include recruitment strategies for participants NOTE: VA policy prohibits "cold calls" to potential VA research participants. Initial contact must be made in person or by letter prior to making any telephone contact, unless there is written documentation that the subject is willing to be contacted by phone about the specific study or the provise kind of recearch. The initial telephone contact must also provide a telephone number or other					
means for the potential participant to use to	verify the study constitutes VA research (VHA Handbook				
1200.05)					
2. Will the recruitment strategies described	above be allowed to vary among sites?				
Yes 🗆 No 🗆 🛛 N/A					
3. Are model recruitment materials going to	be made available to Local Participating Sites?				
Yes ⊔ No ⊔ ⊠ N/A					
If yes , list all type of materials that will b	be used and indicate whether each type of material is				
being submitted with this application or whether	it will be submitted later as an amendment. If there will be				
telephonic contact during the recruitment pr	ocess, a script must be provided and listed below.				
Recruitment Material Type	Included with Application				
	Yes Document attached				
	Yes \Box included as part of protocol				
	No \square Amendment will be submitted				
	Yes Document attached				
	Yes I Included as part of protocol				
	No Amendment will be submitted				
Additional rows can be added as required.					

NOTE: All recruitment materials must be reviewed and approved by the VA Central IRB prior to use as part of any recruitment activities. All recruitment materials must include a statement that the study involves VA research and a telephone number or other means for the potential participant to use to verify that the study is VA research.

Section 9: Payment to Participants

1. Will participants receive compensation in this study? Yes □ No ⊠					
(If <i>no</i> , skip this section and go to Section 10.)					
NOTE: The method (and relative amounts) of payment should be the same at all participating sites whenever possible. Local Site Investigators will be asked to provide justification to the VA Central IRB for differences in method and/or relative amounts.					
2. Indicate the preferred method and mode of payment as follows:					
a. What form of payment will be used, i.e., check, voucher, electronic funds transfer? Click or tap here to enter text.					
b. What is the schedule of payments, i.e., one-time or after specific visits? Click or tap here to enter text.					
c. Provide justification that the proposed payments are reasonable and commensurate with the expected contributions of the participant to the project:					
d. Does the payment include transportation costs? Yes D No D See below					
If no, will transportation costs be paid separately? Yes \Box No \Box					
3. Specify the source of payment:					
\Box Local VA \Box VA Austin \Box PI Site NPC (specify site): Click here to enter text.					
\Box Other (specify): Click or tap here to enter text.					
4. Will an SSN be requested and/or used in making payment/compensation? Yes □ No □					
Note: If yes, be sure and include in the HIPAA authorization and in the informed consent the name of the organization making payment to include any VA-affiliated Non-profit Corporation or other non-VA entity.					

Section 10: Biological Specimens

1. Will biological specimens be used in this protocol?

Yes \square No \boxtimes (If **no**, skip this section and go to the next.)

2. List the specimens that are being collected and indicate the purpose of the collection (one or both boxes may be checked.)

Type of specimens	Research Use	Clinical Use
Click or tap here to enter text.		
Click or tap here to enter text.		

Additional rows may be added as required.

3. Respond to the following questions by checking the appropriate box: YES NO

4.	Will specimens be de-identified?
	Yes D No D
	If yes , describe how the data will be de-identified, who will do, it and at what point in the process will the specimens be de-identified. Click or tap here to enter text.
5.	What measures will be taken to minimize the potential for physical, psychological, financial, social, or legal harm from breaches of confidentiality and privacy resulting from unauthorized access to or loss of the specimens? Click or tap here to enter text.
6.	Describe how the destruction of samples will be substantiated:
	Click or tap here to enter text.
7.	If specimens are to be banked for future use in other studies the following questions must be answered: \Box N/A
	a. Indicate where the tissue will be banked.
	Click or tap here to enter text.
	b. If above is a VA location, what IRB is responsible for overseeing the operations of the tissue bank (i.e., local IRB or other multi-site or central IRB?)
Cli	ick or tap here to enter text.

	Section 11:	Privacy,	Confidentiality	, and Information	Security in	Research
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What type of data will be received by the Principal Investigator/Study Chair study team?
 Check all that apply:
 Decidentified – Data does not contain any identifiers that could link the data to a specific

De-identified – Data does not contain any identifiers that could link the data to a specific participant. (See VHA Handbook 1605.01, Appendix B, para 2b, for a list of identifiers that must be removed before data can be considered de-identified. Data must be de- identified in accordance with HIPAA and Common Rule criteria. Scrambling of names and social security numbers is not considered de-identified information.

- □ **Identified** Data contains direct identifiers sufficient to identify participants as indicated in VHA Handbook 1605.01, Appendix B, para 2b.
- □ **Coded** Data linked to a specific subject by a code rather than a direct identifier. While the data may contain some protected health information only someone possessing the code can link the data to a particular participant.

If coded data is checked, specify how the link or code will be maintained, and list each person/role who will have access to the link or code: Click or tap here to enter text.

2. Indicate how the PHI will be obtained by checking one or more of the boxes below:

□ From existing sources such as medical records, clinical databases, or research records.

If above box checked, specify each source and who maintains the database:

Database Name	Who Maintains the Database

	Additional rows may be added as required.				
3.	Directly from project participants during protocol procedures as described elsewhere in this application or in the protocol.				
Names	es ⊠ N/A				
🗆 E-	Check which of the following Hill	PAA identifiers will be collected	and recorded during the study:		
□ (89 Specify:		□ Social security numbers or scrambled SSNS (See below)	Device identifiers and serial numbers		
	mail addresses	Medical record numbers	URLs (Universal Resource		
	All elements of dates except year) and any age over	 Health plan beneficiary numbers 	IP Addresses (Internet Protocol		
	Click to enter text.				
Specify:	Telephone numbers	□ Account numbers	□ Biometric Identifiers including finger and voice print		
4.	Fax numbers	□ Certificate or license numbers	Full face photographic images and comparable images		
	geographic subdivisions'	Vehicle ID and serial	□ Other unique identifying		
a.	smaller than a state	numbers including license plate	number, characteristic, or code		
	Click to enter text.		Specify: Click to enter text.		
	specify each entity and identify their roles in the study:				
	Name of Non-VA Entity	Role in S	Study		
b.					
	Additional rows may be added as	required.			
5. List the	Specify if there is or will be a Data Use Agreement (DUA) or a CRADA. \Box Check if a copy will be provided with this application.				
N/A					
	ta. (Specify o-investigators, 4 Coordinators,				
Vhite, PhD; Project Mentor, Tracey Johnson-Glover DNP, Project Team, and Catie Chung, Academic Mentor					

6.	Will specially obtained software be used? Yes □ See below No ⊠
	If yes , describe the software, the source of the software, whether a license will be required and who will fund the license, as well was any data that will be stored in temporary files on the computer's hard drive.
	Click or tap here to enter text.
7.	Will any web-based applications be used? Yes □ See below No ⊠
	If yes , identify the application and its security features. Indicate how it will be used, e.g., for recruiting subjects, completing questionnaires, or processing data.
	Click or tap here to enter text.
8.	How will electronic data and/or paper records be secured? If data is being stored on a computer hard drive, indicate if it is encrypted per VA guidelines.
	N/A
9.	Will mobile devices be used in the study, i.e., laptops, audio recorders?
	Yes □ See below No ⊠
	If yes , indicate that mobile devices will be encrypted and that the encryption is FIPS 140-2 validated.
	Click or tap here to enter text.
10.	How will data be transmitted and/or shipped, and how will it be protected during transmission or shipping? $N\!/\!A$
11.	How will project research data be stored?
	 Indicate precisely where data will be stored to include physical site, network location/server name, type of mobile storage device, building and room number etc. N/A
No and tha Infe	te: If data will reside on a non-VA server or non-VA equipment, specify that the server is certified d accredited as required by the Federal Information Security Management Act of 2002 (FIMSA) and at the required permissions for use of a non-VA server have been obtained. Contact your facility's formation Security Officer (ISO) for more information.
	 b. If VA sensitive information is being stored outside the protected VA environment, the following questions must be answered: N/A

(1) How are the data being protected? N/A

(2) Indicate what VA information will be returned to the VA, how the information will be returned, and/or the plans for its eventual destruction at the alternate non-VA site.

No data will be removed for the VA

(3) Is there an MOU and/or a Data Use Agreement (DUA) in place regarding the transfer and storage of the data outside the VA environment?

Yes 🗆 No 🖂
If yes, specify and/or attach agreement. If no, indicate why not.
There will be no transfer or storage of data for the QI project
12. How long will the research data be stored and describe how the data will be destroyed once the maximum retention period as specified by the VHA Records Control schedule or the indicated retention period, if longer, is met?
N/A
13. What is the plan for protecting project research data from improper use or disclosure? As part of the response to this question, indicate that removal of access to research study data will be accomplished for study personnel when they are no longer part of the research team. Include that the ISO and Privacy Officer will be notified immediately of the improper use or disclosure.
N/A
14. Will a Certificate of Confidentiality be obtained?
Yes \Box No \boxtimes If yes , include this information in the informed consent form.
participants enrolled in biomedical, behavioral, clinical, and other forms of sensitive research. Certificates protect against compulsory legal demands, such as court orders and subpoenas, for identifying information or identifying characteristics of a research participant. For more information on Certificate of Confidentiality go to: <u>http://grants.nih.gov/grants/policy/coc/</u> .
15. Will data be disclosed (copy given) outside of VHA?
Yes □ See below No ⊠
If yes , describe to whom the data are to be disclosed, the justification for such disclosure, and the authority for the disclosure, e.g., HIPAA authorization or VA Form 10-5045, Request for and Authorization to Release Medical Records or Health Information.
Click or tap here to enter text.
16. Will data be banked for re-use in future studies? Yes \Box See below No \boxtimes
a. Where will the data be banked?
Name of entity: Location:

b.	Is this an or, if a noi Agreemer	existing da n-VA entity nt?	ta repository with appropriate oversight mechanism per VHA Handbook 1200.12 , are the appropriate safeguards addressed in the CRADA or Data Use
	Yes 🗆	No 🗆	See below
	If no, indic approval study or a repository	ate for VA will be sou amendmen /, or for no	entities that ght from the local IRB where the repository will be housed, whether a separate it will be submitted to the VA Central IRB for review for creation of the data n-VA sites, whether the CRADA or Data Use Agreement is still being negotiated.

Section 12: FDA-Regulated and Other Products

r

1. Does the project require use of FDA-regulated drugs, biologics, or devices?							
Yes □ No ⊠ (Skip to Section 13)							
2. Indicate	2. Indicate the type of clinical trial if applicable?						
🗆 P	hase I 🛛 Phase II 🔅 Phase IV						
3. Does the Device I	3. Does the project involve an Investigational New Drug Application (IND) or Investigational New Device Exemption (IDE)?						
Yes If yes following:	Yes See below No I If yes , attach a copy of any applicable correspondence with the FDA and complete the following:						
a. Indicat	e the name of the person or organization holding the IND or IDE: ${ m Click}$ to enter text.						
b. Is there	e a plan for onsite data monitoring?						
Yes	□ See below No □						
lf y e	es, specify who will conduct monitoring responsibilities and how often:						
Clic 4. How wil	Click or tap here to enter text.4. How will FDA-regulated products used in this study be dispensed and tracked to participating sites?						
Click o	or tap here to enter text.						
5. If using	5. If using FDA-regulated drugs or biologics, indicate use: N/A						
	Investigational or Unapproved Drug(s) or Biologics (Attach a copy of the FDA's						
	 acknowledgement letter stating that FDA received the IND application.) Approved Drug(s) or Biologics for Approved Uses 						
	Approved Drug(s) or Biologics for Unapproved Uses (Use will be inconsistent with product labeling or involves a new use, labeling, advertising change, or a change in dose, dosage form, administration schedule, or recipient)						

6. List all drugs, biologics, or supplements to be used below. Check here if N/A: \Box

Generic Name	Trade Name	Manufacturer	Use Consistent with Product Labeling? Yes/No	IND Number if Applicable

٨	Note: Add additional rows to table if necessary							
a.	Is an Investigator's brochure included with the application materials?							
	Yes \Box No \Box If no, please indicate why? Click or tap here to enter text.							
b.	b. For all approved drugs used for an unapproved use, describe the unapproved use: \Box							
	Click or tap here to enter text.							
C.	If an IND is not re	quired, explain and/or provide sponsor or FDA documentation:						
	\Box N/A							
	Click or tap here to enter text.							
7.	If using FDA-regulated devices, indicate use: \Box N/A							
		Investigational or Unapproved Device(s)						
		Approved Device(s) for an Approved Use						
		Approved Device(s) for an Unapproved Use						
8. Other (e.g., humanitarian use device; 510k clearance) Specify: Click to enter								

Name	List the FDA-regulated devices that will be used. N/A							
Name Manufacturer		Use Consistent w/ Product Labeling?	Significant Risk (SR) or Non-significant Risk	IDE Number if				
		Yes, No, or N/A	(NSR), Unknown, or N/A	Applicable				
Click to Click to enter		Click to enter text.	Click to enter text.	Click to enter text.				
enter text.	text.							
Click to	Click to enter	Click to enter text.	Click to enter text.	Click to enter tex				
enter text.	text.							
Click to	Click to enter	Click to enter text.	Click to enter text.	Click to enter tex				
enter text. text.								
a. Is manu	I Ifacturer's device info	ormation included with th	e application materials?					
Yes L NO L								
b. If this is	a non-significant ris	k device study, is docum	entation attached with the					
b. If this is applicat Significa	a non-significant ris ion materials explair nt Risk (SR) device?	k device study, is docum ing the manufacturer's o 2 (See 21 CER 812)	entation attached with the r a sponsor's determination	why the device is				
b. If this is applicat Significa	a non-significant ris ion materials explair nt Risk (SR) device?	k device study, is docum ing the manufacturer's o ? <i>(See 21 CFR 812)</i>	entation attached with the r a sponsor's determination	why the device is r				
b. If this is applicat Significa Yes □	a non-significant ris ion materials explair nt Risk (SR) device? No □	k device study, is docum iing the manufacturer's o ? <i>(See 21 CFR 812)</i>	entation attached with the r a sponsor's determination	why the device is i				
b. If this is applicat Significa Yes □ c. If applyi	a non-significant ris ion materials explair nt Risk (SR) device? No □	k device study, is docum ing the manufacturer's o ? <i>(See 21 CFR 812)</i> opy of the dated IDE app	entation attached with the r a sponsor's determination	why the device is				
b. If this is applicat Significa Yes □ c. If applyi	a non-significant ris ion materials explair nt Risk (SR) device No □ No □	k device study, is docum ing the manufacturer's o ? <i>(See 21 CFR 812)</i> opy of the dated IDE app	entation attached with the r a sponsor's determination lication letter to the FDA att	why the device is a				
 b. If this is applicat Significa Yes □ c. If applyi 	a non-significant ris ion materials explair nt Risk (SR) device? No □ ng for an IDE, is a c	k device study, is docum ning the manufacturer's o ? <i>(See 21 CFR 812)</i> opy of the dated IDE app	entation attached with the r a sponsor's determination lication letter to the FDA att	why the device is a				

1. Will a separate Local Site Investigator Application be submitted from the PI/SC site?

(Required only if potential participants in the study will be recruited at the PI/SC site)

 \Box Yes, See below \boxtimes No

If yes, submit VA Central IRB Form 104 as part of this application without any site-specific documents such as the informed consent or recruitment materials. These can be submitted once the template documents submitted as part of the PI Application are finalized.

2. What is the total number of Local Participating Sites to include PI/Co-PI sites? 5 Nurses

List below all other Local Participating Sites and the Local Site Investigators, along with their contact information. If all local sites have not been identified, notify the VA Central IRB administrative office when they are identified. If sites have been identified but not the Local Site Investigators, include "TBD" for the LSI and fill in the name of the facility.

(Copy and paste table as a "nested table" as many times as needed to list all Local Site Investigators.)

Local Site Investigator: Rebekah Friday	Local VA Facility: WTVAHCS
Telephone: 432-263-7361 7118 Email: Rebekah.friday@va.gov	VA Facility Address: Line 1: 300 Veterans Blvd Line 2: Big Spring Line 3: TX, 79720

NOTE: Each Local Site Investigator must submit a separate Local Site Investigator Application VA Central IRB Form 104) after approval of the PI/SC Application by the VA Central IRB. Additional Local Participating Sites may be added in the future through submission of an amendment and/or a Local Site Investigator Application to the VA Central IRB. Section 14: Request for Expedited Review 🖂 Check if not requesting expedited review

1. Check the below boxes as applicable for this study. All three boxes must be checked for the study to qualify for expedited review:

□ The project presents no more than minimal risk to participants.

□ The identification of participants or their responses will not reasonably place them at risk of criminal or civil liability or be damaging to their financial standing, employability, insurability, reputation, or be stigmatizing, unless reasonable and appropriate protections will be implemented so that risks related to invasion of privacy and breach of confidentiality are no greater than minimal.

□ The project is not classified.

2. If all three boxes are checked above, indicate one or more categories below for which this study would qualify for expedited review:

□ **Category 1:** Clinical studies of drugs and medical devices only when one of the following conditions are met.

□ 1a: An investigational device exemption application (21 CFR Part 812) is not required.

□ **1b:** The medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.

Category 2: Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows:

- □ 2a: From healthy, non-pregnant adults who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 550 ml in an 8-week period and collection may not occur more frequently than 2 times per week.
 - □ 2b: From other adults and children, considering the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these subjects, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8-week period and collection may not occur more frequently than 2 times per week.
- □ **Category 3:** Prospective collection of biological specimens for research purposes by noninvasive means.

 \Box **Category 4:** Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x- rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing.

□ **Category 5:** Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for non-research purposes (such as medical treatment or diagnosis). This category also includes research involving materials that were previously collected for either non-research or research purposes, provided that any materials collected for research were not collected for the currently proposed research.

□ **Category 6:** Collection from voice, video, digital or image recordings made for research purposes.

□ **Category 7:** Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies. *If the project does not fit into one of the below categories, it does not qualify for expedited review*

Section 15: Contents of Application (Check all documents included in this package) *Asterisk indicates a mandatory document for all studies. All VA Central IRB forms indicated below can be found on the VA Central IRB website: Image: Image:

\boxtimes	Study Team Biosketches (Merit Review/	Investigator's Drug Brochure
	NIH format) *	Investigator Device Information
		Investigator's Phone/Video Scripts

□ Co-PI/SC New Project Application Supplement □ Model Participant Instructions

(VA Central IRB Form 108a) □ Model Recruitment Materials □ Model VA Research Informed Consent Form □ Model Questionnaires or Surveys □ Model VA Broad Research Informed Consent Form □ Model VA Investigational Drug Information Model Information Sheet for Waiver of (VA Form 10-9012) Documentation of Informed Consent □ Request for Waiver or Alteration of Informed □ Data Collection Forms/Tools/Case Consent (VA Central IRB Form 112a) Forms/etc. Report LSI Application for PI Site (VA Central IRB Form 104) □ Request for HIPAA Waiver of Individual □ CSP Coordinating Center PI/SC New Authorization (VA Central IRB Form 103) Project Application Supplement (VA □ Separate HIPAA Authorization (VA Form 10-0493) Central IRB Form 108b) □ Prior Study Informed Consent Form (If this is a □ *Local ACOS/R&D Review follow-up study) Supplement (VA Central IRB Form 102) List any other documentation included in this package: (e.g., Certificate of Confidentiality, Data Use Agreements, DMC charter, etc.)

Section 16: Principal Investigator/Study Chair Statement

As the Principal Investigator/Study Chair for this project accept the investigator responsibilities as outlined in V these include but are not limited to the following:	ct, I certify that I have read, understand, and /HA Handbook 1200.05, paragraph 5g and that
 Giving first priority to the protection of human subje and practices; and adhering to all applicable VA and IRB and the local VA Facility's policies and procedure protection of human subjects. 	ects; upholding professional and ethical standards other Federal requirements, include VA Central es regarding the conduct of research and the
 Ensuring all investigators and other staff participation have the appropriate training, education, and experient that they have been appropriately credentialed and p and VA requirements. 	ng in this human subjects research are qualified; nce to perform procedures assigned to them; and rivileged as applicable per current local facility
 Submitting all amendments to the project or changes for review and approval prior to initiation, except whe participants. Any changes implemented because of the VA Central IRB as a project deviation and an amended 	in the informed consent to the VA Central IRB n necessary to eliminate immediate hazard to the an immediate hazard will be promptly reported to endment submitted if determined necessary.
 Obtaining and documenting legally effective inform authorized representative (LAR), as well as a HIPAA applicable waiver. 	ed consent of the subject or the subject's legally authorization, unless the IRB approves an
 Reporting problems, adverse events, and apparent local research deaths, in accordance with VHA Hand and VA Central IRB SOPs (to include the VA Central 	serious or continuing noncompliance, including book 1058.01, local VA Facility requirements, IRB Table of Reporting Requirements.)
 Ensuring appropriate research records are maintained by a VA Investigator over the entire lifecycle of the re- maintained in accordance with the VA Records Contri- 	d that includes all information made or received search activity and that these records are rol Schedule and local policies and procedures.
 Providing continuing review and/or requested update and in accordance with the VA and VA Central IRB p of a closure reports for both local sites and the overa 	s for the study as applicable in a timely manner olicies and procedures. This includes submission Il study upon completion. noncompliance.
 Ensuring research does not start until final approval h written notification from the local Facility ACOS/R&D approval policies and procedures. 	nas been received from the VA Central IRB, and in accordance with local R&D Committee
Principal Investigator/Study Chair Signature	Date
Additional form requirement: VA Central IRB Form	102, Local ACOS/R&D Review Supplement, must

also be submitted and signed by the local ACOS/R&D for the PI site.

Appendix N

	Faired Samples Statistics					
		Mean	Ν	Std. Deviation	Std. Error Mean	
Pair 1	Pre-test (score)	91.75	8	5.726	2.024	
	Posttest (score)	100.00	8	.000	.000	

Paired Samples Statistics

Appendix O

