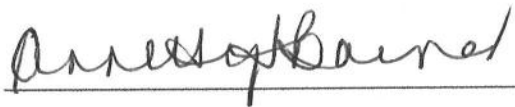


The Use of a Standardized Telehealth Visit Tool to Improve Care Outcomes of Veterans
in Home-based Primary Care

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APPROVED BY:



8/17/2022

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8/20/22

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RUNNING HEAD: TELEHEALTH FOR HOMEBOUND VETERANS

The Use of a Standardized Telehealth Visit Tool to Improve Care Outcomes of Veterans
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By

Chrystal Chan Talley

DNP Project submitted to the School of Nursing
of Salisbury University in partial fulfillment of the requirements
for the degree of
Doctor of Nursing Practice
April 29, 2022

TELEHEALTH FOR HOMEBOUND VETERANS

Copyright

By

Chrystal Chan Talley

2022

DEDICATION

First and foremost, I would like to thank God for giving me the knowledge, wisdom, and strength to persevere through this endeavor. Special thanks to my husband Cartier, daughter Chaniya, and sons Chi, Caleb, and Cayden for their support and tolerating me during this undertaking.

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ABSTRACT

In the United States, approximately two million homebound, older adults have chronic health conditions and disabilities. Providing primary care to this high-risk population is challenging and requires evidence-based strategies to address higher treatment noncompliance, lower medication adherence, decreased continuum of care, higher risk for hospitalizations, and disproportionately high healthcare costs. This project implemented evidence-based practice (EBP) of a standardized telehealth visit tool to increase access to primary care for homebound veterans. Anticipated outcomes included an increase in telehealth visits, holistic documentation, and a decrease in emergency room (ER) visits post-implementation. A synthesis of literature highlighted best practices during telehealth visits to include utilization of a standardized tool. A telehealth visit tool was developed to guide visits conducted by nurse case managers and other providers in a home-based primary care (HBPC). During a three-month period, telehealth visits were offered to all veterans enrolled in the HBPC program located in the Northeast region in the United States. Data including demographics, number of telehealth visits, tool usage, and number of ER visits and hospitalizations with diagnosis were analyzed pre- and post-implementation. Telehealth visits improved access to care for homebound veterans with a 373.3% increase in the total number. The standardized tool assisted nurse case managers and providers to maximize the benefits of and promote continuity of primary care using telehealth. Hospitalizations and ER visits did not decrease, perhaps due to the short implementation period, an increase in COVID-19 cases, and the high-risk population's multiple comorbidities.

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Project Overview

Introduction

Adults aged 60 years or older will increase by 56% in the world by 2030, and adults aged 65 or older are estimated to total approximately 1.5 billion by 2050. In addition, six in ten adults in the United States (U.S.) have a chronic disease with four in ten adults having more than one (Maresova et al., 2019, p. 2). Older adults have a high likelihood of chronic diseases and increased utilization of healthcare resources leading to disproportionately high healthcare costs (Dang et al., 2019).

Two million older adults in the U.S. are homebound and receive home-based care. These adults tend to have higher treatment noncompliance, lower medication adherence, and decreased continuum of care (Kim et al., 2018). Since home-based primary care (HBPC) veterans are older adults with comorbid chronic diseases that increase their risk for emergency room visits and hospitalizations, chronic disease management and patients' involvement in their care is imperative. The HBPC model is comprehensive and utilizes an interdisciplinary team to deliver care in veterans' homes.

Homebound older adults have barriers that can limit access to care including health-related challenges and transportation; therefore, telehealth visits may improve access to care and care outcomes (Slightam et al., 2020). The expansion of health care technology increases access to care through video visits, remote monitoring, patient portals with email communication and access to health records (Slightam et al., 2020). Telehealth can reduce access gaps for patients with chronic diseases, and integrating

telehealth into care management of homebound, older adults will improve their health-related self-efficacy without them having to leave their home (Kim et al., 2018; Rush et al., 2018; Slightam et al., 2020).

In addition, home telemonitoring of chronic patients has been shown to reduce the number of emergency department visits (Martín-Lesende et al., 2017). In chronic disease management, patients often have difficulty recognizing symptoms, lack comprehension of health information, and have incorrect beliefs and assumptions about their care (Seljelid et al., 2020). These patients have an important role in their care which includes healthy lifestyle choices, monitoring symptoms, and self-administering treatment; therefore, self-management and educational support are vital to their management (Rush et al., 2018; Seljelid et al., 2020). For care to be patient-centered, collaboration between the patient and the health care team is needed. Incorporating shared decision making (SDM) tools in telehealth visits can address individuality and variability in patient symptoms and improve patient outcomes (Seljelid et al., 2020).

Problem Statement

In the U.S., approximately two million homebound, older adults including HBPC veterans have chronic health conditions and disabilities leading to higher treatment noncompliance, lower medication adherence, decreased continuum of care, higher risk for hospitalizations, and disproportionately high healthcare costs (Dang et al., 2019; Kim et al., 2018). Older adults who have emergency room (ER) visits are admitted at almost four times the rate of the general population, and approximately 70% of hospital admissions for older adults originate in the ER creating a significant expense (Ahn et al., 2020; Stuck et al., 2017).

Purpose of Project

For this Doctor of Nursing Practice (DNP) project, the nurse should assess a system problem, process, or practice in a clinical setting then use research evidence to improve the process, practice or outcomes (Waldrop et al., 2014). The purpose of this DNP project was to address health care utilization of homebound veterans in the home-based primary care (HBPC) department and identify evidence-based practices (EBP) that could reduce the high number of ER visits and improve the patients' access to primary care. Development of a clinical question guided the review and synthesis of research evidence to implement a standardized telehealth visit tool to improve care outcomes.

Clinical Question (PICOT)

Using the population (P), intervention (I), comparison (C), outcome (O), and time (T) or PICOT format, the clinical question for this DNP project developed was: "In home-based primary care patients (P), do telehealth visits by nurse case managers and providers using standardized documentation (I), compared to no telehealth visits or telehealth visits with no standardized documentation (C) increase access to primary care and reduce the number of emergency room (ER) visits and hospitalizations (O) within three months (T)?". The PICOT question was a critical part of the EBP process as it guided the literature search to determine best practice and provide recommendations that were implemented to improve organizational processes and health outcomes (Ford & Melnyk, 2019).

Synthesis and Analysis of the Literature

The literature search was guided by the PICOT question, and several databases were used in the search including CINAHL, Medline, and PubMed. Search terms included

telehealth, telemedicine, emergency room/department, home-based, primary care, chronic disease, standardized documentation, elderly, older adult, and geriatric in different combinations to find articles that answered the clinical question. In the literature search, limits such as the publication date range from 2016 to 2021 and English-only were applied. Initial database searches returned 1,461 articles, and an additional 13 articles were found through internet searches and review of references from previously found articles. Duplicate articles were removed, leaving 602 articles. These remaining articles were screened by title and abstract, and an additional 559 articles were excluded leaving 43 articles for full-text review.

Articles were excluded if they did not discuss the impact of telehealth on primary care access or ER visits, or focused primarily on economic analysis, pharmacology, inpatient telemonitoring, and children. The remaining 13 articles were used to answer the PICOT question, and the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) flow diagram illustrates the different phases of the literature search discussed (Page et al., 2021; Appendix A).

A table of evidence (Appendix B) overviews the level and quality of evidence of the 13 articles using the Johns Hopkins Nursing Evidence-Based Practice (JHNEBP) tool (Johns Hopkins Nursing Evidence-Based Practice, 2020). The articles varied in level of evidence with five level I randomized control trials (RCTs), three level II systematic reviews of RCTs and quasi-experimental studies, four level III qualitative studies, and one level IV literature review. The literature revealed inconsistencies in the benefit of using telehealth. However, good quality evidence supported that telehealth improved access to care, increased self-management, decreased ER visits, hospitalization and

readmissions, improved communication between patient and provider, and reduced chronic care cost (Amdie & Woo, 2020; Comín- Colet, 2016; Huygens et al., 2016; Kim et al., 2018; Lyth et al., 2021).

Rush et al. (2018) showed that telehealth was comparable or more effective than usual care. Ishani et al. (2016) and McFarland et al. (2021) showed no difference between telehealth and usual care for mortality, hospitalization, ER visits, and quality of life (QO). Liang et al. (2021) discussed that telehealth significantly reduced mortality and ER visits and improved patient's QOL with no significant effect on readmission. However, consensus among the researchers again supported that telehealth improved access to care. In addition, several themes emerged from the literature to include access to care/communication, self-management/patient engagement, emergency room (ER) visit/hospitalization, quality of life (QOL), telehealth versus usual care, and telehealth tool. These themes will be discussed further.

Telehealth vs. Usual Care

The studies used a variety of modalities for telehealth such as telephone, tablet, or computer; and some reported on remote monitoring of blood pressure (BP), blood sugar, and weight. Telehealth modalities included synchronous such as videoconferencing, while others were asynchronous including a patient portal. These modalities increased access to care to overcome barriers including travel and time limitations (Rush et al., 2018).

The literature suggested that telehealth visits did not pose any harm to patients; and, when compared to usual care, it was comparable or showed improved health outcomes. Comín-Colet et al. (2016) demonstrated that telehealth reduced the risk of non-

fatal heart failure (HF) events, HF, and cardiovascular-related hospital readmissions.

Rush et al. (2018) showed that telehealth was comparable or more effective than usual care for elderly patients with chronic conditions such as diabetes, chronic obstructive pulmonary disease (COPD), irritable bowel syndrome, and HF. Ishani et al. (2016) and McFarland et al. (2021) showed no difference between telehealth and usual care among older adult patients with multiple chronic conditions. Seljelid et al. (2020) discussed using telehealth modalities and tools as a supplement to usual care for elderly patients with chronic conditions.

Access to care/ communication

Telehealth was supported as an effective way to communicate with patients and improve access to healthcare for older adults with chronic comorbidities (Amdie & Woo, 2020; Kim et al., 2019; McFarland et al., 2021; Rush et al., 2018). Communication can be improved using telehealth through a shared decision making (SDM) tool incorporated into existing patient portals that provide meaningful interaction and communication between patient and provider. SDM tools incorporated behavioral, psychosocial, and lifestyle aspects of care and engaged patients in their care through collaboration with their provider (Seljelid et al., 2020). For example, a SDM tool, InvolveMe, allowed patients to report symptoms, needs, and healthcare preferences, and use secure messaging to communicate with their provider (Seljelid et al., 2020). SDM-tools have demonstrated improved patient knowledge, increased awareness of what matters to them, and more involvement in the decision-making process. Telehealth visits that incorporated SDM-tools addressed individuality and variability in patient symptoms and improved patient outcomes (Seljelid et al., 2020).

Self- management/ patient engagement

Self -management is reported as a vital part of chronic disease care (Huygens et al., 2016; Rush et al., 2018). Telehealth gave patients the opportunity to engage with providers and provided comparable or improved self-management (Amdie & Woo, 2020; Comín- Colet et al., 2016; Kim et al., 2019; McFarland et al., 2021; Mudiyansele et al., 2019).

Patients' anticipated benefits of using telehealth to support self- management impacted their willingness to use telehealth modalities (Huygens et al., 2016). In addition, although telehealth provided opportunity for engagement, efforts to engage patients were found to be lower than expected (Parker et al., 2018). To improve engagement, it was suggested that using a shared decision-making (SDM) tool would assist collaboration between patients and providers (Seljelid et al., 2020).

Emergency Room (ER) visits and Hospitalizations

Although varied results were reported, telehealth was effective in reducing hospitalizations, length of stay, and emergency room (ER) visits; and participants perceived that telehealth had been or would be effective for decreasing admission and rehospitalization (Kim et al., 2019). Telehealth reduced heart failure (HF) and cardiovascular readmissions, and reduced hospitalizations for patient with HF and Chronic Obstructive Pulmonary Disease (COPD) (Comín- Colet et al. 2016; Lyth et al., 2021). Telehealth decreased length of stay and significantly reduced ER visits but had no effect on readmission for patients with diabetes, HF and COPD in other studies (Liang et al., 2021; Mudiyansele et al., 2019). However, additional studies showed that implementing telehealth did not show any difference in hospitalization and ER rates, or

COPD exacerbations leading to ER visits or hospitalizations, when compared to usual care (Ishani et al., 2016; McFarland et al., 2021; Rush et al., 2018; Soriano et al., 2018).

Quality of Life (QOL)

Quality of life (QOL) indicators studied included improved mobility, self-care, pain/discomfort, anxiety/depression, coping, relationships, and independent living (Liang et al., 2021; Mudiyansele et al., 2019). Telehealth interventions demonstrated varied results with regards to QOL. In several studies, telehealth was comparable to usual care and improved QOL for older adults with chronic illnesses (Liang et al., 2021; Mudiyansele et al., 2019; Rush et al., 2018). For home-care patients with long-term conditions, telehealth did not affect QOL in one study (McFarland et al., 2021). During telehealth visits, nurses discussed health issues with high-risk older adult patients, recommended appropriate care, and motivated them resulting in improved QOL (Liang et al., 2021). Therefore, the majority of studies reviewed supported that telehealth can improve QOL for older adults with chronic diseases.

Telehealth Tool

Several different tools were identified and used to guide telehealth visits with patients for chronic care management to improve health outcomes, including shared decision-making (SDM) tools, the TELehealth in CHronic Disease (TECH) model, and the age-friendly health systems 4Ms framework. SDM tools incorporated patients' reported symptoms, needs, and preferences for care to improve engagement and communication between patients and providers, which led to improved patient outcomes, healthcare knowledge, and self-awareness (Bunn et al., 2018; Pel-Littel et al., 2020; Seljelid et al., 2020). The TECH model incorporated engagement of patients and health

care providers for efficient chronic disease management and improved collaboration between providers and patients within both social and health system contexts (Salisbury et al., 2015). The 4Ms framework included goals and preferences, medication, mentation, and mobility (Cacchione, 2020; Martha et al., 2020).

The standardized tools utilized a holistic approach and engaged patients in their care using aspects of chronic disease management of the older adult such as self-management, medication and treatment safety and optimization, monitoring mentation and mobility, and care coordination. For telehealth visits to be effective, it was concluded that they should incorporate these elements of chronic disease management.

Summary of the Evidence

A debate regarding the extent of benefits that telehealth provides older adults with chronic diseases has been reported. However, consensus that telehealth improves access to care and does not pose harm to older adults with chronic diseases was evident. Benefits of telehealth for the population included increased self-management; improved QOL; decreased ER visits, hospitalization, and readmissions; improved communication between patient and provider; and reduced chronic care costs (Amdie & Woo, 2020; Comín- Colet et al., 2016; Huygens et al., 2016; Kim et al., 2018; Liang et al., 2021; Lyth et al., 2021; Mudiyansele et al., 2019). In addition, incorporation of a telehealth tool could promote patient engagement in their care and with the provider, as well as improve patient awareness and knowledge about their comorbidities.

The home-based primary care (HBPC) clinic provides primary care services to home-bound, older adult veterans with chronic diseases in their homes. Telehealth visits provide an option to increase access and better manage patient care for this high-risk

population. Implementing a standardized tool to guide telehealth visits with home-bound veterans will assist nurses and other health care providers to have a more efficient visit. Standardization and providing more holistic assessment with a telehealth tool should lead to better health outcomes for the patients including improved quality of life (QOL); improved access to care; increased communication between patient and provider; increased healthcare knowledge; improved self-management/ patient engagement; decreased emergency room (ER) visits, hospitalizations, and readmissions; and reduced chronic care costs.

Conceptual Framework: TECH Model

This DNP project developed and implemented a standardized telehealth visit tool used by nurse case managers and providers in HBPC to improve health outcomes of home-bound veterans. The conceptual model for this project was the TELehealth in CHronic Disease (TECH) model. The objectives of the model are to improve health outcomes, access to care, patient experience, and cost-effective care with a focus on engagement of patients and health professionals, effective chronic disease management (i.e., self-management, optimization of treatment, care coordination), and collaboration between providers and patients within the social and health system contexts (Salisbury et al., 2015). The model can be used to design and evaluate telehealth programs that are both cost-effective and acceptable to patients and providers. The TECH model was a good fit as a conceptual model for this DNP project aimed at improving health outcomes by implementing telehealth.

Additionally, the organization utilized for the project had a pre-existing telehealth department, and an initiative to expand telehealth services to patients was underway. This

project expanded upon the organization's initiative and benefited from utilization of the TECH model as it incorporated the use of technology for chronic disease management with a goal of enhancing communication between patients and providers. In addition, due to the coronavirus (i.e., COVID-19) pandemic surge in the fall of 2021, a need to expand telehealth services to seamlessly provide safe, quality care to patients was present. The DNP student co-investigator met with the organization's telehealth department to collaborate on the project as means to provide effective and comprehensive visits via telehealth for the chronic disease management of homebound, older adult veterans.

Evidence-based Practice (EBP) Model

The evidence-based practice (EBP) model used to guide and organize the DNP project was the Johns Hopkins EBP model. The goal of the Johns Hopkins EBP model is to ensure that the latest research findings and best practices are incorporated quickly into patient care (*Johns Hopkins Nursing Evidence-Based Practice*, 2020). An EBP toolkit was used to identify the clinical question, identify the best evidence to answer the question, and translate the evidence into practice. Initially, a discussion with HBPC's program manager about possible processes for improvement was initiated which determined that the telehealth process was a focus because no protocol or standardized documentation was in place. In addition, high hospitalizations and ER visits were documented and routinely reviewed for the population of homebound veterans in HBPC.

A literature review was completed to determine the best evidence and the benefits of telehealth for care of older adults with chronic diseases. Evidence was identified that telehealth may be beneficial for older adults with chronic diseases, such as the veterans in HBPC. It was then determined that the DNP project had good fit and feasibility for

HBPC, since goals of the department included reducing hospital readmissions, shortening length of stay, training and supporting family members in caring for veterans, providing primary care, and finding resources in the community that may assist veterans.

The aim of the DNP project was to increase access to primary care and reduce ER visits and hospitalizations of the population which aligned with the goals of the department. The organization and HBPC were trying to expand the use of telehealth, were ready for change, and had necessary resources available for the DNP project. The project of implementing a standardized telehealth tool to assist nurse case managers and providers was supported by the program manager and HBPC.

Theoretical and operational definitions of key concepts

Theoretical definitions give meaning to the concepts under investigation. Operational definitions aim to transform theoretical definitions into observable events by stating which characteristics will be measured (Sekhon et al., 2017). This DNP project required some key concepts to be defined such as telehealth and the outcomes of ER visits and hospitalization (i.e., admission) rates.

Telehealth

Telehealth is the delivery of health care, health education, and health information services via remote technologies (Doarn et al., 2014). A variety of modalities for telehealth including telephone, tablet, computer, and attachments to track vital signs and other clinical information such as blood pressure (BP), blood sugar, and weight. Some modalities are synchronous while others are asynchronous. Synchronous modalities include live videoconferencing.

Similar to face-to-face visits, confidentiality and Health Insurance Portability and Accountability Act (HIPAA) compliance is important for telehealth visits to keep patients' personal and health information private. To encourage compliance, payors including Medicare and Medicaid, impose reimbursement restrictions on the types of technologies that can be used. Since COVID-19, reimbursement of telehealth visits has improved and many services provided by providers including nurses, nurse practitioners, and physicians are covered by insurance at rates comparable to face-to-face visits (Shachar et al., 2020).

Emergency Room (ER) visits

Emergency room (ER) visits were defined as care received in the ER whether admitted to the hospital or discharged to home. ER visits were currently tracked and discussed during weekly interdisciplinary team meetings in HBPC. ER visits are costly to patients and the organization, and HBPC patients have comorbidities which increased the likelihood of ER visits; however, a goal to help patients remain at home and minimize symptoms that drive ER visits and hospitalizations was identified. Quarterly periodic reviews were also currently completed to assess a patient's status, including ER visits, to evaluate the care plan and make needed adjustments.

Hospitalization rate

The hospitalization rate was the number of HBPC patients admitted to the hospital during a month compared to the HBPC population times 100 percent. For example, if 20 patients were admitted to the hospital and 400 patients were in the program, then 20 divided by 400 equals 0.05 times 100 percent equals a five percent (5%) admission rate

for the month. The ideal hospitalization rate goal for HBPC is 0%, however, a 20% decrease from the current rate was proposed by leadership given the high-risk population.

Project Design

Methodology

A gap analysis was performed to determine deficiencies in the telehealth visit process used in the HBPC program of a veteran's facility in the Northeast region of the U.S. Collaboration with the telehealth department to determine their telehealth practices and available resources was also initiated. An evidence-based telehealth visit tool was then developed to guide telehealth visits in HBPC (Appendix D). HBPC staff were trained on the purpose and use of the telehealth visit tool. There was collaboration with the clinical informatics department to incorporate the telehealth visit tool into the electronic health record (EHR). Enrollment into the study was offered to all veterans enrolled in the HBPC program during the implementation period. Verbal consent was obtained prior to telehealth visits and consent or refusal of the telehealth visit was recorded in the EHR. ER visit data pre- and post-telehealth visit with the standardized tool was compared to determine if the implementation of the tool reduced the number of ER visits and hospitalizations.

Participants

Eligible participants were patients enrolled in the HBPC program of a veteran's administration (VA) hospital in the Northeast region of the U.S. Veterans in the program were generally male, older than 55 years, a variety of ethnicities and socioeconomic status, had multiple chronic comorbidities, and were homebound. Veterans enrolled in HBPC lived in both inner-city and rural areas surrounding the VA hospital.

Veterans recruited to participate in the project had a personal smart phone, tablet, laptop, desktop computer, a family member or caregiver that has a smart device, or received a device supplied by the VA. Patients could decline telehealth services, and veterans enrolled in hospice were excluded from the project. Personal and health information was treated as confidential and private, in compliance with the Health Insurance Portability and Accountability Act (HIPAA) and organization's telehealth protocol. The sample size for this DNP project was estimated to be 30- 40 participants.

Setting

The setting was a HBPC in a Northeast veteran's hospital and included nurse case managers and providers in offices or remote work locations. Participants received telehealth visits with nurse case managers or providers using devices in a place of their convenience.

Tools

To guide the telehealth visits in HBPC, a standardized tool was used to assist the nurse case managers and providers to have a more efficient visit. The telehealth visit tool (Appendix D) promoted a holistic approach to engage patients in their care, by including aspects of chronic disease management of the older adult which were self-management, medication and treatment safety and optimization, monitoring mentation and mobility, and care coordination.

Intervention

For each telehealth visit which was a videoconference format, the nurse case managers and providers accessed the telehealth visit tool in the patient's chart within the EHR and used the tool to engage patients, document important information for effective

treatment, and follow through on care coordination. Nurse case managers, providers, and the program director were educated on the use and essential chronic care management elements of the telehealth visit tool. The timeline for implementation and evaluation of the project was discussed with the nurse case managers, providers, and program director. The telehealth visit tool was utilized during each telehealth visit with consenting veterans during the implementation period.

Data Collection Procedures

During the weekly interdisciplinary team meetings in HBPC, team members reported and the administrative staff collected data on emergency room (ER) visits and hospitalizations including the diagnosis and type of ER utilized (i.e., community or veteran's hospital). The HBPC staff stores this information on their shared drive for review. Hospitalizations were not direct admissions and instead were usually a result of the ER visits. Therefore, to accurately tally ER visits, the ER visits and the hospital admissions were combined. Due to the Mission Act, the cost of community ER visits may also be incurred by the VA and important to capture if possible (U.S. Department of Veterans Affairs, 2021).

Before implementation of the telehealth visit tool, the ER visits and admission rates were documented and tracked. After implementation of the telehealth visit tool, the ER visits and admission rates were documented, noted, and stored on the shared drive. The data was then used to compare three months pre- to three months post- telehealth visit using the standardized tool to determine if implementation reduced the number of non-emergent ER visits and hospitalizations for participants. Data was collected for

participants who received a telehealth visit and those who did receive a telehealth visit prior to an ER visit.

Formative evaluation was completed during the implementation period to determine if the standardized tool was being used, used correctly, used by nurse case managers and providers each visit, and to address any challenges identified by the tool users. All information was kept on the co-investigator's password-protected computer and access to the data was encrypted and required password to access. The information was only accessible by the VA research and medical team. The results of the study were reported in summary or aggregate of all participants' results.

Analysis

Excel and the Statistical Package for the Social Sciences (SPSS) were utilized to review and analyze data collected. Descriptive statistics included demographics, diagnoses, and length of time in HBPC. Analysis also compared characteristics of participants who received telehealth visits to those who did not receive a telehealth visit, total number of ER visits, and admission rate. Utilization of the standardized telehealth tool by nurse case managers and providers was analyzed and categorized as "always used", "sometimes used", or "never used".

Organizational System Analysis

An analysis of the HBPC organization was completed to identify strengths, weaknesses, opportunities, and threats (i.e., SWOT) that could impact EBP implementation (Appendix E). Some of the strengths identified included that the veteran's hospital was one of the first organizations to use an electronic health record (EHR), encouraged and utilized EBP, had a telehealth department, utilized the chronic

care model, and had interdisciplinary patient aligned care team (PACT) teams.

Weaknesses included no telehealth protocol or standardized documentation, nurse managers and providers were trained on telehealth but did not frequently use it, and not all patients had access to technology. Opportunities included potential expansion of telehealth to improve access to care and utilizing a standardized tool during visits with veterans that was holistic and comprehensive. Threats included technical difficulties and patients who may not want to use technology.

Sustainability of this DNP project was an important consideration to maintain positive change and improve health outcomes of the high-risk patient population. One of the organization's strengths was encouraging and utilizing EBP. The organization had a telehealth program and was trying to expand these services, especially given the lessons learned from the COVID-19 pandemic. Showing the effectiveness of the project would support sustainability given the written organizational support (Appendix C).

Implementation Timeline

A timeline was developed for the DNP project (Appendix H). Prior to implementation, several objectives needed to be accomplished including (a) training HBPC nurse case managers and providers on the telehealth visit tool, (b) provide an overview of the DNP project's purpose and goals, (c) work with clinical informatics to embed the telehealth visit tool into the EHR. Implementation of the project occurred from November 2021 to January 2022, with data analysis and dissemination during the spring of 2022.

Institutional Review Board (IRB) and Agency Approval

Review of the proposed project by the university's Institutional Review Board (IRB) assured that the rights and welfare of human participants were protected. The IRB ensured that respect for persons, beneficence, and justice were upheld. As part of the IRB process, Collaborative Institutional Training Initiative (CITI) certifications were obtained regarding research and rights of human subjects (Appendix F). IRB approval was obtained from the university in May 2021 and then from the veteran hospital's HBPC department in August 2021 (Appendix G).

Project Implementation

Barriers and Facilitators

Challenges arose and were addressed pre-implementation and during implementation of the Doctor of Nursing Practice (DNP) project. An unforeseen change in HBPC management delayed implementation as weekly interdisciplinary team (IDT) meetings were held longer than usual to discuss patient issues and ethical concerns. As a result, time allotted to overview the project and train staff on the telehealth visit tool was postponed for one month and started in October 2021. Another challenge was the transition of positions within the telehealth department. Although the telehealth department had been previously consulted, a delay due to new members led to starting the intervention in November 2021.

Data Collection Challenges

Key to the project was an accurate count and documentation of participants' emergency room (ER) visits and hospital admissions. The project aimed to decrease the number of ER visits with use of the EBP tool; therefore, accurate data was important to

determine the effectiveness of the standardized telehealth visit tool. Initially, an issue with standardized documentation of data due to staff changes occurred; however, this issue was quickly rectified. Patients and caregivers in HBPC occasionally delayed notifying the clinical team of a hospital visit until a month or two after it occurred. In addition, the clinical team did not always alert the administrative team of hospital visits to be documented. Due to the delay or omission in notification, the recording of hospitalizations was occasionally missed or incorrectly recorded in a later month. Another challenge occurred for veterans with hospitalizations at external community hospitals, as that data would not be captured in the study site's EHR and required self-report by the patient on follow-up.

In addition, the nurse case managers and providers needed to alert the administrative team when a telehealth visit occurred. However, some users admitted to forgetting to inform the administrative team about telehealth visits conducted. During a feedback session, a suggestion to add the co-investigator as an additional signer to each telehealth visit note was recommended to capture data. The co-investigator would then be able to track the data as soon as the telehealth visits were documented. However, some nurses and providers followed this suggestion and others did not, which may have affected the accuracy of telehealth visit data collection.

Device Challenge

During the strength, weakness, opportunity, and threat (SWOT) analysis, a weakness identified was that some veterans in HBPC lacked a device to participate in telehealth visits. Although the implementation of the project was delayed for two months,

this time created the opportunity for more veterans to be provided tablets through the digital divide consult and conduct more telehealth visits.

Challenge Implementing the Telehealth Visit Tool

A challenge to implementation of the telehealth visit tool was a change in the home-based primary care (HBPC) interdisciplinary template for periodic reviews. The periodic review note is initiated by nurse case managers or providers then addended by other disciplines to give a summation of the occurrences, patient status within the review period, and the care plan for the next review period. The new note was more time-consuming and laborious than the previous one, which may have negatively affected the use of the telehealth visit tool during visits. However, during each weekly interdisciplinary team (IDT) meeting, the nurse case managers and providers were reminded by the DNP project co-investigator to utilize the tool to guide telehealth visits and subsequent documentation.

Another challenge to implementation of the telehealth visit protocol was a new policy that nurses needed to have a face-to-face encounter with new patients within fourteen days of admission to the HBPC department. This requirement was an organizational initiative to assess and potentially admit high-risk, high-needs patients. An increase to up to ten admissions in the department per week occurred and increased the nurse case managers workload in each sector. In addition, the influenza season was well under way and recommendations for a booster or third COVID-19 vaccine for immunocompromised and elderly patients required face-to-face visits. The office nurse position also remained unfilled, and nurse case managers rotated into that position to

process consults and other office duties. These various priorities decreased the number of telehealth visits available to veterans in HBPC during the first month of the three-month implementation period.

COVID-19 Influence

As a result of the surge in COVID-19 cases in December 2021, the organization decreased the number of face-to-face visits and increased the number of phone and telehealth visits. This increase in telehealth visits was beneficial to use of the telehealth visit tool during the last six weeks of the three-month implementation period.

Access of the Telehealth Visit Tool

The co-investigator collaborated with nursing informatics personnel to input the telehealth visit tool into the electronic health record (EHR). However, the template was not in the community health HBPC's folder which was easily accessible to trained staff, but instead was under the clinical informatics folder which was less accessible. This limited access to the telehealth visit tool in the HER may be a reason why the template was not used as expected for all telehealth visits. To formalize the template, an application and approval process through the Template and Forms Committee has to occur, but the process is lengthy and did not gain approval before the end of implementation. However, discussion with the geriatrics and extended care (GEC) and nursing leadership to gain approval of the tool through the Template and Forms Committee to make the tool official was initiated. If the tool can be moved to a more accessible folder in the EHR, it would improve sustainability of the use of the telehealth visit tool.

According to Roush and Tesoro (2018), an issue with DNP project implementation may be inadequate duration of data collection which may affect data analysis, project evaluation, and outcomes. To allow for an adequate implementation period or data collection, challenges were addressed to proceed with the planned implementation time of three months, November 2021 through January 2022. This implementation period allowed for an adequate number of telehealth visits and use of the standardized telehealth visit tool in HBPC to be assessed.

Barriers and delays are common when implementing a DNP project, but strategizing and effective communication was an important facilitator throughout the DNP project (Morris et al., 2021). In addition, nurse executive competencies such as communication, knowledge, leadership, professionalism, and business skills should be utilized during interprofessional collaboration to improve the quality of patient care (AONL, 2015). To overcome the challenges, these competencies were applied to communicate the goal of improving patient outcomes to HBPC staff. In addition, several DNP essentials including scientific underpinnings for practice, information systems technology and patient care technology for the improvement and transformation of health care, interprofessional collaboration for improving patient and population health outcomes, person-centered care, and professionalism were utilized to facilitate project implementation (AACN, 2006; AACN, 2021).

Summative Evaluation of Implementation Process

The aim of the Doctor of Nursing (DNP) project was to address a system or practice issue by implementing an evidence-based (EBP) intervention and applying DNP competencies and essentials (Benetato et al., 2021). During evaluation, it is important to

collect data to analyze the process, implementation, and sustainability to improve practice and patient outcomes of a DNP project (Jones et al., 2021). A summative evaluation was conducted to determine if the implementation of standardized documentation utilizing a telehealth visit tool improved the telehealth visit process in home-based primary care (HBPC), increased access to primary care, and reduced the number of emergency room (ER) visits among HBPC patients.

Standardization and Usage

Before implementation of the telehealth visit tool, no standardization in the documentation of telehealth visits by nurse case managers and providers was available. The telehealth visit tool provided standardization and guidance to these clinicians during telehealth visits, in addition to being more holistic when addressing chronic disease management of the older adult (Cacchione, 2020; Martha et al., 2020; Salisbury et al., 2015). Users of the telehealth visit tool relayed ease of use; however, inconsistency in use perhaps due to the tool not being readily accessible in the electronic health record (EHR) and nonadopters of the change was identified.

Access to Care and Emergency Room (ER) Visits

An increase in access to primary care for home-bound veterans in HBPC occurred, especially during the COVID-19 surge with the inability to provide face-to-face visits. The HBPC population which is elderly with multiple comorbidities had an increased risk of ER visits and high healthcare costs (Dang et al., 2019). The participants had multiple comorbidities, and the number of ER visits pre- and post-implementation was consistently high for those age 75 years and older. The participants younger than 75 years had a decrease in ER visits.

The project did not have any negative effects on the HBPC population as the use of telehealth and the tool increased access to care, and participants were affected equitably by the project. Telehealth visits were offered to all HBPC patients and if they declined, then a face-to-face or telephone visit was offered.

The organization encouraged the use of EBP to improve processes and patient outcomes and was receptive to the project. Feedback was sought during weekly interdisciplinary team meetings and was positive with nurse case managers and providers mostly receptive to the project and continuation of the practice change during telehealth visits. Nurse case managers and providers increasingly started to utilize the telehealth visit tool throughout the implementation period.

HBPC leadership had the opportunity to utilize the telehealth visit tool first-hand and appreciated the holistic care and guidance the tool provided nurse case managers and providers when engaging with the elderly, veteran population with multiple comorbidities. As a result, the telehealth visit tool has been adopted into practice in the geriatric patient-aligned care team (Geri PACT) clinic that provides care to veterans with similar demographics to HBPC, except the veterans are not homebound. The senior leadership of the HBPC and Geri PACT clinics are the same. Leadership support and adaptation of the tool in this area increases the promise for sustainability of the standardized telehealth visit process in HBPC.

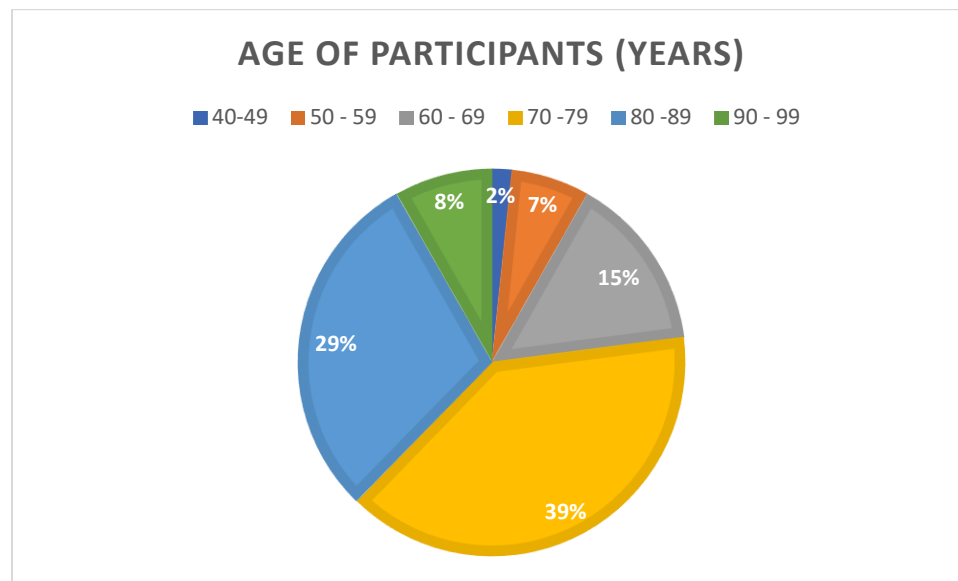
An increase in interest in the HBPC department regarding a culture of evidence-based change to improve system and patient outcomes has occurred during implementation of this project. Other nurse case managers have realized that the DNP degree provides advanced practice registered nurses (APRNs) with skills and

competencies as leaders and innovators to address clinical challenges and improve the current healthcare system and patient health outcomes through implementation of evidence-based practice (Beeber et al., 2019; McNett et al., 2021; Sherrod & Goda, 2016). The DNP project has given these healthcare professionals some insight into what to expect during their journey in their respective DNP programs.

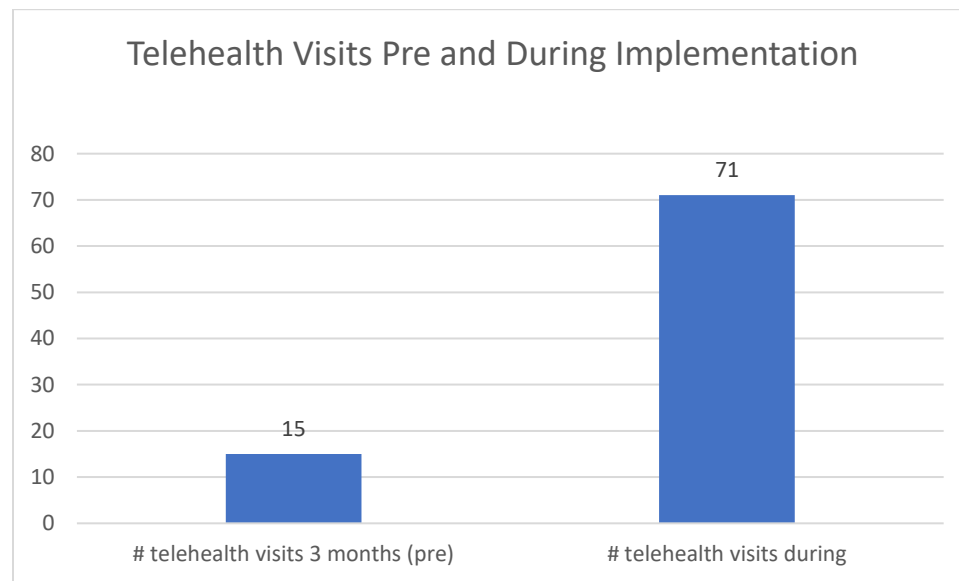
Analysis and Discussion of Findings

Demographics

The demographics of the 61 participants in this project reflected the targeted population in HBPC. Of the 61 participants, 58 were male and three were female. Ages of participants ranged from 46 to 97 years old with a mode of 78 years and an average of 76.6 years; therefore, the participants were older homebound adults (Figure 1). Race was reviewed and included 28 Caucasian, 31 African American, and two participants of unknown ethnicity. The average body mass index (BMI) was 28 with mode of 33 meaning the average participant was overweight and most participants were obese. All participants were homebound with at least two or more comorbidities, and 67% of participants had three or more comorbidities. The most common diagnoses were chronic diseases such as hypertension, diabetes mellitus type 2, chronic obstructive pulmonary disease (COPD), and history of cerebrovascular accident (CVA). Fifty six percent of the participants were well established in the HBPC program, with 27 participants admitted to the program for less than one year. Twenty-three participants had been patients for 1-5 years, and eleven participants for 6-10 years.

Figure 1*Distribution of Ages of Participants***Telehealth Visits**

An increase in access to care for the HBPC veterans occurred during the implementation period. In the three-months preceding implementation, August through October 2021, a total of 15 telehealth visits were conducted by nurse case managers and providers. Only 10 participants had telehealth visits during the pre-implementation period, with two participants having two visits and one participant with four visits. During the implementation period, November 2021 through January 2022, 71 telehealth visits were conducted equating to an increase of 373% when compared to the pre-implementation period (Figure 2). During the implementation period, some participants had multiple telehealth visits with eight participants completing two visits and one participant receiving three visits.

Figure 2*Telehealth Visits Pre- and During Implementation***Telehealth Visit Tool**

Thirty of the 71 telehealth visits were conducted by the nurse case managers and 41 by providers. Thirty-nine, or 54.9%, of the telehealth visits utilized the visits tool. Twenty-two of the visits that utilized the telehealth visit tool were conducted by nurse case managers with 17 being conducted by providers. Two-thirds of nurse case managers that utilized the tool “always used” or “sometimes used” the tool, while 50% of the providers “sometimes used” the tool.

Emergency Room (ER) Visits and Hospitalizations

During pre-implementation, the participants had 13 emergency room (ER) visits compared to 17 ER visits post-implementation of the telehealth visit tool. Of the 61 participants, eight had ER visits pre-implementation and fourteen had ER visits post-implementation. Seven participants, 11% of the project sample, had a decrease in the

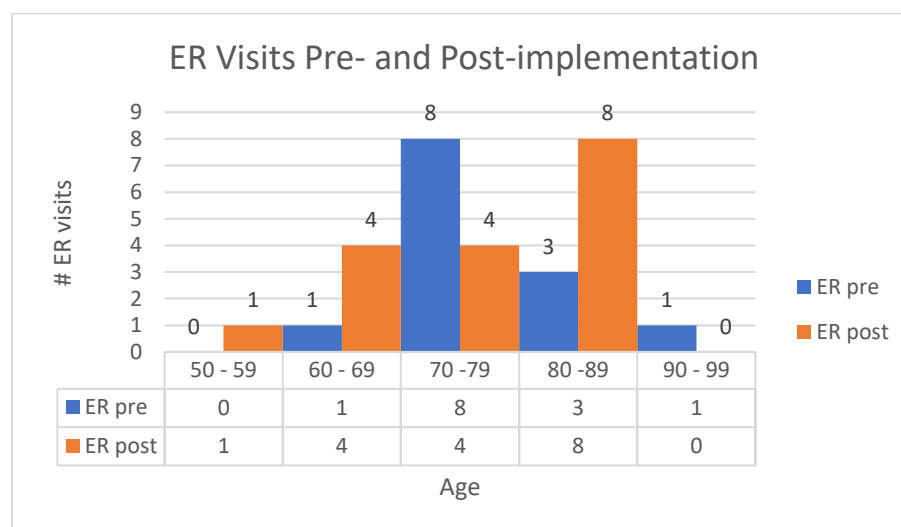
number of ER visits post-implementation. Three participants had ER visits pre- and post-implementation, and two of these participants decreased from two to one ER visits.

ER visit diagnoses included urinary tract infection (UTI), falls, pneumonia (PNA), wounds, hypotension, emesis, dislodged tube, altered mental status, respiratory distress, and COVID-19. Three of the 17 ER visits, or 18%, post-implementation were due to COVID-19 in participants younger than 70 years old. Three of the ER visits were due to falls, and another three visits were participants treating for UTI.

Twelve of the 17 ER visits, or 70.5%, post-implementation were for participants older than 75 years old, and three additional participants were 65-74 years old (Figure 3). Although the post-implementation ER visits were higher by four visits, this increase may have been impacted due to the surge of COVID-19 cases during the time-period. ER visits remained consistently high in the 75 years and older participants.

Figure 3

Emergency Room (ER) Visits Pre- and Post-Implementation

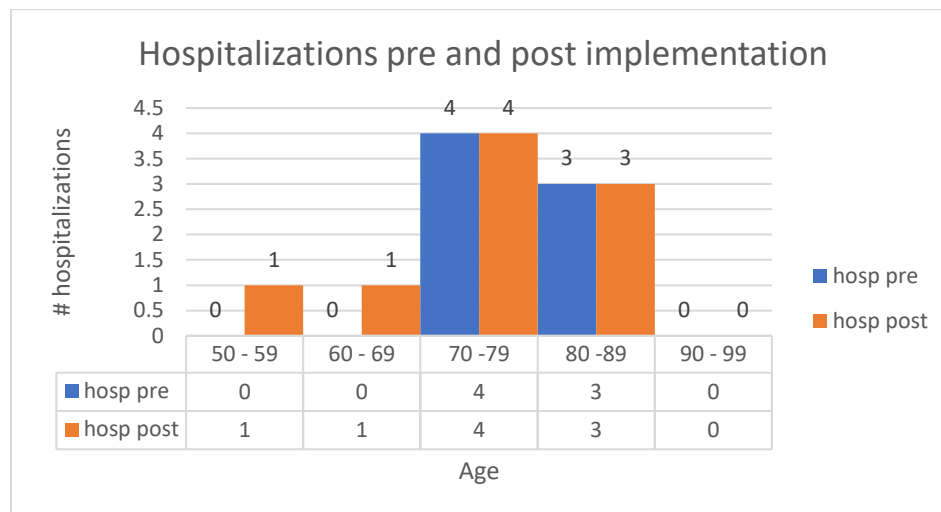


Four telehealth visits were conducted with participants after the ER visits, and one participant had two telehealth visits following their ER visits. Two participants had

telehealth visits prior to ER visits, and one of those two participants had two telehealth visits prior to two ER visits and two telehealth visits post ER visits. This participant had two ER visits pre- and no ER visits post-implementation with one hospitalization pre- and no hospitalizations post-implementation, which was promising to note.

Seven hospital admissions occurred pre-implementation and nine post-implementation of the telehealth visit tool. Diagnoses were similar to ER visits and included COVID-19, UTI, fall, PNA, CVA, hypotension, wound, and emesis. The majority of hospitalizations, six of seven pre- and seven of nine post-implementation, were for participants over 75 years of age (Figure 4). The post-implementation hospitalizations for three participants less than 65 years old were due to COVID-19 and PNA. Of five participants with hospitalizations pre-implementation, four had decreased admissions post-implementation.

Due to the small number of hospitalizations, the number of visits was utilized and compared pre- and post-implementation versus a hospitalization rate as initially planned. For future analysis using the entire population, the hospitalization rate could be reviewed by HBPC more readily with additional analysis regarding diagnoses and hospitalizations per each veteran enrolled in the program.

Figure 4*Hospitalizations Pre- and Post-Implementation***Summary of Data Analysis**

Increased access to primary care for veterans of HBPC was demonstrated by the significant increase in the number of telehealth visits conducted. Although the number of ER visits and hospitalizations did not decrease as anticipated, a decrease in the number of participants with both pre- and post-implementation ER visits and hospitalizations did occur. In addition, participants who received multiple telehealth visits during the implementation period exhibited a decrease in ER visits. Although not generalizable to the entire HBPC population, increased access to care through telehealth visits appears to provide continuity of care and enhanced monitoring since the number of ER visits and hospitalizations decreased for several participants after implementation of the standardized telehealth visit tool.

Overall, from the data analysis and implementation process review, the standardized telehealth visit tool was well received by nurse case managers, providers, and participants. In consideration of the short implementation period, inconsistent use of

the telehealth visit tool, and the home-bound veterans' comorbidities, challenges remain to maximize the impact of the project's intervention for the population and HBPC.

Recommendations

Economic Considerations

The average cost of a medical-surgical inpatient stay at a veteran's hospital is \$685 per day, and the average cost of hospitalization that leads to rehabilitation has increased during COVID-19 with costs up to \$40,000 per stay (Wagner et al., 2022). The home-bound veterans in HBPC have a high risk for emergency room (ER) visits and hospitalizations due to chronic health conditions and disabilities. These ER visits and hospitalizations are linked to high healthcare costs (Dang et al., 2019).

Although the overall ER visits and hospitalizations did not decrease during this project, most participants who had pre-implementation ER visits and hospitalizations had a decrease in ER visits and hospitalizations post-implementation. This finding demonstrates that sustained utilization of the standardized telehealth visit tool has the potential to decrease ER visits and hospitalizations leading to a decrease in health care spending and improved quality of life (QOL) for these veterans.

DNP Role as Leader/Innovator

The current, complex healthcare environment requires evidence-based practice (EBP) innovation to keep up with the changing demands to provide safe, quality care (Sherrod & Goda, 2016). To meet these demands, the Doctor of Nursing Practice (DNP) degree provides advanced practice registered nurses (APRNs) with skills and competencies to address these challenges and improve the current healthcare system

along with patient health outcomes through EBP implementation (Beeber et al., 2019; McNett et al., 2021; Sherrod & Goda, 2016).

DNP programs also utilize advanced essentials, nurse practitioner core competencies, and nurse executive competencies as guidelines to develop students' skills and abilities, with application to the DNP project being key (Giardino & Hickey, 2020; Minnick et al., 2019). To facilitate culmination of these skills and competencies, the DNP student co-investigator utilized several DNP essentials including (a) clinical scholarship and analytical methods for evidence-based practice (EBP), (b) organizational and systems leadership for quality improvement and systems thinking, (c) information systems/technology and patient care technology for the improvement and transformation of health care, (d) interprofessional collaboration for improving patient and population health outcomes, along with leadership competencies of person-centered care and professionalism, to facilitate the DNP project's implementation (AACN, 2006; AACN, 2021).

To identify, appraise, and synthesize evidence to address an identified practice problem requires skill and a planned process to implement the evidence into practice (Zuzelo, 2021). The Johns Hopkins EBP model was utilized to identify current, relevant literature related to telehealth and synthesize evidence to implement the standardized telehealth visit tool into patient care.

The DNP essential for organizational and systems leadership for quality improvement and systems thinking was applied through the change in HBPC's process for telehealth. To promote change, staff in the department and organization needed to be motivated and inspired to implement the practice change which was accomplished

through nursing leadership competencies of effective communication, knowledge, professionalism, and business skills (AONL, 2015; Giardino & Hickey, 2020). In addition, the project was considered from a systems level thinking approach by completing a strength, weakness, opportunity, threat (SWOT) analysis and comparing goals of the project to the organization's to determine fit.

The information systems, technology, and patient care technology for the improvement and transformation of health care essential addresses the co-investigator's ability to utilize information technology (IT) to support and improve clinical practice (Giardino & Hickey, 2020). The DNP project incorporated telehealth modalities, used the electronic health record, and extracted data through reporting functions to evaluate the project.

The DNP essential interprofessional collaboration for improving patient and population health outcomes was utilized initially when determining the clinical issue and throughout the implementation process. Communication and collaborative skills were utilized in inter- and intra-professional teams to provide leadership, set mutual goals, implement the change, and perform evaluation of the project (Gaspar et al., 2016; Giardino & Hickey, 2020). The DNP student co-investigator motivated the interdisciplinary team to adopt use of the telehealth visit tool by showing that the change aligned with best evidence including standardization of telehealth visit documentation and with organizational goals to expand telehealth visits. It was also vital to communicate with the team for formative evaluation to make changes during implementation to overcome challenges and improve the process.

Barriers and delays are common when implementing a DNP project, but strategizing and effective communication were important facilitators throughout the DNP project (Morris et al., 2021). Nurse leadership competencies such as communication, knowledge, leadership, professionalism, and business skills were utilized throughout the implementation process (AONL, 2015). The project allowed the DNP student co-investigator the firsthand experience in utilizing several DNP essentials and nurse leadership competencies to translate the evidence into practice to improve the system's delivery of healthcare and patient outcomes.

Process and Outcome Recommendations

Based on the findings, it is recommended to utilize the standardized telehealth visit tool in HBPC to improve access to primary care for homebound veterans as evidenced by a significant increase in telehealth visits and decreased ER visits and hospitalizations for several veterans. The tool assisted nurse care managers and providers to conduct holistic assessment and improved documentation. Similar populations could benefit from utilizing the standardized documentation tool to improve the telehealth process and patient outcomes as indicated by adoption of the tool by the Geri PACT within the organization.

Limitations to the change process were recognized, since all stakeholders did not adapt and use the telehealth visit tool. To make the change sustainable, further education, EHR placement of the tool to aid use, and ongoing motivation through transformational leadership would assist the department. In addition, dissemination to the organization will be key to share findings and support sustainability of the evidence-based practice (EBP) change.

Dissemination Plan

Dissemination of the project's findings to all stakeholders is important to create awareness regarding the evidence-based practice (EBP), use of a standardized telehealth tool during visits with homebound veterans, and its impact to increase access to care and decrease ER visits and hospitalizations. In addition, dissemination can help to nurture a culture of evidence-based practice change within the organization.

The DNP project presentation in May 2022 provided dissemination of findings to the student co-investigator's committee, university faculty, and graduate nursing students. The DNP project findings were also shared with all staff involved in the project, including home-based primary care (HBPC), geriatric and extended care leadership, nursing leadership, geriatric patient-aligned care team (Geri PACT), clinical informatics, and the telehealth department.

Project findings will also be disseminated to other members of the organization through a poster presentation during the Veterans Affairs Geriatric Extended Care (GEC) and Geriatric Research Education and Clinical Center (GRECC) educational conference. This presentation will allow departments caring for similar, older adult populations to be educated about the practice recommendation and potentially adopt the change. In the future, the co-investigator plans to respond to a call for an abstract on the DNP project, and subsequent publication to a peer-reviewed journal to disseminate project findings and recommendations to healthcare professionals and the public.

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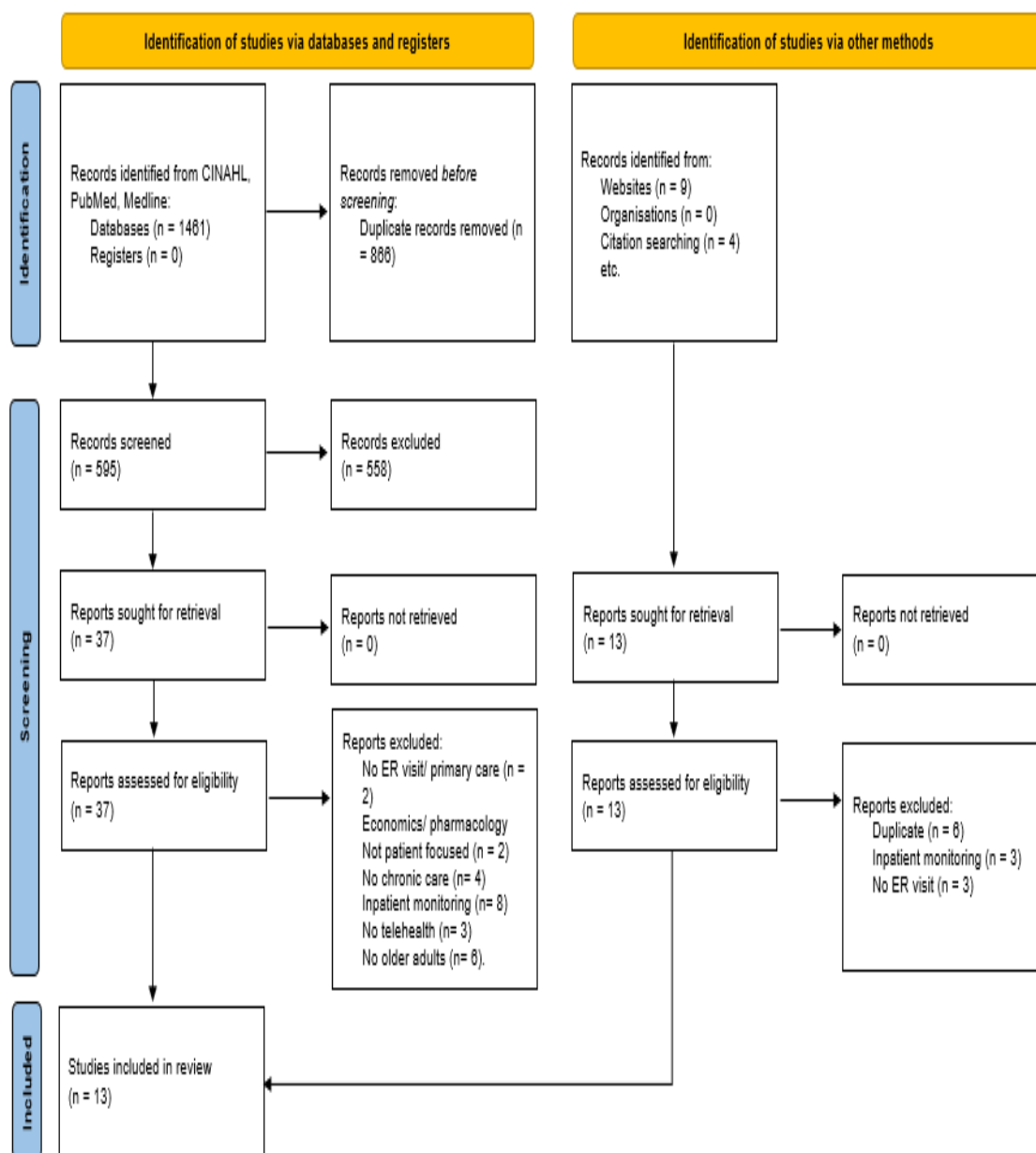
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APPENDIX A

PRISMA: Telehealth to Improve Care Outcomes



Appendix B

Table of Evidence

Citation	Conceptual Framework	Design/Purpose	Sample/Setting	Measurement of Major Variables	Study Findings	Appraisal of Worth to Practice	Strength & Quality of Evidence
Chronic care management with telehealth							
Amdie, F. Z., & Woo, K. (2020). The use of mHealth technology for chronic disease management: the challenges and opportunities for practical application.	Chronic care model	Literature review Integration of mobile technologies to manage chronic diseases	Literature review- chronic illness self-management and mHealth technology. Medline, CINAHL, Nursing and Allied Health Source on ProQuest, EMBASE, PubMed, Google Scholar. 89 studies were included	mHealth chronic disease management chronic disease and mHealth management: integration and utilization patient management and education shared decision making and evidence-based practice system performance and efficiency citizen engagement health equality	-beneficial quality and accessible care - improve patient care outcomes, and reduce chronic care cost. - usability challenges - potential unreliable information, and limitations of technology	89 studies were included Challenges of chronic disease management discussed Benefits and limitations of mHealth technology discussed	VB

				mHealth limitations			
Comín-Colet, J., Enjuanes, C., Verdu-rotellar, J. M., Linas, A., Ruiz-Rodriguez, P., González-Robledo, G., Farre', N., Moliner-Borja, P., Ruiz-Bustillo, S., & Bruguera, J. (2016). Impact on clinical events and healthcare costs of adding telemedicine to multidisciplinary disease management programmes for heart failure: Results of a randomized controlled trial	Chronic Care Model	<p>RCT</p> <p>Evaluate the impact of adding telemedicine to a multidisciplinary HF program</p> <p>Randomization</p> <p>Recruited during 23 moths</p> <p>Followed for 6 months</p> <p>Chart review, medical history, physical, lab tests and functional evaluation at baseline at hospital discharge. Psychological evaluation: self-efficacy - European Self-Care Behavior scale and health-related quality of life – Minnesota Living with Health Failure Questionnaire at baseline and end of</p>	<p>N= 178 CHF patients</p> <p>N= 97 (control group, usual care: face- to-face)</p> <p>N= 81 (telemedicine)</p> <p>> 18 years old</p> <p>Median age 77 years</p> <p>41% female</p> <p>25% frail patients</p> <p>Clinical diagnosis of CHF With either reduced ejection fraction or preserved ejection fraction</p> <p>One medical center-specialized, multidisciplinary, nurse-based</p>	<p>IV: Telemonitoring: remote daily monitoring of signs (weight, heart rate, blood pressure) and symptoms of HF</p> <p>Video- or audio-conferencing</p> <p>DV: Non-fatal HF events after 6 months of follow-up</p> <p>HF readmission</p> <p>CV readmission</p> <p>Mortality</p> <p>Direct hospital costs</p> <p>Self-efficacy - European Self-Care Behavior scale</p> <p>Health-related quality of life –</p>	<p>- improved outcome and reduced costs.</p> <p>-reduce the risk of non-fatal HF events</p> <p>-reduced risk of HF and CV related admissions.</p> <p>Hazard ratio for non-fatal HF events after 6 months of follow-up was 0.35, p<0.001) in favor of telemedicine.</p> <p>In telemedicine group, HF readmission (hazard ratio 0.39 p= 0.007) and CV readmission (hazard ratio 0.43 p= 0.008) were reduced.</p> <p>Mortality was similar in both groups (TM 6.2%, control 12.4% p >0.05)</p>	<p>Study- 6 months</p> <p>Extended benefit of intervention unknown</p> <p>Single center study</p> <p>Two independent teams: usual vs telemedicine</p> <p>Future research needed to evaluate generalizability, impact on mortality, and determine the optimal duration of intervention</p>	1B

		follow- up in 6 months.	<p>hospital primary care integrated HF program for high- risk CHF patients</p> <p>Exclusion criteria: moderate or severe cognitive impairment without a caregiver, lack of social support, institutionalized, life expectancy <1 year, planned end of-life care, cardiac invasive procedure, hemodialysis, death before hospital discharge and inability or unwillingness to give informed consent.</p> <p>Inclusion: stable without signs of fluid overload or low- cardiac output, and receiving oral standard medication for CHF.</p>	Minnesota Living with Health Failure Questionnaire	TM group had a significant net reduction in direct hospital cost per patient per six months of follow-up.		
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<p>Huygens, M. W. J., Vermeulen, J., Swinkels, I. C. S., Friele, R. D., van Schayck, O. C. P., de Witte, L. P. (2016). Expectations and needs of patients with a chronic disease toward self-management and eHealth for self-management purposes.</p>	None	<p>Qualitative</p> <p>Investigate expectations and needs of people with a chronic condition</p> <p>Questionnaire, focus group based on chronic condition</p> <p>5 focus groups moderated by researcher or care professional and research assistant</p>	<p>5 focus groups: N= 30 N= 14 (diabetes) N= 9 (COPD) N= 7 (CV)</p> <p>2 groups with diabetes (n= 7 and n=7) 2 groups with COPD (n= 4 and n= 5) 1 group with CV (n=7)</p> <p>4 primary care centers</p> <p>Inclusion criteria: > 18 years old, diagnosed with COPD, diabetes, or CV disease.</p> <p>Mean age 68 years (50-83)</p> <p>73% male</p> <p>Exclusion criteria: severe psychiatric illness or cognitive impairment, insufficient mastery of Dutch</p>				
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			resulting in not understanding information				
Ishani, A., Christopher, J., Palmer, D., Otterness, S., Clothier, B., Nugent, S., Nelson, D., & Rosenberg, M. E. (2016). Telehealth by an Interprofessional Team in Patients With CKD: A Randomized Controlled Trial.	Chronic Care Model	<p>RCT</p> <p>Investigate whether an interprofessional team using telehealth was a feasible care delivery strategy and whether this strategy could affect health outcomes in patients with CKD.</p> <p>Screen for inclusion, chart review, randomization, intervention group discussed daily, reviewed monthly, and both groups 3-month telephone calls, follow-up 1 year</p>	<p>N= 451 (interprofessional team and telehealth device)</p> <p>N= 150 (usual care)</p> <p>Mean age 75.1±8.1 years</p> <p>98.5% men</p> <p>97.3% white</p> <p>Mean estimated GFR 37± 9 ml/min/1.73m²</p> <p>Minneapolis Veterans Affairs Health System (VAHCS), St. Cloud VAHCS and affiliated clinics.</p> <p>Exclusion: not able to consent, life expectancy less than 1 year, lived in a skilled nursing facility, primary care</p>				

			provider unwilling to allow participation.				
Kim, E., Gellis, Z. D., Bradway, C., & Kenaley, B. (2018). Key determinants to using telehealth technology to serve medically ill and depressed homebound older adults.	None	<p>Identify factors that determine telehealth technology adoption.</p> <p>Mixed study</p> <p>Quantitative: online survey</p> <p>Qualitative: 45-minute telephone interview</p> <p>The participants for the qualitative portion were recruited at the end of the online survey.</p> <p>Questions regarding perceptions of telehealth, the key determinants of telehealth adoption and use, recommendations on telehealth adoption</p>	<p>20 directors from National Association for Homecare & Hospice</p> <p>Mean age 48.5 years</p> <p>80% Caucasian female</p> <p>85% nurses</p> <p>29.4 years of experience in profession</p> <p>18.08 years of experience in home health care</p>				
Liang, H. Y., Lin, L. H., Chang, C. Y., Wu, F. M., & Yu, S. (2021). Effectiveness of a	None	<p>RCT</p> <p>Evaluate the effectiveness of an integrated nurse-led</p>	200 patients from a regional hospital scheduled for				

nurse-led tele-homecare program for patients with multiple chronic illnesses and a high risk for readmission: A randomized controlled trial.		<p>tele-homecare program for patients with multiple chronic illnesses and a high-risk for readmission.</p> <p>Data collected baseline, 3 months after intervention, and 6 months.</p>	<p>home care after discharge N= 100 intervention group (integrated tele-care program) N= 100 control group</p> <p>Mean age 80.67 years Mean 2.72 chronic illnesses Mean LACE score 9.81</p> <p>Women 58%</p> <p>Inclusion: age > 65, high risk for readmission with a length of stay, acuity of admission, comorbidity, and ED visits LACE index of ≥ 7, and willingness to participate.</p> <p>Exclusion: terminal stage cancer, dementia with inability to communicate, or admitted to a</p>				
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			medical institution or nursing home.				
Lyth, J., Lind, L., Persson, H., L., & Wiréhn. (2021). Can a telemonitoring system lead to decreased hospitalization in elderly patients?	None	<p>Investigate the effects of the intervention (4-year telehealth) on healthcare costs and the number of hospitalizations, as well as other care needed in COPD and HF patients.</p> <p>Cohort study- actual outcome date compared to expected outcome data. Expected data based on 5-year history of studied group.</p> <p>Health diary system- patients report daily health status (symptoms, measurements, as needed meds taken) using a digital pen and a Health Diary in paper form. Supervised daily with alerts</p>	<p>36 COPD patients and 58 HF patients with advanced stages of disease.</p> <p>Age ≥ 65 years</p> <p>1 hospital, inpatient or primary care.</p> <p>Frequently hospitalized due to exacerbations. At least 2 inpatient episodes in last 12 months.</p> <p>Exclusion: compromised dementia, cognitive impairment, psychotic illness, does not understand Swedish, severe hearing loss, surgery in last 6 months or next 6</p>				

			<p>months, or life-threatening illness.</p> <p>Supervised by specialized hospital-based home care unit</p> <p>Usual care dcd to primary care when stable.</p>				
McFarland, S., Coufopolous, A., & Lycett, D. (2021). The effect of telehealth versus usual care for home-care patients with long-term conditions: A systematic review, meta-analysis and qualitative synthesis.	None	<p>Identify whether telehealth is a useful intervention for homecare patients with long term conditions.</p> <p>Systematic review, meta- analysis, and qualitative synthesis</p> <p>Keywords and MESH terms used in CINAHL and MEDLINE.</p> <p>Quantitative and qualitative studies included adult home care patients diagnosed with at least one long-term condition comparing telehealth to usual home care.</p>	<p>9 studies included using criteria.</p> <p>2 qualitative</p> <p>Quantitative: 1 single-site cohort study, 2 multi-site cluster trials, 4 randomized trials.</p> <p>2611 home care adults with chronic conditions, sample sizes from 7 to 1201</p> <p>Males 59% to female 41%</p> <p>Age 49-90 years, mean 71 years</p> <p>At least one chronic</p>				

		<p>Meta-analyses and sensitivity conducted using RevMan 5.</p> <p>Qualitative findings thematically synthesized and narratively reported.</p>	<p>condition, most prevalent COPD but also CHF, DM, and mixed comorbidities</p>				
<p>Mudiyanselage, S. B., Stevens, J., Watts, J. J., Toscano, J., Kotowicz, M. A., Steinfort, C. L., Bell, J., Byrnes, J., Bruce, S., Carter, S., Hunter, C., Barrand, C., & Hayles, R. (2019). Personalised telehealth intervention for chronic disease management: A pilot randomized controlled trial.</p>	None	<p>RCT and economic analysis</p> <p>Assess the impact of home-based telehealth monitoring on health outcomes, quality of life and costs over 12 months for patients with diabetes and/or COPD who were identified as being high risk of readmission.</p>	<p>People with DM and/or COPD admitted for any reason. High likelihood of readmission next 12 months.</p> <p>N= 171 n=86 intervention n=85 control group</p> <p>1 hospital Able to submit data by computer or similar device English speaking Live in own home Willing to take biometrics and vital signs Exclusion: high expected mortality over 12</p>				

			months, pregnancy, vision or hearing impairment that affect use of telehealth device, severe cognitive impairment, sub-optimal mental health management, enrollment in hospital admission reduction program, active palliative care, drug or alcohol dependency				
Parker, S., Prince, A., Thomas, L., Song, H., Milosevic, D., & Harris, M. F. (2018). Electronic, mobile and telehealth tools for vulnerable patients with chronic disease: A systematic review and realist synthesis.	REAIM framework, TIDieR framework, PROGRESS framework	Systematic review using Rameses and PRISMA Assess the benefit of using electronic, mobile and telehealth tools for vulnerable patients with chronic disease and explore mechanisms by which these impact patient self-efficacy and self-management.	Studies in community-based primary care involving adults with one or more diagnosed chronic health condition and vulnerability due to demographic, geographic, economic and/or cultural characteristics. 18 trials				

		<p>Searched MEDLINE, all-evidence-based medicine, CINAHL, Embase and Psych INFO for electronic, mobile or telehealth interventions.</p> <p>Quality assessed according to rigor and relevance.</p> <p>Studies were synthesized using a realist matrix.</p>	<p>RCTs and cluster RCTs were predominant</p>				
<p>Rush, K. L., Hatt, L., Janke, R., Burton, L., Ferrier, M., & Tetrault, M. (2018). The efficacy of telehealth delivered educational approaches for patients with chronic diseases: A systematic review.</p>	None	<p>Systematic review</p> <p>Compare the efficacy of virtual education delivery on patient outcomes compared with usual care.</p> <p>Reviewed citations from MEDLINE, CINAHL, EMBASE using search terms telehealth, chronic disease, patient education, and related concepts.</p> <p>PRISMA guidelines</p>	<p>16 studies high to moderate quality studies reviewed.</p> <p>Articles compared virtual education to usual care using designs allowing for assessment of causality.</p>				

Seljelid, B., Varsi, C., Solberg Nes, L., Stenehjem, A.-E., Bollerslev, J., & Børøsund, E. (2020). Content and system development of a digital patient-provider communication tool to support shared decision making in chronic health care: InvolveMe	None	<p>Qualitative</p> <p>To develop a digital tool for patient-provider communication in chronic health care settings and describe the data collection and subsequent content and software development of the InvolveMe tool.</p> <p>Interviews with patients</p> <p>Focus groups with HCPs</p> <p>Tool development workshop with patients and HCPs</p> <p>Data collected from interview and focus group analyzed using thematic analysis</p> <p>Content and software development used data collected and tool development workshop</p>	<p>Convenience sample</p> <p>Renal transplant recipients or non-functioning pituitary adenoma (NFPA) patients</p> <p>interviews N=25 n=14 patient n=11 HCP</p> <p>Tool development workshop n=6 patients n= 6 HCP</p> <p>HCP from nephrology or endocrine outpatient clinic at a large university hospital</p> <p>Patients- renal transplant or non-functioning pituitary adenoma</p>				
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			Patients ≥ 18 years, able to read and speak Norwegian, long period of deterioration negatively impacting QOL				
Soriano, J. B., García-Ríob, F., Vázquez- Espinosa, E., Confortod, J. I., Hernando-Sanze, A., López- Yepese, L., Galera- Martínez, R., Peces-Barbaf, G., Pérez-Warnisherf, M. T., Segrelles- Calvog, G., Zamarrog, C., González-Ponceh, P., Ramosd, M. I., Jafrii, S., & Ancochea, J. (2018). A multicentre, randomized controlled trial of telehealth for the management of COPD.	None	RCT Estimate the effectiveness of a home telehealth strategy I managing patients with severe-very severe COPD when compared to routine practice. 12-month trial Severe COPD patients randomized to telehealth or routine clinical practice. Evaluated at baseline and every 3 months.	N= 229 N= 115 telehealth N= 114 routine care Age 71 ± 8 years 80% men Inclusion: Age 50 -90 years Diagnosis COPD With severe airflow obstruction FEV1 below 50%, treated with chronic home oxygen therapy, suffering 2 or more moderate or severe exacerbations in previous year, currently clinically stable Exclusion: palliative home				

			care, institutionalized, inability of patient or caregiver to understand telehealth procedure, life expectancy less than 1-year, terminal cardiac failure, advanced renal failure, dialysis, cirrhosis, liver transplant program, minimal mental less than 24, considered by doctor to be less likely compliant with treatment, study protocol or follow-up for lung disease.				
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AQoL-8D: Assessment of quality-of-life instrument
BORG: Shortness of breath score
CAT: COPD assessment test
C-EQ5D-5L: Chinese version of EuroQol scale
CESD-10: Centre for Epidemiologic Studies Depression Scale
CKD- chronic kidney disease
CHF: congestive heart failure
CMABS: Chinese version of medication adherence behavior scale
DV: dependent variable

ED: emergency department
EQ-5D: EuroQol-5Dimensions
EQ-VAS: EuroQol-Visual Analogue Scale
FEV1: Forced expiratory volume
FVC: Forced vital capacity
GAD 7: generalized anxiety and depression scale
HCP: health care provider
HeiQ: Health Education Impact questionnaire
HF: heart failure
IV: independent variable
PHQ-9: Patient Health Questionnaire
PROGRESS: Place, Race, Occupation, Gender, religion, Education, Socioeconomic status, social capital
QOL: quality of life
RCT- randomized control trial
REAIM: Reach, Efficacy, Adoption, Implementation, Maintenance
SGRC-C: St. Georges Respiratory Questionnaire for COPD
STAI: Brief-Sate Trait Anxiety Index
TIDieR: Template for intervention description and replication

APPENDIX C**Site Authorization Letter**

April 12, 2021

Human Subjects Review Committee (HSRC)
Salisbury University
1101 Camden Avenue
Salisbury, MD. 21801

Dear HSRC Members,

After reviewing the proposed Quality Improvement Project, "The Use of a Standardized telehealth Visit Tool to Improve Care Outcomes of Veterans in Home-based Primary Care", I have authorized for Chrystal Chan Talley to conduct a Quality Improvement Project at our hospital.

I understand that the purpose of the Quality Improvement Project is to support Home Based Primary Care staff at the [REDACTED] Veterans Administration Health Care System [REDACTED]. The proposal uses a standardized telehealth visit tool to increase access to primary care. Use of the tool is expected to improve access and patient engagement with primary care, reduce the need for non-urgent emergency room visits, and promote better management of home-bound veterans with chronic diseases.

The study will answer the clinical question, "in home based primary care patients, do telehealth visits increase access to primary care and reduce the number of emergency room visits in three months?"

The project is supported by [REDACTED], Chief Nurse of Geriatric Extended Care, *Loch Raven Community Living Center, VAMHCS* and [REDACTED], Medical Director Home Based Primary Care Program Geriatric Extended Care Center.

Recruitment and informed consent of participants is not required as this is a quality improvement project.

I hereby acknowledge the University of Maryland Baltimore (UMB) Institutional Review Board (IRB) as the official IRB of Record for the VAMHCS. The VAMHCS does not have its own internal IRB, instead choosing to utilize that service externally through Memorandum of Understanding and contracting. Under this long-established arrangement, all VAMHCS research protocols requiring IRB review get submitted to the UMB IRB on their CICERO submission platform. UMB IRB is recognized in this way on the VAMHCS Federal Wide Assurance or FWA.

Chrystal Chan Talley has agreed to provide a copy of the project results, in aggregate, to VA System.

(Signature and name redacted)
Director, Nursing Education, Research, Practice and Outcomes

**FULL CONTACT INFORMATION OF SITE
CONTACT**
(name redacted) Nurse Research Coordinator

APPENDIX D

HBPC Telehealth Visit Tool

Veteran consented to this telehealth visit for this encounter. This Veteran is appropriate for a telehealth visit.

Veteran was identified by 2 identifiers: Name, Last 4 & facial recognition.

Location of Veteran during this visit:

Patient telephone number confirmed in case connectivity is lost:

Emergency contact name:

Emergency contact phone number:

Anyone else present during this visit:

Visit Length:

Purpose of this telehealth visit/ Chief Complaint:

History of Present Illness:

Self-management

What does your day usually look like? Activities? Social contacts?

How would you rate your health (0-10)?

What would need to happen to raise this score?

What are your concerns at this time?

Problem List: *for patients with DM, HTN, CHF, obesity, COPD- consider the Annie App or remote patient monitoring*

Medication List:

Allergies:

Social History:

Subjective

General:

HEENT:

Respiratory:

Cardiovascular:

Gastrointestinal:

Genitourinary:

Skin:

Musculoskeletal:

Hematological:

Endocrine:

Psychological:

Neurological:

Fall:

Pain:

Location:

Description:

Pain Score:

Response of pain medication:

Objective

Vitals:

Temperature:

Pulse:

Blood Pressure:

Pulse Oximetry:

Weight:

General:

HEENT:

Vascular/Edema:

Mobility:

Neuro/ psych:

Skin: *incorporate store and forward if needed*

INTERVENTION:

Medication and treatment safety and optimization

Medication reconciliation done.

Current written medication list with name, dose, dosing schedule, and any changes brought to the attention of the patient and/or caregiver. Medication list will be mailed to the home or viewed through MyHealtheVet.

Monitoring mentation and mobility

* Complete reminders and follow up accordingly- Fall risk assessment, depression screen, suicide screen, alcohol audit, education needs assessment, etc.*

Care coordination

*Make appropriate referrals and place consults as needed- dietitian, PT/OT/KT, chaplain, SW, psychologist, community care, etc. *

ASSESSMENT/PLAN: RETURN VISIT:

Appendix E**SWOT Analysis of VA Home-based Primary Care**

STRENGTHS	WEAKNESSES	OPPORTUNITIES	THREATS
<p>Early HER adopter</p> <p>Encourages and utilizes EBP</p> <p>Telehealth department</p> <p>Chronic care model used</p> <p>Interdisciplinary PACT teams</p> <p>Teams trained on telehealth</p>	<p>No telehealth protocol or standardized documentation in HBPC</p> <p>Nurses & providers do not use telehealth regularly</p> <p>Not all patients have technology for telehealth</p>	<p>Expand telehealth to improve access</p> <p>Standardize tool during visit to be holistic</p> <p>High number of ER visits & hospitalizations</p> <p>VA can supply technology to veterans</p>	<p>Technical difficulties</p> <p>Elderly patients may not want to or know how to use technology</p> <p>Population high-risk with multiple co-morbidities</p>

Appendix F

CITI Training Certificates (3 pages)



Completion Date 22-Sep-2020
Expiration Date 22-Sep-2023
Record ID 38558452

This is to certify that:

Chrystal Chan Talley

Has completed the following CITI Program course:

Not valid for renewal of certification through CME.

Responsible Conduct of Research
(Curriculum Group)
Responsible Conduct of Research for Student Researchers
(Course Learner Group)
1 - Basic Course
(Stage)

Under requirements set by:

Salisbury University

CITI
Collaborative Institutional Training Initiative



Completion Date 30-Jan-2019
Expiration Date 29-Jan-2024
Record ID 30371721

This is to certify that:

Chrystal Chan Talley

Has completed the following CITI Program course:

Not valid for renewal of certification through CME.

Social and Behavioral Responsible Conduct of Research
(Curriculum Group)
Social and Behavioral Responsible Conduct of Research
(Course Learner Group)
1 - RCR
(Stage)

Under requirements set by:

Salisbury University

CITI
Collaborative Institutional Training Initiative



Completion Date 01-Feb-2019
Expiration Date 31-Jan-2022
Record ID 30371720

This is to certify that:

Chrystal Chan Talley

Has completed the following CITI Program course:

Not valid for renewal of certification
through CME.

Students conducting no more than minimal risk research

(Curriculum Group)

Student Researchers

(Course Learner Group)

1 - Basic Course

(Stage)

Under requirements set by:

Salisbury University

CITI
Collaborative Institutional Training Initiative



Completion Date 01-Feb-2019
Expiration Date N/A
Record ID 30371723

This is to certify that:

Chrystal Chan Talley

Has completed the following CITI Program course:

Not valid for renewal of certification
through CME.

Information Privacy Security (IPS)

(Curriculum Group)

Students (IPS)

(Course Learner Group)

1 - Basic Course

(Stage)

Under requirements set by:

Salisbury University

CITI
Collaborative Institutional Training Initiative



Completion Date 30-Jan-2019
Expiration Date 29-Jan-2023
Record ID 30371722

This is to certify that:

Chrystal Chan Talley

Has completed the following CITI Program course:

Not valid for renewal of certification
through CME.

CITI Conflicts of Interest
(Curriculum Group)

Conflicts of Interest
(Course Learner Group)

1 - Stage 1
(Stage)

Under requirements set by:

Salisbury University

CITI
Collaborative Institutional Training Initiative

Appendix G

University and Agency IRB Approvals (3 pages)

Salisbury University
Institutional Review Board
Committee on Human Research
Phone: (410) 548-3549
Fax: (410) 677-0052
Email: humanresearch@salisbury.edu

IRB Research Protocol Approval Notification

Date: 5/14/21

To: A. Barnes

C. Chan Talley

RE: Protocol #38

Type of Submission: Exempt

Type of IRB Review: Exempt

Protocol is scheduled to begin 8/2021 end 5/2022

Approval for this project is valid from 5/14/2021 to 5/30/2022.

This letter serves to notify Dr. Annette Barnes and Chrystal Chan Talley that the Salisbury University (SU) Institutional Review Board (IRB) approved the above referenced protocol entitled, The Use of Telehealth to Improve Care Outcomes of Home-base Veterans in Primary Care on May 14, 2021.

Pursuant to Federal regulations 21 CFR 56.109, the IRB has determined that this protocol qualifies for Exempt review.

Federal regulation 45 CFR 46.103 (b)(4)(iii) requires Primary Investigators (PI), except when a subject is in immediate danger, to assure any change to an approved protocol is not initiated prior to IRB review and approval. Additionally, the PI must also inform the IRB of unanticipated problems involving risks to participants.

Your research is scheduled to begin 8/2021 and end 5/2022. It is the PI's responsibility to submit continuing review reports in a timely manner (at least 3 weeks prior to scheduled end date on the protocol approval).

The SU IRB is organized and operated according to guidelines of the United States Office for Human Research Protections and the United States Code of Federal Regulations and under Federal Wide Assurance No. FWA00020237.

If you have any questions about this review or questions, concerns, and/or suggestions regarding this process, please do not hesitate to contact the Office of Graduate Studies and Research at 410-548-3549 or humanresearch@salisbury.edu.

Institutional Review Board

NOT HUMAN RESEARCH DETERMINATION

OF NOTE: The Principal Investigator should review the University (redacted) criteria for performing research during the current COVID-19 pandemic emergency. Understand that IRB approval of this research does not suggest that performance of this research under current guidelines is allowed. Failure to comply with the (university redacted) President's directives would be considered non-compliance. The (university redacted) Research directives can be found at <https://www.umaryland.edu/coronavirus/>. If you need clarification or guidance please call the Human Research Protections Office at (phone # redacted).

Date: August 10, 2021

To: (name redacted)

RE: HP-00097297

Name: The Use of Telehealth to Improve Care Outcomes of Home-based Veterans in Primary Care

This letter is to acknowledge that the (university redacted) IRB reviewed the information provided and has determined that the submission does not require IRB review. This determination has been made with the understanding that the proposed project does not involve a systematic investigation designed to develop or contribute to generalizable knowledge **OR** a human participant (see definitions below).

This determination applies only to the activities described in the IRB submission and does not apply should any changes be made. If changes are made and there are questions about whether these activities are human subject research in which the organization is engaged, please submit a new request to the IRB for a determination.

Definitions – Human Research: Any activity that either:

- Is “Research” as defined by DHHS and involves “Human Subjects” as defined by DHHS (“DHHS Human Research”); or
- Is “Research” as defined by FDA and involves “Human Subjects” as defined by FDA (“FDA Human Research”).

Research as Defined by DHHS: A systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.

Research as Defined by FDA: Any experiment that involves a test article and one or more human subjects, and that meets any one of the following:

- Must meet the requirements for prior submission to the Food and Drug Administration under section 505(i) of the Federal Food, Drug, and Cosmetic Act meaning any use of a drug other than the use of an approved drug in the course of medical practice;
- Must meet the requirements for prior submission to the Food and Drug Administration under section 520(g) of the Federal Food, Drug, and Cosmetic Act meaning any activity that evaluates the safety or effectiveness of a device; OR
- Any activity the results of which are intended to be later submitted to, or held for inspection by, the Food and Drug Administration as part of an application for a research or marketing permit.

Human Subject as Defined by DHHS: A living individual about whom an investigator (whether professional or student) conducting research obtains (1) data through Intervention or Interaction with the individual, or (2) information that is both Private Information and Identifiable Information. For the purpose of this definition:

- Intervention means physical procedures by which data are gathered (for example, venipuncture) and manipulations of the subject or the subject’s environment that are performed for research purposes.

- Interaction means communication or interpersonal contact between investigator and subject.
- Private Information means information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (for example, a medical record).
- Identifiable Information means information that is individually identifiable (i.e., the identity of the subject is or may readily be ascertained by the investigator or associated with the information).

Human Subject as Defined by FDA: An individual who is or becomes a subject in research, either as a recipient of the test article or as a control. A subject may be either a healthy human or a patient. A human subject includes an individual on whose specimen (identified or unidentified) a medical device is used.

Please keep a copy of this letter for future reference. If you have any questions, please do not hesitate to contact the Human Research Protections Office (HRPO) at (phone number redacted) or (email redacted).

Appendix H

Timeline for DNP Project

- **Fall 2020**-Topic exploration and identification, identified organization and initiated collaboration, and identified DNP project committee members.
- **Winter 2021**-Assessed organization processes and practices related to telehealth.
- **Spring 2021**-Proposal development (Feb- May), IRB application for SU and Agency (April- August), proposal defense (May).
- **Fall 2021/ Winter 2022**-Implementation of project (November- January).
- **Spring 2022**- Evaluated project (January/ February), submitted final project to committee (March), disseminated findings, and recommended changes (April/ May).