DEVELOPMENT AND EVALUATION OF A NURSE PRACTITIONER-DIRECTED VITAMIN D SCREENING AND TREATMENT PROGRAM IN A RURAL PRIMARY CARE PRACTICE

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Title: Development and Evaluation of a Nurse Practitioner-Directed Vitamin D Screening and Treatment Program in a Rural Primary Care Practice

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This DNP quality improvement (QI) project added an EMR prompt for serum 25-hydroxyvitamin D to an existing fasting lab order set to screen at-risk elderly patients over 65 for vitamin D deficiency annually during a Medicare annual wellness visit (MAWV). The implementation of the project occurred over 90 days, and these data were compared to the 90 days before the implementation. There were 125 MCAW visits pre-implementation and 149 MCAW visits post-implementation. Before the project implementation, 10% of eligible patients were offered screening for vitamin D deficiency; this number increased to 100% after deployment of the EMR prompt. Eight patients were screened before the project implementation as opposed to 112 patients post-implementation. Compliance rates for completing the lab work were similar pre- and post-implementation at 75%. Before the implementation, six patients lacked vitamin D and needed supplementation; this number increased to 47 patients requiring supplementation post-intervention. The project results suggest that vitamin D screening at MCAW visits provides an opportunity to address a need for this preventive service in a vulnerable population with regards to vitamin D deficiency and the mitigation of chronic disease states associated with vitamin D deficiency.

Keywords: Vitamin D Deficiency, Vitamin D Supplementation, Medicare Annual Wellness Examination

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ABBREVIATIONS

DNP – Doctor of Nursing Practice

MAVW - Medicare Annual Wellness Visit

PCP - Primary Care Provider

PICOT – Population, Intervention, Comparison, Outcome, and Time

QI - Quality Improvement

CHAPTER ONE

INTRODUCTION

Description of the Problem

Vitamin D is a fat-soluble, steroid-based vitamin synthesized by the skin when an individual is exposed to sunlight (Charoenngam, 2019). The vitamin is found in fortified foods, including dark, oily fishes (Charoenngam, 2019). Vitamin D deficiency is defined as a serum 25-hydroxyvitamin D level less than 30 ng/mL and is associated with preventable adverse health sequelae (Holick & Chen, 2008). Vitamin D deficiency is the most common micronutrient deficiency globally (Holick, 2007; O'Shea et al., 2020), and approximately one billion individuals worldwide are vitamin D deficient (Charoenngam & Holick, 2020).

Deficient vitamin D levels are associated with chronic illnesses involving the musculoskeletal, respiratory, cardiovascular, and immune systems. These chronic illnesses affect people over the age of 65 at a disproportionate rate (Charoenngam & Holick, 2020). Approximately 41.6% of American adults are vitamin D deficient (Forrest & Stuhldreher, p.48, 2011), and in 2019, 61% of elderly patients in the U.S. were vitamin D deficient (Sizar et al., p.1, 2021). However, vitamin D deficiency is preventable with oral supplementation, and, at present, no universal recommendations exist for systematic screening of serum vitamin D in geriatric populations.

Vitamin D is produced in the skin when exposed to adequate sunlight. Unfortunately, individuals living in temperate climates have limited sunlight exposure during cold-weather months. Therefore, large groups of people may be vitamin D deficient during months when viral illnesses are most common (Greiller & Martineau, 2015; Holick, 2007). Vitamin D deficiency also predisposes vulnerable populations to multiple chronic disease states. Primary care

providers (PCPs) can decrease the risk and burden of disease associated with vitamin D deficiency by screening and providing appropriate supplementation. Utilizing an electronic medical record (EMR) prompt during annual geriatric wellness visits can streamline the screening process for PCPs.

There are no specific parameters in place for routine serum 25 hydroxyvitamin D testing at Berwick Medical Professionals. In addition, commercial and government-funded insurance companies often deny laboratory billing claims for vitamin screening. As a result, bills for vitamin screening may be passed to the patient resulting in a hesitancy for PCPs to order routine vitamin screening tests, including 25-hydroxyvitamin D.

At a Medicare Annual Wellness Visit (MAWV), the cost of serum vitamin D screening is covered at 80%, with patients responsible for approximately $10 via copayment (U.S. Centers for Medicare and Medicaid Services [CMS], 2021). Recently, expanded coverage for at-risk diagnoses has resulted in full payment for serum 25-hydroxyvitamin D annually (CMS, 2020; Scott & Gronowski, 2015). Current at-risk diagnoses included in this coverage include BMI greater than 30, at risk for falls, and malabsorptive conditions (CMS, 2020).

Rationale

The purpose of this Doctor of Nursing Practice (DNP) project was to implement a vitamin D screening and treatment program utilizing an EMR prompt to evaluate and treat geriatric patients for vitamin D deficiency. All patients presenting for a MAWV were screened, though only deficient patients received supplementation (Holick, 2007; Muschitz et al., 2015). Prior research suggested that people over 65 are more vulnerable to chronic diseases associated with vitamin D deficiency (Holick, 2007; Muschitz et al., 2015). Therefore, a logical approach to addressing vitamin D deficiency is implementing a systematic vitamin D screening initiative

during a MAWV. In addition, an EMR order prompt for a serum 25-hydroxyvitamin D level added to an annual fasting lab order set can streamline vitamin D screening and subsequent treatment, as clinically indicated.

Theoretical Framework

Dorothea Orem's Self-Care Nursing Theory was selected to guide this DNP project. This grand nursing theory, also known as the Orem Model of Nursing, suggests that patients want to care for themselves (Petiprin, 2020). Furthermore, patients recover more quickly and thoroughly if empowered to perform their self-care as much as possible (Petiprin, 2020). Self-care requisites, according to Orem, are threefold: universal, developmental, and health deviation (Petiprin, 2020). Universal requisites include essential needs like food, water, rest, and safety (Petiprin, 2020). Developmental requisites include maturational factors that help patients progress toward maturity and situational factors that protect them against developmental harm(Petiprin, 2020). The final requisite is related to health deviation, which arises from a patient's physical or mental condition (Petiprin, 2020). If any of these requisites are not met, a self-care deficit occurs.

Nurses and nurse practitioners are tasked with teaching patients to prevent or correct existing self-care deficits. This DNP project can help patients avoid chronic illnesses associated with vitamin D deficiency. In addition, self-care and wellness teaching occurred during geriatric annual wellness exams to reinforce the importance of vitamin D adequacy in the primary prevention of chronic illness.

Specific Aims

This DNP project addressed the following PICOT question: among Medicare recipients in rural primary care practice, how does the addition of an electronic medical record (EMR) prompt for vitamin D screening, when compared to current practice without an EMR prompt,

influence vitamin D deficiency diagnosis and subsequent treatment over 12 weeks? An EMR order prompt was implemented during MAWVs to screen for vitamin D deficiency. In addition, incorporating a serum 25-hydroxyvitamin D order into the existing Medicare annual wellness fasting lab order set enabled PCPs to address a patient's vitamin D status.

Primary prevention of chronic disease states through risk factor modification is paramount in primary care practices, particularly in rural settings. Vitamin D deficiency presents a unique opportunity for PCPs to be agents of change and patient advocates. By implementing this DNP project, a framework for a systematic approach to the screening of vitamin D in a vulnerable population will be developed, implemented, evaluated, and disseminated.

Definition of terms

Annual Wellness Visit - a primary care visit occurring yearly where the focus is on preventative care and age-related screenings for several chronic disease states (U.S. Centers for Medicare and Medicaid Services [CMS], 2021).

Supplementation - the addition of an extra element or amount to something (Merriam-Webster, 2021).

Vitamin D - also known as cholecalciferol or calciferol - a fat-soluble, steroid-based vitamin produced in the skin when adequate exposure to sunlight occurs regularly. The vitamin plays a vital role in several essential metabolic functions (Holick, 2007).

Vitamin D deficiency - serum levels of 25-hydroxyvitamin D less than 20 nanograms/mL (Holick, 2007).

Vitamin D insufficiency - serum levels of 25-hydroxyvitamin D from 21-29 nanograms/mL (Holick, 2007).

Vitamin D toxicity - a dangerous state of excess vitamin D (80+ nanograms/mL), resulting in liver and neurologic damage and eventually death (Holick, 2007).

Vitamin D sufficiency - serum levels of 25-hydroxyvitamin D that are 30-60 nanograms/mL (Holick, 2007).

Chapter Summary

Chapter one introduced the problem of vitamin D deficiency and the importance of vitamin deficiency screening, particularly among the geriatric population. The problem description was presented, including the rationale and specific aims for the project. Orem's self-care deficit nursing theory was identified as a framework to guide this evidence-based DNP project, and essential terms were defined. Chapter two will provide a detailed analysis and synthesis of the available knowledge.

CHAPTER TWO

LITERATURE REVIEW

Search Strategy

A review of literature related to vitamin D preceded this project. Databases queried included Healthsource: Nursing and Academic, EBSCO, CINAHL Complete, MEDLINE, GALE OneFile: Health and Medicine, Sage Journal, ScienceDirect, and Springerlink. Key search terms included vitamin D and viral illness, vitamin D and immunity, and vitamin D and chronic disease. Search limiter parameters included: scholarly articles, peer-reviewed, full-text online, published within the last five years.

The search yielded 516 articles, and 399 articles were screened on title and abstract for appropriateness. Of the screened articles, 41 full-text studies were analyzed after being deemed directly related to the stated PICOT question. Studies were excluded if they were unrelated to the project or target population. In addition, four pieces older than the five years were included as either sentinel articles or particularly relevant to the project topic.

EBP Model

The Johns Hopkins Nursing EBP Model was utilized to guide the project from inception to dissemination. This model employs a problem-solving approach to clinical decision-making. The Johns Hopkins Nursing EBP uses a three-step process known as PET: practice question, evidence, and translation (Johns Hopkins Nursing, 2017). The model facilitates applying the latest research findings and best practices quickly and effectively to clinical practice. Specific to this project, vitamin D screening and clinically appropriate supplementation in vulnerable

geriatric adults led to an extensive literature review. The Johns Hopkins EBP model facilitated the synthesis of supporting a clinical practice change for vitamin D screening.

Available Knowledge

Several themes emerged from the literature review and appraisal: (1) vitamin D deficiency is associated with increased fracture risk, low calcium absorption, and decreased bone and muscle health (Wang, et al., 2017). (2) Vitamin D levels correlate inversely with the incidence of metastatic and fatal cancer (Chandler, et al., 2020). (3) Vitamin D levels affect the risk for certain metabolic disorders such as hypertension, hyperlipidemia, type II diabetes (Wenclewska et al., 2019). (4) Vitamin D adequacy minimizes cardiovascular risk (Holick, 2007). (5) Adequate vitamin D is associated with optimal immune function with deficiency increasing risks related to upper respiratory infections, community-acquired pneumonia, and COVID19 severity (including cytokine storm) (Bergman et al., 2013; Fantacone et al., 2020; Martineau et al., 2017).

Vitamin D and Musculoskeletal Health

Vitamin D deficiency is associated with increased fracture risk, low calcium absorption, decreased bone health, and diminished muscle health (Holick, 2007). Vitamin D, or calciferol, is a fat-soluble, steroid-based vitamin that can be supplemented orally (Holick, 2007). Venous blood samples measure 25-hydroxyvitamin D levels. Vitamin D is a necessary nutrient in dietary calcium absorption and metabolism (Holick, 2007), with deficiency resulting in musculoskeletal problems in the elderly, including brittle joints, muscle weakness, and an increased risk of falling (Wang et al., 2017). This elevated risk of falling relates to a heightened incidence of fractures. Due to vitamin D's role in musculoskeletal health, PCPs should screen for vitamin D deficiency

in at-risk elderly groups (Charoenngam et al., 2019). In addition, vitamin D and calcium supplementation can preserve bone density later into the lifespan (Zhou et al., 2020).

Vitamin D is synthesized in the skin when individuals have adequate sunlight exposure. Experts estimate that 20 minutes of sun exposure is enough for endogenous production of sufficient vitamin D (Holick, 2007). Aljefree et al. (2017) reported that individuals who generally understand vitamin D's role are unaware of vitamin D sources. Participants in this qualitative study further described their knowledge of vitamin D dietary sources, including fortified foods (Aljefree et al., 2017).

Moreover, vitamin D screening and supplementation guidelines quantify deficient levels (<20 ng/mL), insufficient levels (20-30 ng/mL), and adequacy (>30 ng/mL) (Bordelon et al., 2009). Unfortunately, though, no universal recommendation exists for selecting the optimal dosage of D3 for supplementation if a patient is vitamin D insufficient or deficient. Multiple factors can determine vitamin D dosing, including age, race, gender, and body mass index (BMI). PCPs should expect genetic variations within the target population regarding vitamin D absorption and metabolism and address variations through systematic serum testing and adjustment of D3 dosing (Charoenngam & Holick, 2020).

Two of the most significant factors for vitamin D deficiency are age and BMI. Nearly half of the elderly patients screened for vitamin D deficiency worldwide are vitamin D deficient (Muschitz et al., 2015). The high prevalence of vitamin D deficiency suggests a necessity for systematic vitamin D screening in the elderly (Muschitz et al., 2015). Obese adults are also considered at-risk for vitamin D deficiency. Since many geriatric adults in the United States have a BMI above 30, their need for vitamin D screening and supplementation is twofold (Scott & Gronowski, 2015).

Studies addressing vitamin D supplementation report "u-shaped" outcomes frequently (Grant et al., 2016). "U-shaped" outcomes suggest that supplementation can achieve therapeutic levels, yet excessive supplementation (serum levels 80+ ng/mL) is associated with the deleterious risks of vitamin D toxicity (Grant et al., 2016). One randomized controlled trial of 30 adult U.S. patients identified a supplementation threshold of 10,000 international units (IU) of D3 daily results in optimal vitamin D levels regardless of genetic differences in study participants ($p = 0.05$) (Shirvani et al., 2019).

Vitamin D and Cardiovascular Risk

Vitamin D levels are inversely related to cardiovascular risk (Holick, 2007). Patients who are vitamin D deficient and reside in seasonal climates often require supplementation to maintain therapeutic serum D levels (Holick & Chen, 2008). Adequate vitamin D levels can mitigate chronic conditions that predispose elderly patients to premature cardiovascular disease (Wang et al., 2017). Vitamin D deficient patients are often significantly more hypertensive, according to a recent meta-analysis of 12 randomized controlled trials (Farapti et al., 2020). Moreover, in a retrospective study of 92 vitamin D deficient adult patients in Poland, vitamin D supplemented patients had more favorable lipid profiles, High-Density Lipoprotein was on average 19 mg/dL higher, and lower blood sugar levels, fasting blood sugars were on average 17 ng/mL lower (Wenclewska et al., 2019). Therefore, including vitamin D for its cardioprotective properties make supplementation a sound nonpharmacologic treatment option to prevent common chronic disease states like atherosclerotic cardiovascular disease. Cardiovascular risk modification remains a staple of primary care, and evidence supports a correlation between vitamin D and blood pressure, lipid levels, and blood sugar levels. The correlation between vitamin D and

cardiovascular health supports the systematic screening and treatment of vitamin D deficiency in a vulnerable elderly primary care population.

Vitamin D and Cancer

A less convincing relationship exists between vitamin D levels and certain types of cancers. One large, retrospective study demonstrated the absence of a correlation between vitamin D supplementation and invasive cancer risk (Manson, et al., 2019). The Vitamin D and Omega-3 Trial (VITAL) examined the effects of vitamin D supplementation on cancer risk in 25,871 adult participants over 5.3 years (Manson, et al., 2019). During this period, 1,617 patients were diagnosed with cancer, of which 793 took vitamin D supplements, and 824 did not (Manson, et al., 2019). Researchers, therefore, determined that vitamin D supplementation made no difference in new-onset invasive cancer diagnoses (Manson, et al., 2019). However, another analysis of the same VITAL study stratified the data according to BMI and found a significant decrease in metastatic and fatal cancers in patients with normal BMI (hazard ratio = 0.83; 95% confidence interval = 0.69-0.99; $p = 0.04$) (Chandler et al., 2020). No such relationship was observed in overweight or obese patients in the Chandler et al. (2020) analysis.

More research is needed to replicate the VITAL study to establish the presence or absence of a protective role for vitamin D relating to cancer risk and incidence. Further statistical analyses of the VITAL trial and future studies should consider confounding factors that may cloud the benefits of vitamin D and antineoplastic processes. BMI, age, race, gender, comorbidities, and geographical location influence vitamin D levels. The VITAL study did not consider these factors, only vitamin D supplementation, and cancer risk.

Vitamin D and Respiratory Illness

The most considerable focus of the available literature underscores vitamin D status concerning respiratory illnesses. Recent studies have been in response to the current global pandemic of COVID-19 and Sars-CoV2. These studies support vitamin D's importance in preventing and treating various respiratory illnesses, including viral URIs, community-acquired pneumonia, and severe COVID-19 infections (Bergman et al., 2013; Fantacone et al., 2020; Martineau et al., 2017; Shimizu, et al., 2018).

Vitamin D and Upper Respiratory Illness (URI)

Experts in nutritional science have long postulated an association between vitamin D and respiratory health (Holick, 2007). Several studies have noted lower rates of upper respiratory tract infections (URIs) in patients supplemented daily with vitamin D (Bergman et al., 2013; Fantacone et al., 2020; Martineau et al., 2017). According to a two-cohort study of 396 adults in the U.S., patients with vitamin D levels of 38 ng/mL and higher had a two-fold risk reduction in URI incidence, particularly in temperate climates during cold weather months (Grant et al., 2020; Sabetta et al., 2010). Daily supplementation of 1,000 IU of D3 also decreased the severity and duration of URI symptoms in 428 outpatient adults in Japan ($p = 0.061$) (Shimizu et al., 2018). The results were not statistically significant, though the clinical implications suggest a correlation between vitamin D adequacy and decreased severity of viral respiratory illnesses.

In one retrospective observational study, there was an inverse relationship between vitamin D and URI risk. A seven percent decrease in URI risk for every ten nanograms incremental increase of serum vitamin D (Gruber-Bzura et al., 2020). Furthermore, laboratory studies investigating the immunomodulatory effect of vitamin D on respiratory epithelial cells infected with respiratory viruses showed vitamin D-modulated pathways inhibiting

pro-inflammatory interferons, chemokines, and cytokines (Greiller & Martineau, 2015). These in vivo studies support vitamin D's role as a potent respiratory inflammation suppressor.

Vitamin D and Pneumonia

Vitamin D deficiency increases the risk of community-acquired pneumonia (CAP) (Zhou et al., 2019). In a large meta-analysis of eight observational studies, vitamin D levels of pneumonia patients were, on average, nearly six ng/mL lower across almost 21,000 patients (Zhou et al., 2019). Another article reviewed proposed that vitamin D inhibits viral replication and dampens hyper-inflammation in the lungs, protecting patients from CAP development (Mohan et al., 2020). This same article recommended that maintaining the serum vitamin D level above the 20 ng/mL threshold was critically important to avoid severe respiratory symptoms associated with CAP (Mohan et al., 2020).

Vitamin D and COVID-19

Speculation about vitamin D and COVID-19 has led epidemiologists worldwide to explore the merit of vitamin D supplementation to prevent and mitigate the effects of SarS-CoV2 during the current global pandemic. An observed correlation between vitamin D levels and the incidence and severity of COVID19 symptoms has been identified (Galmes et al., 2020; Kaufman et al., 2020; Liu et al., 2020; O'Shea et al., 2020). Specifically, vitamin D sufficiency is associated with a lower incidence of respiratory cytokine storm (Brockman-Schneider et al., 2014; Daneshkhah et al., 2020; Hoe et al., 2016). This hyper-inflammatory respiratory state is often associated with severe COVID-19 cases and poor clinical outcomes (Brockman-Schneider et al., 2014; Daneshkhah et al., 2020; Hoe et al., 2016). For example, in one case-control study of 413 hospitalized adults in Spain, 82% of hospitalized patients had vitamin D levels less than 20 ng/mL (Hernandez et al., 2020). In another recent case series study of 235 hospitalized

COVID-19 patients in Asia, patients with serum vitamin D levels over 30 ng/mL had an 11% lower mortality rate than vitamin D-deficient patients (Maghbooli et al., 2020).

Several ongoing trials regarding vitamin D status and COVID-19 severity are being followed closely, with valuable data on vitamin D's protective role in respiratory-immune function at the forefront (Hamada et al., 2020; Xu et al., 2020). Several authors have identified that an optimal target serum 25-hydroxyvitamin D level could be 30-40 ng/mL to protect patients from COVID-19 and decrease the severity of COVID-19 symptoms in infected patients (Castillo et al., 2020; Hribar et al., 2020). In addition, a recent retrospective case series of 185 hospitalized COVID-19 patients in Germany suggested that vitamin D adequacy decreased the need for mechanical ventilation and the mortality rate from COVID19 at a statistically significant level ($HR = 6.12$; 95% CI = 2.79-13.42; $p < 0.001$) (Radulovic et al., 2020).

A review of relevant current literature strongly suggests that vitamin D plays an essential role in preventing and mitigating respiratory illnesses, including COVID-19 (Castillo, et al., 2020; Hamada et al., 2020; Radulovic, et al., 2020; Xu et al., 2020). Vitamin D deficiency is associated with increased severity and duration of symptoms in respiratory diseases (Grant et al., 2020; Sabetta et al., 2010). Recent studies have highlighted the importance of vitamin D as an essential micronutrient in the fight against the COVID-19 pandemic (Castillo, et al., 2020; Hamada et al., 2020; Radulovic, et al., 2020; Xu et al., 2020). Biologic processes occur within a complex framework of intertwined chemical reactions creating equilibrium within the human body. Nutritional science, or applied biochemistry, is a science in its infancy, and highlighting the role of one micronutrient may prove short-sighted. But, compelling evidence suggests that vitamin D screening and supplementation may help alleviate suffering and save lives during the

current global health crisis (Castillo, et al., 2020; Hamada et al., 2020; Radulovic, et al., 2020; Xu et al., 2020).

Medicare Wellness Visit as a Platform for Preventive Care

MAWVs are a platform for PCPs to provide evidence-based preventive care to mitigate chronic disease risk in patients over 65 (Ganguli et al., 2017). MAWVs provide an opportunity for PCPs to perform a thorough physical exam and a series of health maintenance screenings. Such screenings include prostate cancer, breast and cervical cancer, osteoporosis, colorectal cancer, diabetes, depression, hepatitis, tobacco cessation, age-related immunizations, obesity, and heart disease, among others (CMS, 2021; Simpson & Kovich, 2019). Moreover, this annual visit is often the only opportunity for PCPs to solely focus on health promotion and preventive services rather than treating existing disease states. However, vitamin D screening is not a required component of Medicare annual wellness visits. In addition, vitamin D screening efforts during Medicare annual wellness examinations have not previously been reported in the literature.

Similar evidence-based practice projects have been reported. For example, one cohort study of 60,000 adult patients in the U.S. reported increased hepatitis C screenings by 25% when an EMR prompt was utilized *(*$p<0.01$) (MacLean et al., 2017). Another cohort study of over 54,000 adult patients in California reported a 31.5% increase in abdominal aortic aneurysm screenings in a year after the addition of EMR prompt (Hye et al., 2014). In addition, comparable successes have been realized in primary care with EMR prompts for osteoporosis screening resulting in a 13% improvement in screening rates ($p=0.02$) after adding an EMR prompt (Loo et al., 2011; Williams et al., 2017). Moreover, an EMR prompt utilized to remind PCPs to offer

influenza vaccinations led to an increase in influenza immunized patients by 37.3% (p<0.001) (Patel et al., 2017).

Chapter Summary

Chapter two presented a review of relevant recent literature related to vitamin D and chronic disease states. Vitamin D is an essential factor in musculoskeletal health, cardiovascular health, and a preventative role in specific neoplastic processes. In addition, the importance of vitamin D adequacy in protecting respiratory illnesses and vitamin D's role in preventing and mitigating COVID-19 symptoms was presented. Finally, chapter three will describe the context, measures, and ethical considerations for this DNP project.

CHAPTER THREE

METHODOLOGY

Context

The DNP project was implemented during a three-month period from March 15, 2021, to June 15, 2021, in a primary care clinic located in rural, northeastern Pennsylvania. The clinic is part of an unaffiliated, privately-owned community hospital in Columbia County named Berwick Hospital Center. There are three family practice clinics within the Berwick Hospital Center system with two physicians and two nurse practitioners. Office managers for each clinic report to a Director of Provider Services who reports to the Chief Executive Officer (CEO) and the system owner. The system CEO provided organizational support for the DNP project early in the project development process. The organization's culture supports providing highly personalized, high-quality, cost-effective care in a progressive, caring, evidence-based, outcome-driven environment.

Early in the project planning process, perceived barriers and facilitators were considered. Facilitators included nurses and Nurse Practitioners who supported the project. Moreover, the system CEO embraced the evidence-based practice change supporting the autonomy of Nurse Practitioners. The clinical mentorship of Dr. Kevin Carey, the clinical project mentor, and the faculty mentorship of Dr. Aaron Sebach further aided in facilitating this practice change. In terms of barriers, the most significant obstacle was resistance to change within the EMR from providers not directly involved in the intervention. Some providers in the group had no interest in the practice change because they saw no apparent benefit in addressing vitamin D status regardless of the evidence presented.

Key project stakeholders were identified. The health care team members, including physicians and Nurse Practitioners, health system leadership, ancillary, laboratory, informational technology, and support staff were key stakeholders for this project. Each stakeholder was engaged and informed about the clinical practice change through planned informational meetings to outline expectations. Other key stakeholders were the patients who verbally consented to the screening during the MAWV.

This project improved an existing process for vitamin D screening in an at-risk elderly population by streamlining serum hydroxyvitamin D level monitoring in a current MAWV fasting surveillance laboratory order set. Benefits to the organization may be realized by minimizing chronic disease states associated with vitamin D deficiency. The project further benefited patients by emphasizing a preventative health approach rather than a reactive approach to worsening chronic disease states. Through the systematic screening of at-risk elderly patients for vitamin D deficiency, the economic burden associated with the care of preventable chronic disease states involving low vitamin D can be minimized.

Intervention

The project intervention included adding an EMR prompt to screen serum 25 hydroxy-vitamin D in a pre-existing fasting lab order set given to patients during MAWVs. The existing order set consisted of a complete blood count, basic metabolic profile, thyroid panel, urinalysis, lipid panel, liver function tests, and prostate-specific antigen (for male patients only). The MAWV was the most predictably consistent platform to implement systematic screening of vitamin D status in an at-risk elderly population. Therefore, a new order set termed "MCAWD" was created. Providers could type the abbreviation MCAWD into the EMR, Athenaclinicals, for the order set to populate in the MAWV EMR template. The vitamin D screening order, along with the other orders, was then sent to the patient's preferred laboratory. Diagnosis linked to the vitamin D order included: Z68.3X-BMI greater than 30 (if applicable), Z91.81-at-risk for falls (if applicable), M62.9- musculoskeletal disorder (if appropriate), and K90.9- malabsorptive syndrome (if applicable). Only patients in one of the four categories, justifying the screening from an insurance standpoint, were screened. Tying the lab test to a covered diagnosis was also a consideration for low-income patients who may not have been able to afford the cost of the lab test.

The addition of an EMR prompt for 25 hydroxyvitamin D to an existing annual fasting lab order set was chosen to simplify the screening process. Additionally, the MAWV, recommended annually for Medicare patients, provided a platform to address health maintenance standards systematically. Ideally, this initiative should screen all at-risk elderly patients who are compliant. Using the 25 hydroxyvitamin D test was felt to be the most accurate and cost-effective way to screen.

In terms of project design, inclusion and exclusion criteria were purposefully selected. Inclusion criteria included Medicare insurance, aged 65 and older, and having a MAWV schedule during the 90-day implementation period. Exclusion criteria were refusal of care and Medicare patients not deemed at-risk or aged below 65.

The role of the DNP project leader was to assess at-risk patients during the implementation period, order appropriate screening tests, evaluate the results, recommend supplementation where applicable, and educate patients about the necessity of vitamin D sufficiency as a precursor to the minimization of chronic disease states. Thus, from inception to conclusion, the project leader was the keystone of the project and a driver of change in the primary care practice.

Measures

All patients aged 65 and older who consented to the screening and had a MAWV during the 90-day implementation period were included in the intervention. Descriptive statistics were utilized to examine the participants' demographics, including age, gender, race, BMI, vitamin D level, and compliance with screening. In addition, data were compared pre- and post-implementation of the EMR order prompt for the serum 25 hydroxyvitamin D blood test. Before implementing the EMR order prompt, no modalities for systematic screening of vitamin D deficiency existed in the current practice. Therefore, data points were collected for 90 days before the intervention and 90 days during the intervention. These data may serve as the basis for a supplementation schedule and an ongoing QI initiative to support project efficacy and sustainability. Using the selected parameters, the providers systematically identify high-risk individuals and correct vitamin D deficiency.

Using published and generally accepted values for vitamin D deficiency (<20 mg/dL), vitamin D insufficiency (21-29 mg.dL), and vitamin D sufficiency (30+ mg/dL), recommendations for supplementation schedule were formulated. If a patient was deemed vitamin D deficient, they were supplemented with 50,000 IU of vitamin D3 weekly. If the patient was considered vitamin D insufficient, they were supplemented with 5,000 IU of vitamin D3 daily. If the patient's vitamin D level was sufficient, no supplementation was recommended.

Budget

Budgetary concerns for the project were considered. The most considerable cost associated with this project was the time of the Nurse Practitioner and ancillary staff. No additional costs were realized in the EMR system, and the cost to the patient was minimized utilizing diagnoses for which Medicare covered serum 25-hydroxyvitamin D screening. The healthcare-related savings produced by early detection of vitamin D deficiency and avoidance of chronic health conditions associated with vitamin D deficiency should theoretically justify the project's financial existence in terms of sustainability. A detailed project budget is included in Appendix A.

Ethical Considerations

Human subjects were protected during the project. All participants were English speaking, over the age of 18, and able to consent to participate in the practice change. In addition, all patients deemed vitamin D deficient or insufficient were offered supplementation uniformly. Thus, patients could have a MAWV completed and decline serum vitamin D monitoring without repercussion.

Ethical considerations directly related to the project included de-identifying patient data and storing the data in a password-protected computer accessible only by the project leader.

Steps were taken to protect patient privacy, including transparently informing patients of the project and gaining verbal consent to screen for vitamin D deficiency. The project also encompassed the concept of beneficence, which is the moral obligation to act in the patient's best interest (Chism, 2019). The PCP's actions represented foresight into chronic disease prevention through screening and treatment of vitamin D deficiency. A similar concept, nonmaleficence, or the obligation of the Nurse to do no harm to the patient, can be observed throughout this DNP project (Chism, 2019). An environment of mutual respect, where the patient trusts the clinical judgment of the PCP and feels safe under their care, is a necessary precursor to the proposed practice change. Respecting patient wishes if service was refused follows the ethical principle of respect for autonomy (Beauchamp & Childress, p.12). Distributive justice was also observed, as the project's teaching, screening, and supplementation steps were offered to all eligible patients during the implementation period (Beauchamp & Childress, p. 12). Moreover, the project was reviewed and received exempt approval from Wilmington University's Human Subjects Review Committee (see Appendix B). Before this approval, the project leader completed the requisite Collaborative Institutional Training Initiative (CITI) modules (see Appendix C). The project was also approved by the CEO of Berwick Hospital Center (see Appendix D).

Chapter Summary

Chapter three outlined the methodology of the project, including the intervention and measures. Next, ethical and budgetary considerations were discussed. Chapter four will present the results of the project.

CHAPTER FOUR

RESULTS

Sample Characteristics

Before implementing the quality improvement project, baseline data of MCAW visits from December 14, 2020, to March 14, 2021 were examined. A total of 125 patients had a MCAW, of which 56 (44%) were female, and 70 (56%) were male. Most patients were Caucasian (n = 121, 96%) while five patients (4%) were Black or Hispanic. Patients ranged in age from 65 to 89 (M = 72, SD = 6.6). By age group, 65 (52%) patients were 65 and 69 years of

age, 43 (34%) were 70 to 79 years of age, and 17 (14%) were 80 to 89 years of age. There were no patients aged 90 and above. The average BMI of patients was 32.2 (*SD* = 8.4). The diagnoses utilized to justify the medical necessity for vitamin D screening during the pre-implementation phase of the project were known history of hypovitaminosis D (n = 57, 56%), BMI greater than 30 (n = 45, 36%), and 23 (18%) had a musculoskeletal disorder. Participants' demographic data are reported in tables 1, 2, and 3.

Conversely, 149 patients had a MCAW during the project implementation period from March 15, 2021, to June 15, 2021. All patients who had a MCAW during this time were Caucasian, and slightly more than half (n = 77, 52%) were female. Patients ranged in age from 65 to 94 (*M* = 71.1, *SD* = 6.8). Examined by age group, most patients (n = 76, 51%) were between 60 to 69 years of age, 58 (39%) were 70 to 79 years of age, 12 (8%) were 80 to 89 years of age, and three (2%) were above 90 years of age. The average BMI of patients was 31 (*SD* = 8.1). Diagnoses used to justify the medical necessity for the vitamin D screening during the implementation phase of the project were BMI greater than 30 (n = 82, 55%), at-risk for falls (n = 48, 32%), and low bone density (n = 19, 13%). Demographic data for participants are reported in tables 1, 2, and 3.

Table 1

Participants' Age and BMI

Variable	*M*	*SD*	*n*	Min	Max

Age Pre-Intervention	72	6.6	125	65	89
Age Post-Intervention	71	6.8	149	65	94
BMI Pre-Intervention	32	8.4	125	19	58
BMI Post-Intervention	31	8.1	149	17	73

Table 2

Gender and Race of Participants

Variable	Pre-Intervention *n* = 125	Post-Intervention *n* = 149
Gender		
Male	70 (56%)	77 (52%)
Female	56 (44%)	72 (48%)
Race		
Caucasian	121 (96%)	149 (100%)
Black or Hispanic	5 (4%)	0 (0%)

Table 3

Diagnoses Utilized to Justify Vitamin D Screening

Variable	Pre-Intervention *n* = 125	Post-Intervention *n* = 149

History of Vitamin D Deficiency	57 (56%)	0 (0%)
BMI Greater than 30	45 (36%)	82 (55%)
Musculoskeletal Disorder	23 (18%)	19 (13%)
Risk for Falls	0 (0%)	48 (32%)

Results

During the pre-implementation period, 12 (10%) of patients who had a MCAW were given a laboratory order for serum vitamin D screening. Most patients (n = 8, 75%) were compliant with screening and of those screened, vitamin D levels ranged from 19 mg/dL to 49 mg/dL with a mean of 28.6 mg/dL (*SD* = 12.06). Six (75%) of the eight patients screened were vitamin D deficient and started on supplementation. Tables 4 and 5 reflect these data points. Of the 6 supplemented patients, 3 were vitamin D deficient (<20mg/dL) and 3 were vitamin D insufficient (20-29 mg/dL).

During the project implementation period, 149 patients presented for a MCAW were given a laboratory order for serum vitamin D screening. A majority of patients (n = 112, 75%) were compliant with the ordered vitamin D screening. Vitamin D values ranged from 7 mg/dL to 97 mg/dL with a mean of 37 mg/dL (*SD* = 17.01). Patients with vitamin D insufficiency (20-29 mg/dL) made up 22.15% of the population (n = 33), while 14 (9.4%) were vitamin D deficient (<20mg/dL). Approximately one-third (47, 32%) of patients required vitamin D supplementation. These data points are reflected in tables 4 and 5.

As a result of the clinical practice change, the percentage of patients who received a laboratory order for vitamin D screening increased from 10% to 100%. Compliance with laboratory testing was similar with pre-and post-practice change data at 75%, with eight and 112 patients screened, respectively, representing a 1,400% increase. Similarly, there was a 783% increase in the number of patients who received vitamin D supplementation, with six patients and 47 patients pre-and post-practice change, respectively.

Table 4

Participants' Vitamin D Screening, Compliance, and Supplementation

Variable	Pre-Intervention	Post-Intervention
Laboratory Slip Provided for Vitamin D Screening	12 (10%)	149 (100%)
Compliance with Vitamin D Screening	8 (75%)	112 (75%)
Supplementation Required	6 (75%)	47 (32%)

Table 5

Participants' Vitamin D Levels

Serum Vitamin D Level	*M*	*SD*	*n*	Min	Max
Pre-Intervention	28.6	12.06	8	19	49
Post-Intervention	37.0	17.01	112	7	97

Summary

Chapter four outlined the results of the project's implementation. Chapter five will discuss the implications of the project on practice and a discussion on sustainability and application of the DNP essentials.

CHAPTER FIVE

DISCUSSION AND IMPLICATIONS

Interpretation

Chapter five will present a discussion and implications of the project findings. Substantial increases were realized in the percentage and number of patients offered the screening and were subsequently screened for vitamin D deficiency. In addition, most patients were determined to have insufficient or deficient levels of vitamin D and, as a result, were supplemented with vitamin D. These gains were directly related to the addition of an EMR prompt for serum 25-hydroxyvitamin D to an existing fasting lab order set used at MCAW visits in elderly patients over the age of 65.

Limitations

There are three primary limitations of this project. First, there will be seasonal variance in endogenous vitamin D production in patients living in temperate climates. Patients may not require vitamin D supplementation in the summer months, as the body produces vitamin D in the skin when exposed to adequate sunlight during warm weather months (Holick, 2007). Therefore, it is important to monitor vitamin D levels during the late fall, winter, and early spring months when patients are least likely to meet sunlight exposure requirements. Second, patients who live in more tropical climates may have access to adequate sunlight all year and may not require surveillance or supplementation of vitamin D. The geographic weather difference limits the need for screening among patients living in temperate climates. Third, the participants in this project were relatively homogenous in terms of race. Almost all participants were Caucasian; therefore, further projects may attempt to replicate its results in geographical areas where patients of different ethnicities are better represented. Additional QI projects related to vitamin D's role in

mitigating viral diseases may clarify the importance of vitamin D sufficiency in large populations.

Implications for Advanced Nursing Practice

This DNP project demonstrates that highly educated, highly experienced, and highly skilled nurses can spearhead preventive projects to promote primary prevention and act as leaders in primary care settings. DNP-prepared nurses are uniquely equipped to solve problems and lead QI initiatives related to health promotion. The mitigation of the burden of chronic disease states associated with vitamin D deficiency through a prudent systematic screening and supplementation program may enable dollars previously allocated to disease treatment to be utilized on further preventive programs. The nursing model of health care delivery embraces the human reaction to health and disease states, placing a high priority on health maintenance and promotion. This project embodies the concepts of the nurse as a teacher and provider of trusted and effective healthcare and a promoter of health at the personal and community level.

Plan for Sustainability

In terms of project sustainability, the project's costs primarily involved the time associated with data extrapolation and staff hours consumed with the execution and follow-up of the vitamin D screening. To ensure the project is financially viable in the long term, key stakeholders, most notably the other clinic nurse practitioners, have been included and educated about all of the details of the project and QI processes associated with the screening initiative. In addition, the data reports can be run by an office manager or other administrative personnel.

Moreover, having key stakeholder support is felt to be an essential component to sustaining the project long-term. Doctorally prepared nurse practitioners can play a vital role in informing management at all levels about the financial benefits of preventive QI programs in

cost-effective care delivery and mitigating late-stage chronic disease states caused by vitamin D deficiency. Maintaining organizational support ensures that the project can continue after staff changes, as it is then "hard-wired" into the workflow involving MAWV.

Application of the AACN DNP Essentials

The AACN DNP Essentials (2006) guided clinical decisions made during the planning, implementation, and evaluation of the DNP Project. The project utilized evidence-based practice principles to use an electronic medical record (EMR) prompt for vitamin D screening and supplementation, as needed, for elderly patients. The ensuing discussion explores how each DNP Essential was met during the entirety of this DNP project.

DNP Essential I: Scientific Underpinnings for Practice

DNP Essential I postulates that DNP-prepared nurses should be prepared to integrate nursing science with knowledge from diverse scientific sources to form the foundation of the highest level of nursing practice (American Association of Colleges of Nursing [AACN], 2006). The use of scientific principles to guide evidence-based nursing practice enables the DNP-prepared nurse to determine the nature and significance of health-related occurrence, formulate plans to mitigate disease state, promote health, and evaluate outcomes continuously (AACN, 2006).

As a result of this knowledge synthesis, DNP-prepared nurses can spearhead new practice approaches drawn from nursing and other scientific theories. These new practice approaches demonstrate mastery of theory application and serve as a foundation for nursing practice. The focus of practice change was preventive, where a high priority is placed on disease prevention and health promotion. In addition, synthesized knowledge can be communicated to patients, as the nurse's role as a teacher and promoter of wellness is paramount. This DNP project drew on

the Nursing Theory of Dorothea Orem and scientific principles of applied biochemistry, namely the Nutritional Sciences, to synthesize knowledge about vitamin D deficiency and its effects on preventing chronic disease states promoting health proactively through screening efforts.

DNP Essential II: Organizational and Systems Leadership for Quality Improvement and Systems Thinking

The basis of DNP Essential II is the concept that DNP-prepared nurses are trained at a level commensurate with leadership both in organizations and in Quality Improvement initiatives to promote healthcare equity, maximize patient safety, and ensure the highest quality of patient care delivered (AACN, 2006). As a result, DNP-prepared nurses can develop and evaluate care delivery approaches that meet the needs of vulnerable health populations and anticipate the needs of these populations moving forward. In addition, nurses can ensure the highest quality of care by demonstrating mastery of communication skills to avoid or minimize ethical dilemmas associated with complex healthcare-related scenarios (AACN, 2006).

This DNP project involved implementing a large-scale preventive initiative aimed at a systematic vitamin D screening in vulnerable patients over 65 to eliminate a healthcare disparity using a Quality Improvement approach. The results of the initial implementation show promise for a sustainable plan to mitigate the effects of chronic disease states associated with vitamin D deficiency, thereby promoting health in this at-risk population.

DNP Essential III: Clinical Scholarship and Analytical Methods for Evidence-Based Practice

Essential III purports that scholarship and research are keystones in doctoral education and that knowledge synthesis, integration, and application into practice extends beyond discovery into the scholarship of nursing practice (AACN, 2006). During the DNP program, the

utilization of analytic methodology to critically evaluate existing literature was employed. The best evidence collected guided implementing a practice change within the organization to positively improve both the current practice and patient outcomes (AACN, 2006).

More specifically, a rigorous search of existing scholarly literature on the merit of vitamin D screening and supplementation was completed. From the high-quality evidence amassed in this search, a pilot QI project was designed to screen vulnerable elderly patients at MAWVs for vitamin D deficiency and supplement those patients who lacked adequate vitamin D. The results produced by adding an EMR prompt to the MAWV template resulted in more patients being screened and supplemented. Statistical analysis pre- and post-intervention was performed and evaluated and will be disseminated. The intervention was merit-worthy to address vitamin D deficiency in a preventive effort to minimize chronic disease states associated with lack of vitamin D in elderly patients.

DNP Essential IV: Information Systems/Technology and Patient Care Technology for the Improvement and Transformation of Health Care

The main focus of this Essential is that DNP-prepared nurses need to be adept in using information technology to improve patient care and aid in assuming leadership positions within organizations. In addition, intimate knowledge of information systems technology is paramount to creating QI programs that produce high-quality, results-driven, and cost-effective care delivery models to improve patient outcomes (AACN, 2006). The use of EMR to gather and analyze data enables the DNP-prepared nurse increased opportunities to provide vast amounts of preventive care, thereby promoting health and shifting the focus of practice to more proactive rather than reactive. Mastery of information technologies also enables the DNP-prepared nurse to make

more educated decisions based on evidence and qualify them better for leadership positions in multidisciplinary healthcare teams.

This DNP project relied heavily on information systems technology. The implementation was an EMR prompt in an existing EMR template that produced a significant change for the better in the screening and diagnosis of vitamin D deficiency. The power of information systems technology was also evident in the data collection and analysis processes, as data mining in the EMR was efficient and thorough using programs within Athenaclinicals during the pre- and post-implementation periods.

DNP Essential V: Health Care Policy for Advocacy in Health Care

DNP Essential V addresses the necessity of an active role for the DNP-prepared nurse in formulating healthcare policy at several levels. Nurses must act as agents of change at the institutional, organizational, and governmental groups to ensure that policies are created that facilitate rather than impede nursing practice (AACN, 2006). The nurse's role as a political activist and an advocate for both the patients and the nursing profession is a central theme to this DNP essential. Activism on the individual and professional organizations is necessary to facilitate healthcare policy changes when critical and block changes to existing effective policies. Through participation in policy-making processes, the DNP-prepared nurse can ensure sound leadership and judgment when formulating policies regarding the quality of care, finance, equity, and social justice (AACN, 2006).

This particular project sought to change healthcare policy at the institutional level, making vitamin D screening necessary for an annual wellness visit for older adults. The results of this practice change may serve as evidence to influence policy changes at the health system

level, justifying the systematic screening for vitamin D deficiency annually as an essential preventive service worthy of reimbursement based solely on its health-promoting merit.

When third-party payers realize the significance of healthcare dollars that can be saved through disease prevention because of the screenings, policy changes may ensue to promote or even incentivize these types of preventive services. Thus, at each step in the policy-making process, the DNP-prepared nurse may serve to educate and influence policy-makers so that policies improve health care delivery and ultimately benefit large populations of vulnerable patients.

DNP Essential VI: Interprofessional Collaboration for Improving Patient and Population Health Outcomes

Essential VI speaks to the role of the DNP-prepared nurse as a highly-qualified member of a multidisciplinary healthcare team who freely collaborates with other professionals to provide "safe, timely, efficient, equitable, and patient-centered care in a complex environment" (AACN, p. 15). The DNP-prepared nurse possesses the skill set necessary to collaborate with team members and effectively lead this team if and when required. Skills required of effective nurse-leaders involve communicating openly, listening actively, interacting with team members respectfully, and making complex decisions based on evidence and sound nursing judgment. These decisions will reflect both the will of the team and the patients' best interest as well.

This DNP project demonstrated the concept of interprofessional collaboration as leaders from nursing, medicine, dietetics, laboratory medicine, and healthcare management all played roles in the approval and execution of the DNP project. There were often active dialogues about project details that needed clarification based on evidence to change protocols to facilitate patient care. Open, respectful communication was the cornerstone of this collaborative effort. When

team members are treated as peers, and this respect is reciprocated, the ultimate endpoint is evidence-based care producing better patient outcomes.

DNP Essential VII: Clinical Prevention and Population Health for Improving the Nation's Health

Although not unique solely to nursing education, core competencies in disease prevention and health promotion are critical educational pieces necessary to meet health-related goals set forth by public health initiatives (AACN, 2006). For example, the objectives of Healthy People 2020 include attaining "high-quality, longer lives free of preventable disease…and to improve the health of all groups" (U. S. Centers for Disease Control [CDC], 2020).

The DNP-prepared nurse has the cognitive foundation to promote the population's health by analyzing epidemiologic, environmental, occupational, and biostatistical data (AACN, 2006). Through rigorous multifactorial analyses, the DNP-prepared nurse can develop, implement, and evaluate public health initiatives guided by the nursing process and using sound nursing judgment.

The project detailed in these pages targets a vulnerable subset of the U.S. population, at-risk adults over 65. It conforms to the calls of public health initiatives like Healthy People 2020 because it focuses on disease prevention, namely diseases associated with vitamin D deficiency like disorders of bone density and musculoskeletal health. This project's focus is genuinely on prevention and health promotion, as evidenced by increased numbers of patients screened for vitamin D deficiency and a supplementation program focused on correcting blatant vitamin D deficiency and subtler insufficiency of calciferol. This project, in addition, aligns with Healthy People 2020 since it promotes quality of life and longevity by mitigating preventable chronic disease states associated with vitamin D deficiency.

DNP Essential VIII: Advanced Practice Nursing

The final DNP Essential involves core concepts unique to all advanced practice nurses, regardless of area of specialty. This core concept is a mastery of assessment skills and applying these skills to a diverse science base in various patient care scenarios (AACN, 2006). The DNP-prepared nurse conducts comprehensive and systematic assessments on a health-illness continuum in complex and dynamic situations. These assessments lead to the design, implementation, and evaluation of therapeutic interventions to ensure optimal care and patient outcomes (AACN, 2006). The DNP-prepared nurse is also obligated to guide and mentor other nurses to promote the nursing profession moving forward so that the future of nursing is welcoming, full of promise and opportunity for newcomers.

The vitamin D screening project was an attempt to use high-quality evidence coupled with didactic and life experiences to help a group of patients prevent chronic disease states associated with vitamin D deficiency. Drawing on classically taught concepts in applied biochemistry (nutritional science) in the presence of two decades of nursing experience and education, the project shows a vision of how all of the nursing Essentials, when appropriately applied, can produce a nurse-led public health initiative that promotes health in a vulnerable health population. The project marks the end of a doctoral journey, but the beginning of a new chapter full of opportunities to promote the profession through a more enlightened approach to patient care and a heightened ability to train new APRNs moving forward.

Conclusion

Initiating a systematic vitamin D screening and supplementation program at MCAW visits allows for predictable surveillance of vitamin D status in a vulnerable elderly population. In addition, the MCAW visit provides the perfect opportunity to address preventive efforts not

only for vitamin D screening but also for many chronic medical conditions. Utilizing an EMR prompt for serum 25-hydroxyvitamin D screening incorporated into an annual fasting lab order set led to significant increases in the number of patients offered the screening, the number of patients screened. In addition, the number of patients diagnosed and subsequently supplemented with vitamin D. The prevention of chronic disease states associated with vitamin D deficiency can be realized without creating an excessive burden to the healthcare provider when the EMR is appropriately utilized. This DNP project also highlighted the importance of the roles of DNP-prepared nurses as autonomous decision-makers, innovators, patient advocates, and QI leaders in an often complex, dynamic health care setting.

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Appendix A

Budget Spreadsheet

		2021		2022		2023	
Expenses	per unit						
CRNP	$60	$24,000		$25,200		$26,460	
CMA	$15	$6,000		$6,300		$6,615	
Lab	$15	$6,000		$6,300		$6,615	
EMR	$10	$4,000		$4,200		$4,410	
total	$100	$40,000		$42,000		$44,100	
Income							
MAWV	$150	$120,000		$126,000		$132,300	
Laboratory	$100	$80,000		84,000		$88,200	
total	$250	$200,000		$210,000		$220,500	
Net Revenue		$160,000		$168,000		$176,400	
Assuming 5% growth per annum							

Appendix B
HSRC Application

HSRC-1

RECORD AND REVIEW OF DOCTOR OF NURSING PRACTICE (DNP) PROJECT

Student:	Gregor	Robert Jr.	A.
	(Last)	(First)	(Middle Initial)

Student ID: W 00327777

DNP Project Chair: Dr. Aaron Sebach

Academic Level

X DNP Project

Forms Checklist

X DNP Project Protocol

X CITI Training Certificate*

Check with the DNP Program Chair for training requirements

Training certificate cannot be older than 3 years

☐ Instrument(s) *(N/A)*

X Other Organizational Support Letter

This section is to be completed by the HSR Committee

Archive Number:	Click here to enter text.
DNP Category:	Choose an item.
Final Approval Date:	Click here to enter a date.

HSRC-2

Complete This Worksheet Prior to Completing This Form

Purpose: The purpose of this worksheet is to provide support for making Quality Improvement Project determinations when there is uncertainty regarding whether the quality activity contains Human Subjects.

Directions: For a proposed DNP project to be classified as containing only Quality Improvement activities—which permits use of the DNP HSRC form—answers to all of the questions in the worksheet must be 'TRUE' for each activity proposed in the DNP project. If one or more answers is 'FALSE', the project requires completion of the HSRC standard form and committee review.

TRUE	FALSE	
X	☐	The intent of the proposed activity is to assess and/or improve the quality of a practice, product or program to ensure established educational, clinical or program service standards are met or best evidentiary practices attained.
X	☐	No activity proposed provides less than standard of care, services or instruction to participants.
X	☐	No practice, product or program changes proposed are experimental and no test interventions or research questions are added that go beyond established or evidentiary best practice.
X	☐	The proposed activity does not: (1) include a 'control group' in whom care, products, services or educational instruction are intentionally withheld to allow an assessment of its efficacy or (2) assign participants to receive different procedures, therapies or educational instruction based on a pre-determined plan such as randomization.
X	☐	The proposed activity does not involve the prospective evaluation of a drug, procedure or device that is not currently approved by the FDA for general use (including "off-label" indications).

X	☐	The proposed activity does not test an intervention or add research questions that go beyond established evidentiary best practice and/or are intended to generate generalizable knowledge.
X	☐	The proposed activity would not increase harm—physical, psychological, social or economic—than would normally be encountered by the individual if s/he was not participating in this activity.
X	☐	The lead person on the project has organizational responsibility and authority to recommend or impose a corrective action plan based on the outcome(s) of the activity, as applicable.
X	☐	Interpretation of the data or any feedback to those who would benefit from the findings will not be deliberately delayed.
X	☐	The proposed activity has merit and will likely be conducted regardless of any possibility of publication or presentation that may result from it.

Adapted from Rutgers HRP-309 (2017) with permission from Judith Neubauer, PhD.

HSRC-3

DNP Project Information

Title of DNP Project (12 to 15 words maximum):

Development and Evaluation of a Nurse Practitioner-Directed Vitamin D Screening and Treatment Protocol During Medicare Annual Wellness Exams in a Rural Primary Care Practice

Problem Description:

Provide a short summary of the clinical practice problem you will address with your DNP project. What is the gap in practice and what evidence will you be translating to practice?

Current periodic surveillance for chronic health problems excludes screening for most vitamin deficiencies, including in Berwick Hospital Center's primary care practice. Vitamin D deficiency is the most prevalent vitamin deficiency globally, with an estimated one billion individuals lacking adequate vitamin D (Charoenngam & Holick, 2019). Systematic screening for vitamin D deficiency aims to prevent diseases associated with deficiency, and promote immune, cardiac, and musculoskeletal health. These claims are supported strongly by scholarly, peer-reviewed, current literature (Chandler, et al., 2020; Martineau et al., 2017; Zhou, et al., 2019). The project will address vitamin D deficiencies among elderly patients in a rural primary care practice.

HSRC-4

External Projects

If the DNP project will involve other organizations, it may be necessary to obtain permission from these organizations prior to collecting data. Some organizations have Institutional Review Boards (IRBs), and it may be necessary to obtain formal approvals from these IRBs. In other cases, a document from an appropriate organizational executive specifically approving the DNP project would be sufficient. The DNP student is responsible for determining what type of approval is required and obtaining the approval.

In cases where approval from Wilmington University's HSRC is required as a precondition to obtaining approval from another organization, the HRSC's approval will be provisional, requiring the additional step of obtaining DNP project approval documents from other organizations before receiving full approval from Wilmington University's HSRC.

If the DNP project involves other organizations, please answer these questions.

	YES	**NO**
Do these organizations require approval by their IRBs?	☐	X
Has IRB approval been obtained? If **YES**, please attach the approval to this submission	☐	X

Have other permission documents been obtained? If **YES**, please attach the approvals to this submission.	**X**	☐

Other relevant information or comments:

Click here to enter text.

HSRC-5

Population Information

Population:	Gender(s)	Age(s)			Race/ethnicity(ies)	
		All		65+		All
PICOT Question: Include the PICOT Question in a complete sentence and then break down each section, Population -; Intervention -; Comparison -; Outcome -; Time -. Include sufficient detail so that someone unfamiliar with the project would understand all aspects of the						

proposed DNP project.						
In an adult primary care practice, how does the addition of an EMR serum 25-hydroxyvitamin D electronic medical record (EMR) order prompt for use during geriatric adult (age 65+) annual wellness exams compared to current practice without an EMR order prompt influence the						

HSRC-6

number of patients screened for Vitamin D deficiency over a 6-week period?

How many participants (patients, providers, etc.) are anticipated for the DNP project?

_____

It is estimated that approximately 200 participants will be screened for vitamin D deficiency.

How will participants be selected for participation? (from PICOT question)

All patients scheduled for a Medicare annual wellness exam over the age of 65 will be included in the project during the 6-week period.

What are the procedures that the participants will undergo in the proposed DNP project including the physical location and duration of participation? Provide a step-by-step outline of the project from start to finish. **Attach a copy of all DNP instruments, e.g., surveys, questionnaires, interview questions, etc. (if being utilized):**

The participants will attend their annual Medicare wellness exam in the primary care practice. During the visit, annual fasting lab work will be ordered. This pre-existing order set will be modified in the EMR to include a serum 25-hydroxyvitamin D level. The patient will have no change to their annual wellness exam experience, and have no extra blood drawn, as the added lab test can be run from the basic metabolic profile sample drawn as part of the usual fasting lab order set. All participants, however, will be educated on vitamin D screening and the clinical significance of hypovitaminosis D. All will be informed about the screening in advance. Any patient who refuses screening will be excluded from the project.

Confidentiality and Security

Select **YES** to certify that:

HSRC-7

	YES	N/A
Procedures have been taken to ensure that individuals cannot be identified via names, digital identifiers (e.g., email address, IP address), images or detailed demographic information.	X	☐

Code to name association data/information is securely and separately stored. (Participants are given codes and the codes are securely stored separately from their answers.)	☐	X
All data is maintained in encrypted and/or password protected digital/electronic files.	☐	X
Individually identifiable information will be securely maintained for three years past the completion of the research, and then destroyed rendering the data unusable and unrecoverable.	☐	X

Describe the procedures you are taking to maintain anonymity, confidentiality, or information security.

All data will be maintained on a password-protected computer accessible only by the DNP student. Data will be presented as an aggregate and individual patient information will not be reported, thereby maintaining anonymity and confidentiality. All data will be maintained for 5 years and then destroyed.

DNP Protocol

Does this DNP project involve?

	YES	NO
Prisoners, probationers, pregnant women (if there is a medical procedure or special risk relating to pregnancy), fetuses, the seriously ill or mentally or cognitively compromised adults, or minors (under 18 years) as participants	☐	X

The collection of information regarding sensitive aspects of the participants behavior (e.g., drug, or alcohol use, illegal conduct, sexual behavior)	☐	X
The collection or recording of behavior which, if known outside the research, could place the participants at risk of criminal or civil liability or could be damaging to the participant's financial standing, employability, insurability, or reputation	☐	X
Procedures to be employed that present more than minimal risk to participants	☐	X
Deception	☐	X
Possible or perceived coercion (e.g., a concern in power relationships such as teacher/student, employer/employee, senior/subordinate)	☐	X
Benefits or compensation to participants (beyond the general benefits of the knowledge to be gained or small gifts/lottery prizes)	☐	X
A conflict of interest (e.g., the researcher's material or other interests may bias collection, interpretation, or use of data)	☐	X

If you answered "**NO"** to all of the questions please proceed to the next page.

If you answered "**YES"** to any of the questions, provide evidence that you have taken the training module or modules that relate to this risk and discuss what you learned about reducing the risk from the training in the textbox below and/or by attaching the evidence to this document.

Click here to enter text.

HSRC-9

Obligations of DNP Student

Any substantive changes made to the DNP protocol must be reported to and reviewed by your college's HSRC representative(s) prior to implementation of such change. Any complications, adverse reactions, or changes in the original estimates of risks must be reported at once to the HRSC chairperson before continuing the project.

Select **YES** to certify that:

	YES
DNP data will be retained for a minimum of three years past the completion of the project in accordance with federal regulations	X
The DNP student will submit document and form revisions and updates, as appropriate	X
The DNP student will submit a renewal petition if the data collection has not been completed within one year of the most recent HSRC approval* **Note**: HSRC approval expires after one year, requiring renewal of the HSRC Protocol	X

The DNP student's signature below certifies that he/she has (a) read and understands the obligations as a DNP student, (b) DNP project approval expires one year after the final approval date shown on page 1, and (c) that the information contained in and submitted with this HSRC protocol is accurate and complete.

DNP Student:

Print name: Robert A. Gregor Jr., CRNP

Signature: Date: 1/28/2021

Obligations of the DNP Project Chair

The DNP Project Chair has two major obligations. First, the DNP Project Chair must ensure the DNP Student completes all relevant training courses. Second, the DNP Project Chair must ensure the DNP Student submits all document and form revisions and updates, as appropriate for the research.

HSRC-10

The DNP Project Chair's signature below certifies that he/she has (a) read and understands the obligations as a DNP Project Chair and (b) that the information contained in and submitted with this HSRC protocol is accurate and complete.

DNP Project Chair:

Print name: Dr. Aaron Sebach

Signature: _____ Date: 1/27/2021

HSRC-11

PROTOCOL REVIEW

This section is to be completed by the HSR Committee.

DNP Student: Robert A. Gregor Jr., CRNP

Date Submitted: Click here to enter a date.

The protocol and attachments were reviewed:

The proposed DNP project is approved as:

X Exempt ☐ Expedited ☐ Full Committee ☐ Provisional (see External Projects section)

The proposed DNP project was approved pending the following changes:

☐ See attached letter

☐ Resubmit changes to the HSRC chairperson

The proposed DNP project was disapproved:

☐ See attached letter for more information.

	YES	N/A
The HSRC representative sent a copy of the HSRC Protocol to the VP of Academic Affairs for research requiring access to Wilmington University students, employees, or data.	☐	☐

HSRC Chair or Representative: Click here to enter text.

Printed Name

Signature

Date: 2/28/2021

HSRC Chair: Click here to enter text.

or
Representative

HSRC-12

Printed Name

Signature

Date Click here to enter a date.

Appendix C
CITI Training Certificate

This is to certify that:

Robert Gregor

Has completed the following CITI Program course:

Human Subjects Research
(Curriculum Group)
Health Professions - Human Subjects Research
(Course Learner Group)
1 - Basic
(Stage)

Under requirements set by:

Wilmington University

Completion Date 31-Dec-2020
Expiration Date 31-Dec-2023
Record ID 40139607
Not valid for renewal of certification through CME.

Verify at www.citiprogram.org/verify/?wff2c0019-676d-46d3-99e5-87bfb2c87886-40139607

Appendix D
Organizational Approval
Berwick Hospital Center

Dear Sir or Madam,

This letter is to inform Wilmington University's Human Subjects Review Board that Robert Gregor, CRNP has full organizational support for his doctoral (DNP) project dealing with Vitamin D screening in a vulnerable health population. We encourage the furtherment of formal education for all our motivated and interested employees.

Sincerely,

Ms. Priyam Sharma CEO/Owner
Berwick Hospital Center
751 E 16th Street Suite 400 , Berwick, PA 18603
Tel: (570) 759-5555Fax; (570) 759-5471berwickhospitalcenter.com