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Standardized Clinical Guideline for Assessment, Documentation, and Treatment of Statins

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This is to certify that the doctoral study by

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has been found to be complete and satisfactory in all respects,
and that any and all revisions required by
the review committee have been made.

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The Office of the Provost

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2019

Abstract

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Esther Onyirimba

MS, Maryville University, 2014

BS, University of Arkansas at Pine Bluff, 2009

Proposal Submitted in Partial Fulfillment

of the Requirements for the Degree of

Doctor of Nursing Practice

Walden University

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Abstract

The purpose of this project was to develop a practice guideline for screening patients at risk for cardiovascular disease, educate the staff at the site about the guideline, and implement the guideline at a primary care clinic. The intention was to identify and treat patients at risk for cardiovascular disease to prevent occurrence of heart disease. Cardiovascular disease includes hypertension, coronary heart disease, heart failure, and stroke. Coronary heart disease is one of the leading causes of death in the Western world. The local practice problem and focus of this project was underprescribed statin therapy for patients at risk for developing heart disease at a clinic in the southern United States. The practice-focused question that guided this project explored whether an evidence-based clinical guideline that might impact the prescription of statins for the prevention of cardiovascular disease would be approved for implementation in a primary care clinic serving adult and geriatric patients. The appraisal of guidelines for research and evaluation and the Fineout-Overholt model were used to guide this project. Sources of evidence to meet the purpose of this project were obtained from the literature and scholarly articles. After the guideline presentation to the expert panel they agreed to implement the clinical practice guideline at the project site and agreed to track the results in a quality improvement initiative. The implications of this project for positive social change might include improved management of patients who are at risk for heart disease and a decrease in premature deaths related to cardiovascular disease.

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Dedication

I dedicate this project to the people who suffer from coronary heart disease and to those family members who have lost a loved one to coronary heart disease. In addition, I would also like to dedicate this project to all the healthcare providers who selflessly devote their time in caring for patients with coronary heart disease.

Acknowledgments

My husband, my three children, and my parents have been my source of strength throughout my educational expedition. At times when I wanted to give up, my dad and husband encouraged me not to. To my three children who have missed soccer and dance tryouts because of my educational journey. I would also like to thank Dr. Barbara Niedz for the guidance she provided me throughout my scholarly project.

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Section 1: Nature of the Project

Introduction

Coronary artery disease (CAD) is the leading cause of death in the United States and is responsible for one out of three deaths in the United States (American Heart Association [AHA], 2017). CAD is the buildup of plaque in the arteries of the heart, which restricts the necessary blood flow to the heart (Gander et al., 2014). This then causes a lack of oxygen rich blood to the heart muscles, which then leads to ischemia of the heart tissue and ultimately significant damage, a myocardial infarction (Lubna, 2014). Risk factors for CAD can be divided into two categories: modifiable and nonmodifiable/conventional (Pencina et al., 2019). Modifiable risk factors are (a) high blood pressure, (b) high blood cholesterol, (c) diabetes, (d) smoking, (e) overweight, and (f) unhealthy diet and lack of physical activity (Lubna, 2014). The nonmodifiable risk factors include (a) increase of age (geriatrics), (b) gender with men at an increased risk, (c) race, and (d) family history (Kannel & Ramachandran, 2009).

Clinical guidelines are used to follow protocol for the best care method for medication delivery (Lawal et al., 2006). A clinical guideline is a tool used to help manage the quality in healthcare transactions by focusing on the standardization of a specific process (Grimsmo et al., 2018). The nature of this doctoral project was to develop and implement a clinical guideline to increase the use of statin therapy to those patients who are considered at risk for coronary heart disease.

In a primary care setting, a clinical guideline can be used to screen and identify those at risk for CAD and treat them with statin therapy to help prevent the development

of CAD. The clinical guideline is a tool that should be used to help manage quality in the healthcare setting on statin use by focusing on the standardization of the care process between the providers and the patient.

A clinical guideline improves the quality of health and outcomes for patients with various diseases (Lawal et al., 2006). In 2012, the Norwegian government's care coordination reform was launched. A clinical guideline was designed for a constant and integrated clinical approach that emphasizes primary care services and primary care's role prominently after hospitalization (Lawal et al., 2006). This section contains explanation of the problem, purpose, and methodology used for this project.

Problem Statement

The practice problem was identified at the primary care clinic that was the subject of this doctoral project. At this clinic, 40% of the patient population who present with risk factors are not on a statin. This may be due to the fact that patients only come to the clinic for sick visits. The nature of the patient population consists of about 60% geriatrics and about 45% women. The patients with insurance have well visits for lab work covered, but again, that population seems to only come for sick visits.

CAD is a type of cardiovascular disease along with heart failure and stroke. Cardiovascular disease was responsible for 25% of deaths in the United States in 2013 (Short, Walls, Smith, & Loustalut, 2014). The use of statins to reduce LDL levels has long been accepted as an important preventive measure to delay or even prevent the onset of cardiovascular disease (Yusuf et al., 2016). However, many primary care practices do not routinely evaluate patients for their risk of developing CAD and fail to prescribe this

lifesaving class of drugs to their patients. In fact, at the primary care clinic that was the subject of this DNP project, over 40% of the current patient population was at risk for developing cardiovascular disease, but they had not been assessed for cholesterol levels nor had their family history been reviewed.

Cholesterol has been broken down into two different components: LDL cholesterol and HDL cholesterol. The LDL type of cholesterol has been identified as the harmful type, while the HDL cholesterol has a protective factor. High levels of LDL cholesterol have been shown to predict the onset of CAD. The AHA and American College of Cardiology (ACC) patient care guidelines recommend treatment with cholesterol-lowering medications in patients at risk for developing CAD (Jones et al., 2016). Medications known as *statins* help prevent coronary heart disease by lowering LDL cholesterol levels; this has been identified through research as a primary precipitating factor in CAD (Jones et al., 2016). The local practice problem that was the focus of this doctoral project is the under prescribed use of statin therapy to those patients at risk of heart disease for prevention at a clinic in a suburban region of the state of Georgia.

Practice guidelines for statin use in primary care is essential (Yusuf et al., 2016). Because many patients at risk for developing CAD appear healthy, they may not recognize the need for cholesterol-lowering medications until they are already symptomatic, which may be too late (Mcnaughton & Shucksmith 2014). Poor patient outcomes may result when there is no clinical guideline in use (Tehrani, Michell, & Pan, 2018). When a drug is introduced, this is an opportune time to have a clinical guideline in

place within the medical institution (Burke et al., 2008). Not having this protocol in place is problematic for the nurses and nurse practitioners because the proper treatment path may not be clear (Sheppard, Fletcher, McManus, & Mant, 2014). The institution and the practitioners are all at risk; they will be held accountable for the outcome of patients being cared for there (Johnson, Blasdell, Walker, & Eggleston, 2000). The primary care clinic may benefit from having a clinical guideline in place to assure consistent practice based on the latest research evidence among the practitioners who practice in that venue. In addition, the use of practice guidelines may reduce variation in practice (Panella, Marchisio, & Di Stanislao, 2003). The practice problem identified at the facility was the underprescription of statin therapy to at-risk patients for prevention of coronary heart disease. This was observed by a random review of 10 patient laboratory studies and recorded daily medication for VI months compiled by the site staff and provided to me as the DNP student. Out of the 10 de-identified patient charts, six patients had increased LDL levels, and a further breakdown showed four patients who smoke cigarettes. Moreover, some of the patients also had other risk factors, such as obesity and diabetes (Panella et al., 2003). In the world at large and at the DNP project site specifically, people who present with risk factors for coronary heart disease are not prescribed statin therapy as evidenced by previous research performed (Sheppard et al., 2014).

Purpose

The purpose of this doctoral project was to develop a standardized clinical guideline for primary care facility nurses and practitioners, guiding thee practitioners to prescribe statins when indicated to prevent the emergence of heart disease. The gap in

practice was that patients who presented with risk factors for developing coronary heart disease were not being properly screened and did not receive a prescription for statins in this primary care setting. The risk factors included high blood pressure, high blood cholesterol, diabetes and prediabetes, smoking, being overweight or obese, being physically inactive, having a family history of early heart disease, having a history of unhealthy diet, and women age 55 or older (Panella et al., 2003). Gamboa et al. (2014) studied 30,239 people, all age 45 or older, in a REGARDS research program who were at high risk for developing coronary heart disease and determined that many of the participants did not receive a statin. Meid et al. (2015) reiterated that cardiovascular disease is a leading cause of death among the elder patient population. Gamboa et al. (2014) also pointed out that important medications to help prevent heart disease are often underutilized and suggested a prescribing criterion be developed for those patients at risk for heart disease.

Plans for implementation were included in this project. The guiding practice-focused question for this doctoral project was: In a primary care clinic serving adult and geriatric patients, will an evidence-based clinical guideline that can potentially impact the prescription of statins for the prevention of cardiovascular disease be approved for implementation?

Nature of the Doctoral Project

Current guidelines that have been established and utilized provided the basis for the practice guideline developed for practitioners at the DNP site, as guidelines have been developed specifically for primary care (Panella et al., 2003). The sources of evidence

collected to meet the purpose of this doctoral project were obtained from literature and scholarly articles. Online database searches were also used to narrow down the dates of the articles reviewed. Keywords included *coronary heart disease, CAD, statins, LDL, statins,* and *heart prevention in primary care*. The dates searched were 2014–2019. Other sources included the latest ACC and AHA guidelines for statin therapy in prevention of coronary heart disease. Other sources that were reviewed were medications and labs of unidentified patients, which assisted in identifying the practice problem.

I implemented a literature review of scholarly articles for relevant evidence. Reviewing the literature on coronary heart disease and how prevention can play a key role in avoiding cardiac-related deaths assisted in formulating a clinical guideline to standardize the care provided to help prevent heart disease. I analyzed the literature for evidence-based recommendations that supported the clinical guideline.

I assembled a team of experts, including nurse practitioners and other primary care providers at the DNP project site, to provide feedback regarding the planning phase in the development of the practice guideline. We discussed the plan and I allowed for feedback from the team to review other possible strategies to guarantee this pathway's success. Thereafter, a revision occurred during a meeting before I finalized the pathway. Staff education on the use of a practice guideline in the practice arena was held. Staff members were also educated on the importance of scheduling well visits for patients, checking labs with specific attention to cholesterol levels, and setting a two-week follow up appointment with the patient to review their lab results. This project included the development and education of clinical guidelines for the staff. However, full

implementation of the guidelines and evaluation of its impact on statin use at the site is beyond the scope of this DNP project. Nonetheless, involving the expert team at the site in the development and education regarding the guideline will ensure its ultimate success in increasing statin use at the primary care site.

Significance of the Project

The stakeholders involved were the primary care providers, nurse practitioners, clinical office manager, and medical assistants who work at the practice and the patients. This practice guideline doctoral project is important to nursing practice because it helped standardize care in a primary care facility, which in turn may prevent deaths related to heart disease. The clinical guideline developed in this DNP project will be used in the primary care setting that is the site for the DNP project to screen individuals at risk and to begin statin therapy to prevent cardiovascular disease. The benefits for the use of the statin therapy practice guideline extends to other settings in addition to the primary care practice that is the setting for the project. Other primary care practices, including nurse-run clinics, hospital-based outpatient clinics, and private practices can benefit from the practice guideline developed for this DNP project.

The implication for positive social change was for patients who are at risk for heart disease to be identified, better manage their health, have a positive outlook of life, resulting in an increased quality of life, and minimizing the chances of premature deaths related to cardiovascular disease. Clinical guidelines lessen costs and advance quality by decreasing errors, refining synchronization among interdisciplinary team members, restructuring case management tasks, delivering methodical records for evaluating care,

and decreasing discrepancy in practice designs (Panella et al., 2003). Research has shown that settings that executed clinical guidelines in practice have shown positive patient outcomes (Jones-Lloyd et al., 2017).

Summary

CAD is a type of cardiovascular disease along with heart failure and stroke. Cardiovascular disease was responsible for 25% of deaths in the United States in 2013 (Short et al., 2014). Stone et al. (2014) recommended treatment with cholesterol-lowering medications called statins to help prevent CAD. At the primary care clinic that is the subject of this DNP project, over 40% of the current patient population at risk for developing cardiovascular disease have not been assessed for cholesterol levels, nor has their family history been reviewed. Thus, this gap in practice leaves several patients at risk for developing cardiovascular disease because statin use was not consistently being prescribed there.

Section 2: Background and Context

Introduction

When there is no clinical guideline, nurses must deal with poor patient outcomes (Tehrani, Michell, & Pan, 2018). The purpose of this project was to develop a clinical guideline for the primary care site that would create standardization for increased prescription use of statin therapy for those individuals at risk for CAD. This DNP project closed the gap between the available evidence-based guideline, literature, and current practice of managing the sick visit only and not attending to the patient as whole, evaluating their risk for CAD, and prescribing a statin. In the following section, I will discuss the model used to guide the development of this practice guidelines project, the relevance of the project to nursing practice, background, and context as well as information about me, the DNP student.

Concept, Models and Theories

Statin Use as a Preventive Measure

Pharmacotherapy for blood pressure and cholesterol lowering are both successful at decreasing cardiovascular risk, and evidence-based guidelines suggest the use of statins in people who have high risk for cardiovascular events (Sheppard et al., 2015). Underuse of cardiovascular disease (CVD) deterrence medication is frequent in healthcare systems all over Europe and North America (Sheppard et al., 2015). The Framingham Heart Study showed that there is a lethal connection between blood-cholesterol LDL-C levels and CVD (Framingham Heart Study, 2019). LDL-C is the primary lipid-carrier protein, and a

buildup of LDL in the blood will affect oxidation and form plaque that will lead to atherosclerosis (Lubna, 2014).

Chou et al. (2016) studied the benefits of the use of statins to prevent heart disease using meta-analysis to summarize multiple randomized clinical trials. The meta-analysis compiled various comparisons: (a) statins versus placebo, (b) fixed dose versus titrated statins, and (c) higher versus lower intensity statins in adults without a history of cardiovascular events (Chou et al., 2016). The target population consisted of adults 40 years and older with no prior history of having a cardiovascular event (Chou et al., 2016). Meta-analysis was used to calculate the risk ratios; the trials included had between 95 and 17,802 participants (Chou, et al., 2016). The researchers found that in adults with high risk for CVD, but with no prior coronary event, statin therapy reduced those individual risk factors and CVD mortality along with coronary events (Chou et al., 2016).

The U.S. Preventative Services Task Force (USPSTF, 2016) recommends that individuals with no known history of CVD and who are between the ages of 40 to 75 with one or more risk factor be started on a low-dose statin, or 80 mg of aspirin, to prevent mortality and coronary events. Statins have demonstrated a medical advantage for the primary prevention of CVD events in adults (USPSTF, 2016).

Statin Use: When It Is Needed and When It Is Not

The USPSTF (2016) proposes starting the use of low- to moderate-dose statins in people 40 to 75 years who do not have a history of CVD or have one or more CVD risk factors and a determined 10-year CVD event risk of 10% or more. The USPSTF (2016) also determined that the existing substantiation of evidence is not enough to recommend

the benefit and problems associated with starting statin use in adults 76 years and older. Although there is a tremendous amount of evidence on the benefits of statin therapy, use of statins in the elderly population (age 76 or older) needs to be analyzed thoroughly (Pedro-Bolet et al., 2015). Quality of life as well as adverse effects that may occur in this age group involving statin drugs should be considered when prescribing decisions are made for this population (Pedro-Bolet et al., 2015).

Healthy Heart Strategies

Cardiovascular disease consists of a class of conditions including, but not limited to, heart failure and stroke (Go et al., 2014). About 78 million adults suffer from hypertension in the United States; hypertension is considered a modifiable risk factor (Go et al., 2014). Maintaining a normal blood pressure is needed to reduce occurrence of CVD-related events (Go et al., 2014).

Obesity, poor diet, and decreased physical activity are also modifiable risk factors (LeFevre, 2014). Improving nutritional intake and healthy eating habits as well as an increase in physical activity all help prevent CVD (LeFevre, 2014). There are more strategies that individuals can implement to improve their odds of staying healthy and avoiding CVD. For example, LeFevre (2014) discussed behavioral counseling as an intervention and evaluated counseling that involved physical activity, tobacco cessation, and a healthy diet and its impact on CVD. Counseling interventions were reviewed for the modification for a healthy diet and physical activities (LeFevre, 2014). The population consisted of adults who were 18 years and older in the primary care arena who were overweight/obese with cardiovascular risk factors. In this systematic review, there

were 74 trials with a total of 77 intervention groups, and evidence pointed to the efficiency of behavioral counseling (LeFevre, 2014). Among participants, the total cholesterol levels were lowered to about 0.08 to 0.16 mmol/L with the LDL being decreased by about 0.004 to 0.13 mmol/L (LeFevre, 2014). Behavioral counseling helps those individuals at risk change habits to live a healthier lifestyle (LeFevre, 2014).

Rosswurm and Larrabee's Model

Rosswurm and Larrabee (1999) developed knowledge of practice-based model studies associated with an evidence-based practice. Their model directed the transformation of evidence-based practice guidelines into practice by adapting the suggested guidelines to different practice settings (Gawlinski & Rutledge, 2008). This model endorses a methodical process for taking research, the highest form of evidence, and integrating findings into practice (Gawlinski & Rutledge, 2008).

Rosswurm and Larrabee's (1999) model lays out a plan for incorporating research-based practices that will work well in various settings and support stakeholders. There are six stages to this model: (a) assess, (b) link, (c) synthesize, (d) design, (e) implement/evaluate and (f) integrate/maintain (Rosswurm & Larrabee, 1999). The first stage encompasses assessing the necessity for transformation in practice. This will include the stakeholders in the development of equating core facts with other findings to detect the problem. The next stage relates the identified problem, intercession, and results to make sure the habit of uniformity of systems and language are being used. The third stage involves the use of blending paramount evidence by studying literature associated to the key variable. The next stage schemes a recommended modification in practice,

recognizes necessary materials, strategizes the carrying out process, and describes the projected results. In the penultimate stage, implementation and evaluation of the change are performed in a pilot study; this is where the decision to adopt the practice change is made. The final stage assimilates and preserves the practice change by informing the suggested practice change to stakeholders by having in-services on the practice change and incorporating the change into practice and continuous observation of the course and results (Rosswurm & Larrabee, 1999). Using this model will help provide guidance to the nurses and other medical professionals to the practice by using systematic steps to enforce the change to the practice. Although this project will not include implementation, this model will help stakeholders in the future for implementation purposes.

Appraisal of Guidelines for Research and Evaluation II and Fineout-Overholt

The appraisal of guidelines for research and evaluation (AGREE II) is a framework used to help advance reporting of clinical practice guidelines (Brouwers et al., 2010). AGREE II was developed to tackle the problem of inconsistency in guideline quality (Brouwers et al., 2010). I used AGREE II in this doctoral project by applying it to the proposed guideline before its application into the practice. It allowed for a methodological development of the proposed guideline and provided room for stakeholders' evaluation of the guideline.

The Fineout-Overholt concept was also used for this project. This concept was applied to analyze the quality of evidence obtained and to rank the evidence level. Ranking of the evidence level will be from I to VII (see Appendix A). This ranking process helped strengthen the reliability of the guideline being proposed. The literature

matrix showed how this clinical guideline aligns with the most recent research evidence, thereby enabling evidence-based practice. Note that in Appendix A, all evidence provided for the clinical guideline ranks from I to VII with the level of evidence provided, indicating that the practice guideline is supported by the research evidence.

Relevance to Nursing Practice

In the history of nursing practice, physicians will write prescriptions or plan of care based on intellectual knowledge (Reuter & Fitzsimons, 2013). This may have caused the underuse of prescriptions employed for preventive care and management (Reuter & Fitzsimons, 2013). Physicians had to manually write a patient's plan of care in order for nurses to carry out the orders (Reuter & Fitzsimons, 2013). In 1893, Lillian Wald, was a graduate nurse from New York Training School. She started the Henry Street Settlement in Manhattan (Keeling, 2015). Initially she and her colleagues started making nursing rounds to the poor as well as making necessary referrals to physicians (Keeling, 2015). The demand for nurses increased, and by 1990, 12 more nurses were hired to carry out physician prescribed medicines (Keeling 2015). With the advent of advanced practice licensure for registered nurses, this dynamic has changed considerably.

Gurzick and Kesten (2010) propose that compliance with the use of care pathways is below average. The authors suggest that the use of clinical guidelines will help improve patient outcomes and reduce healthcare cost all while ensuring that evidence-based practice is being followed in the healthcare setting (Gurzic & Kesten, 2010). In summary, Gurzick and Kesten (2010) have revealed that there is a need for clinical

guidelines to help ensure that evidence-based practice is being used in the healthcare setting.

Quinn (2017) reviewed case studies and analyzed several cases which showed that primary care providers were responsible for the misdiagnosis of cardiovascular disease by not properly screening the patient for heart disease. A clinical guideline can aid in the increase use of statin therapy to prevent heart disease. Likewise, Muller et al.'s (2009) study revealed that in the post-operative unit in the hospital being studied a clinical guideline reduced hospital stay by 28% and decreased nursing hours.

Nurses for many years have been managing risk factors (hypertension, smoking, diabetes) to prevent coronary heart disease. Some of the ways this is done is by the use of programs/guidelines in primary care (Hayman, et al., 2015). The advanced practice nurse practitioner with prescriptive authority (APRN/NP) holds a primary role in disease prevention (Thomas, Hart & Burman, 2014). Nurses can help reduce the risk factors involved with coronary heart disease by following the treatment guidelines.

Local Background and Context

The intended practice setting for this doctoral project was an outpatient primary care setting in Georgia. The practice setting is a primary care office. Close to 60% of the patients are 55 years and older; 45% of the total population are women. This project will help improve patient care outcomes for those with moderate to high risk of developing coronary heart disease at the practice facility. Currently a policy is in place for statin therapy use for those at risk which is not being carried out. This may be due to the practitioners focusing more on the acute reason of the patients visit and not on

prevention. Therefore, a training tool was provided for staff as well as a plan for implementation. Rosswurm and Larrabee's model will help assist in the change in order to implement the clinical guidelines and all its components for their go live date. Primary care practice is often dictated by habit and "the way we have always done things," so incorporating a change based on the latest research evidence may require specific tools, including a practice guideline. In addition, the patients who visit the primary care practice that is the subject of the DNP project often do so for acute care needs. They come to the practice for symptoms of the flu, or an upper respiratory infection. The providers in the practice focus on the need at hand, and the day to day management of chronic illnesses rather than on prevention.

There were four people who served as members of the expert panel. The panel consisted of three nurse practitioners and one physician all in the primary care practice setting. The two medical facility sees roughly about an average of 25 to 30 patients a day with most patients coming in for acute problems not related to their preventive care needs. The practice guideline with accompanying support materials will potentially change what the nurse practitioners and doctors do with patients in the interest of prevention after full implementation which will occur outside of the DNP project's scope. The medical assistants were also trained to print out the patient's last lab results and to attach these to the clipboard with the chief complaint. This allows the nurse practitioners and the physicians to have the patient's lab work results at hand as well as the guideline in the exam room to be able to implement the practice guidelines. If no recent labs are available, the medical assistant should write boldly no recent labs. To ensure that the

proposed practice guidelines be used, a recommendation for quarterly chart audits was made. The decision for chart audits is solely dependent on the key stakeholders and members of the expert panel who will be reviewing the guideline for use in the practice.

According to the Georgia Department of Health (2016), cardiovascular disease is the leading cause of deaths for the state. In 2008, coronary heart disease attributed to 179 deaths in the state of Georgia (Georgia Department of Health, 2016). Almost half of the population in Georgia from 2009-2010 has had high cholesterol levels. This is the reason this topic should be examined more closely in Georgia. Having the opportunity to conduct the DNP project at this setting will help to educate the nursing staff regarding the importance of the initiation of statin therapy and lifestyle modifications which can reduce patients' chances of developing heart disease. Some lifestyle modifications consist of maintaining a healthy diet and staying physically active.

Definitions of Terms

Clinical practice guidelines: A tool that is used to help manage the quality in healthcare transactions by focusing on the standardization of a specific care process (Lawal et al., 2016).

Cardiovascular disease: Includes hypertension, coronary heart disease, heart failure and stroke (Centers for Disease Control and Prevention [CDC], 2014).

Statins: Cholesterol lowering class of medications (CDC, 2014).

Role of the DNP Student

Leadership is an essential skill that is needed in order for the clinical guideline to be effective. A doctoral student should possess strong leadership skills in order to

persuade the stakeholders at the site. Change in an organization is not always embraced by staff. Currently I take on the role as a primary care provider expert in an outpatient center. My motivation for this doctoral project is that I have had a loved-one die from cardiovascular disease within months after the birth of her last child. Her death occurred in the ’90s and since that time healthcare has been much improved.

Anecdotally, staff members at the clinic report that preventive measures for chronic illness have not been a priority, and that there are many opportunities to focus on preventive care even though the primary reason for presentation is for an acute episode of illness. A clinical guideline to increase the prescription use of statin therapy would go a long way to changing practice at the site. I served as project leader for the development of the practice guideline and sought support from the staff during this process. A thorough and comprehensive literature review starting with main sources of evidence such as original research findings and systematic reviews was conducted and presented. I developed the clinical guideline and presented it to the staff for discussion, provided an adjusted workflow that assured implementation and readied a package for the expert panel to approve. I used the Rosswurm and Larrabee’s conceptual framework and the Agree II, Grade models for the development of the practice guideline. Using these conceptual framework models, stakeholder contribution is considered, plus the patient, the practice providers and the practice structure.

Summary

Literature was presented that supports the use of clinical guideline to improve the prescription use of statin therapy to prevent cardiovascular disease. Implementing the use

of care pathway is a solution to increase statin therapy for cardiovascular disease prevention. Thus, filling the gap between the evidence-based guidelines and the current practice of no clinical guideline. This portion of this project focused on the theoretical concepts needed to close the gap in current practice. The next segment of the project will re-visit the problem-focused question and review evidence needed and generated for the development of the project.

Section 3: Collection and Analysis of Evidence

Introduction

The purpose of this practice guideline project was to develop a standardized clinical guideline for the primary care facility nurses and practitioners, specifically around the prescription of statins as it relates to heart disease. To advance positive social change, the initiation of statin therapy for those at risk needs to be addressed with evidence-based strategies and interventions. Presently, at the DNP project setting, most patients come to the primary care practice for minor acute illness; preventive care is not often a priority. Consequently, patients at risk for CVD often are not prescribed statin therapy, nor are they advised on lifestyle modifications that can also be effective in preventing CVD. This project was developed to decrease the incidence of heart disease to those at risk. The goal of this pathway is to increase the prescription use of statins at the primary care facility for those patients at risk for heart disease. When implemented by the organization, the new evidence-based clinical guideline will address the clinical practice gap to initiate statin therapy for those individuals at risk. In the next segment of the project, the practice question will be reviewed along with sources of evidence collected and used.

Practice Focused Question

In the primary care setting, implementation of a clinical guideline is useful to assist clinical personnel in the primary care setting, such as physicians and nurses for patient care (Grimsmo et al., 2018). Presently, as most patients come to the clinic for an acute episode of minor illness, like upper respiratory infections, attention to preventive

care of any kind is not embedded in the practice. This represents the most prominent gap in practice. The practice guideline presents a systematic way for treatment decisions in the primary care facility that may increase the prescription of statin drugs to help prevent heart disease.

The practice-focused question guiding this project is as follows: In a primary care clinic serving adult and geriatric patients, will an evidence-based clinical guideline that can potentially impact the prescription of statins for the prevention of cardiovascular disease be approved for implementation? Full implementation and evaluation of this clinical guideline is the responsibility of the stakeholders at the practice site. The clinical guideline will serve as a guide for the organization. The goal of this clinical guideline is to identify those at risk for coronary heart disease and to initiate statin therapy for prevention purposes.

Sources of Evidence

Published Outcomes and Research

Clinical guidelines are useful in improving patient outcomes when practice is based on sound evidence (Williams & Radnor, 2017). Sources of evidence for this practice guideline project consist primarily of literature that summarizes the positive effects of the use of statins in primary care. CINAHL and Medline databases were searched. Key terms used for the literature search were *coronary heart disease, cardiovascular disease, heart disease, prevention of heart disease, statin therapy, statin indications and contraindications,* and *additional strategies needed*. The collection of

evidence was facilitated by accessing scholarly journals, Georgia Department of Health and the CDC website. The initial search period was between the years 2002 and 2018.

Evidence Generated for the Doctoral Project

Participants. There were three nurse practitioners (NPs) and one internal medicine physician working in the primary care clinic that was the setting for this DNP project, which has two different geographic locations. As clinical practitioners, their activities are directly related to the implementation of the guideline in terms of diagnosing and prescribing medications. The physician is the owner of the practice, and as such, sets the tone for decision-making at the practice. The three NPs do have some autonomy in the practice and serve as licensed advanced nurse practitioners with prescriptive rights (APRN/NPs). Their input, review and evaluation of the practice guideline are necessary as they will address the practicalities of implementation.

Procedures. The evidence-based clinical guideline was presented to a panel of experts to provide feedback that meets criteria in their expert opinion. I provided education on the use of the clinical guideline using a PowerPoint to provide an overview of the guideline for the expert panel. The clinical practice guideline with its accompanying algorithm for managing statin use is found below in Figure 1. Also, a tip sheet with a single page of instructions can be found in Appendix B.

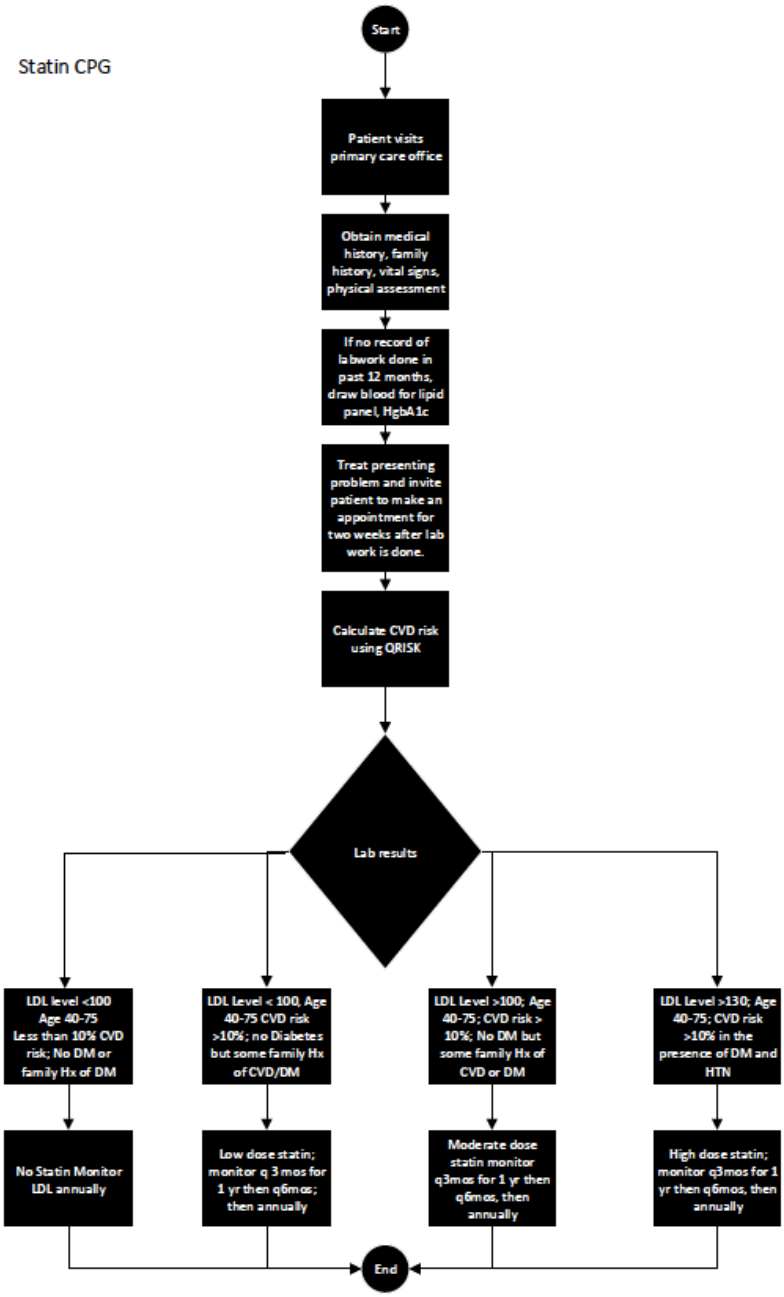

Figure 1. Statin clinical practice guideline for practice use.

There were three two-hour sessions held at each of the two primary care locations to review the details, the revised workflow, algorithm, and clinical guideline being

implemented. The three sessions were the same. This guaranteed that all staff who are required to attend had the opportunity to do so. Education on the clinical guideline was provided. Each clinical staff member was given a copy of the manual and the clinical guideline. Time was allowed for questions and discussion during the presentation of the clinical guideline. Within the DNP project, meetings were held with the nursing staff to define the process for the use of a clinical guideline to increase the prescription use of statin drugs to those patients at risk for heart disease.

The involvement of the expert committee was crucial for the development of the clinical guideline. The participants who were selected were invited by personal request to participate in the review process. There were four panel members who are experts in primary care with a total of over four years of experience in the practice setting.

Protections. The Walden IRB manual for a practice guideline DNP project was followed. The medical director at the site had verbally expressed a commitment to the project and signed the consent. The site does not have an IRB therefore the project was deferred to Walden IRB for protection of human subjects, approval number 06-19-19-0553962.

Analysis and Synthesis

According to Mengual-Andrés, S et al. (2016), the Delphi method has been used for various projects. It assists in the use of expert opinions for different program planning projects. This was applied to the final clinical guideline. This method allowed for feedback as necessary to assure the ultimate success of the guideline in shaping preventive care at the practice. This method allowed for expert feedback on their

willingness to proceed to full implementation. The clinical guideline provided a step by step process on the implementation of statin therapy at the primary care facility.

The Delphi method was used to achieve consensus, increase communication to accomplish certain goals or policy development. The Delphi process consisted of different rounds. In round one open ended questions were used to gather the information (see Appendix D). Round two included additional open-ended questions as well as feedback from round one. The purpose of the questions in the first two rounds was to elicit any needed revisions, or any anticipated barriers to implementation. By the time of round three consensus from the panelists regarding their full support for use of the practice guideline to improve preventive care, in this case, statin therapy for the at-risk individuals was achieved. Rationale on why a clinical guideline in place would be beneficial on the implementation on statin therapy to the at-risk individuals to prevent coronary heart disease was reviewed. The last round, round three, summarized the opinions by the expert panel. The practice guideline for statin therapy implementation was then validated with plans for implementation defined.

Summary

The DNP project proposed is to develop a standardized practice guideline to increase the prescription use of statin therapy for those at risk for heart disease. The practice guideline was developed and presented to an expert panel for their review and consensus, approving the guideline for full implementation at the practice. Section 4 will provide the results of the DNP project.

Section 4: Findings and Recommendations

Introduction

The purpose of this doctoral project was to develop a standardized clinical guideline for primary care facility nurses, practitioners, and physicians, guiding them to prescribe statins when indicated to prevent the emergence of heart disease. The practice-focused question that guided this project was: In the primary care clinic serving adults and geriatric patients, will an evidence-based clinical guideline impact the prescription of statins for the prevention of cardiovascular disease be approved for implementation? Full implementation and evaluation of this clinical guideline is the responsibility of the stakeholders at the practice site. The local gap in practice was that patients come to the clinic for primarily for acute issues and attention to preventive care of any kind was not embedded in the practice.

Findings and Implications

There were three nurse practitioners all who have been nurse practitioners for a minimum of 4 years and a physician with over 10 years of experience who participated as members of an expert panel. There are two primary care clinics in the practice, both located in the inner city of a metropolitan Georgia area. The three nurse practitioners do have some autonomy in the practice with prescriptive rights. At both primary care clinics, 40% of the current patient population had presented with risk factors for heart disease but had not been prescribed a statin. A further breakdown showed that 60% of that number were geriatrics and 45% were women.

Underprescription of statins for patients at risk for heart disease remains a problem at this site's clinic. Underprescription of statins for patients who present with risk factors may lead to an increased number of patients who develop heart disease. This doctoral project allowed for the issue of underprescription of statins to be analyzed in a primary care setting and for nursing interventions to be implemented to address this gap in practice.

Cardiovascular disease is a leading cause of death among the elderly patient population (Meid et al., 2015). The basis of this doctoral project was for the use of a clinical practice guideline to address the underprescription of statins to at-risk patients. This project was developed as a clinical practice guideline to increase health literacy for nurses, practitioners, and physicians.

During the three sessions, an in-depth review of the practice guideline was provided. In addition, feedback from the expert panel was secured. All four providers agreed that the clinical practice guideline represents recent research evidence and was well-founded. During the first session there were a few questions, but by the third session, everyone that this would be best practice for the clinical site.

One limitation was the number of practitioners involved with the project. Four is relatively a low number; therefore, generalizability was not conclusive based on the full representation of workers at the clinic. There were more nurses and other physicians in the clinic as well as medical assistants who were not involved in the education on the use of the clinical guideline; only a select few were involved based on their experience. The

findings from the three sessions showed that the medical professionals involved understood the importance of statins and how they can help reduce heart disease.

The findings implied that when this clinical practice guideline is fully implemented and in place at the site of the doctoral project that the nurse practitioners and physicians are willing to use it. As a matter of fact, discussion on implementation date was raised up by the primary stakeholder (the owner of the clinic) to the other medical professionals involved during the second session. The results reflected in this doctoral project demonstrate that opportunities remain for the use of clinical practice guidelines in primary care to help provide evidence-based practice to all patients at the site. During one of the expert panel sessions, a question was raised by one of the nurse practitioners regarding what should be done if the patient is not a candidate for statin therapy. An example that the nurse practitioner gave was that she had a patient that was a candidate for statins but could not tolerate statins in general. The patient experiences extreme joint pain and her creatine kinase levels become abnormally high. She asked, what are other options for patients like this one? I later explained to that nurse practitioner that what I do in this case scenario where a statin is not tolerated by the patient is that I offer fish oil. Depending on the LDL levels and triglyceride level I may also prescribe Gemfibrozil. I further explained to her that Gemfibrozil mainly targets the triglyceride level but also has some effect on the LDL level. All together everyone agreed to adopt the practice guideline. There were no additional questions besides the one. Proposed date for implementation was set for September 9, 2019. The implementation plan includes the need to provide thorough education for all the clinical staff members,

not just those who were included in the expert panel. Poster boards will be constructed to job specifications. For instance, the first board will map out intake process for the medical assistants. The next board will be for the nurse practitioners and physicians. Last board will discuss check out and the need for follow up. The education will take place different days to accommodate everyone at the practice.

This doctoral project provides awareness on the under-prescription use of statins to those at risk for the prevention of heart disease at this doctoral site. This project allowed for a nurse practitioner led education to occur to other fellow nurse practitioners and physician involvement to create positive social change. Focusing on this practice problem within the practice will improve quality health outcomes for patients.

Recommendations

Based on the findings within this doctoral project, I recommend the implementation of this clinical practice guideline to help bring awareness to the issue and increase the prescription use of statins which in turn can decrease a patient's chances of developing heart disease. This project contributed to addressing the gap in practice regarding under prescription use of statin therapy for the prevention of heart disease and the site lack of a clinical guideline in place to address the gap in practice. This clinical guideline will help improve patient care and increase the use of evidence-based care. As patients' statuses may change a review of this clinical practice guideline may be needed.

It is important to develop a quality improvement project over the next six months to determine the impact of the statin guideline. The quality improvement project should include the number of patients prescribed a statin every month for six months. If certain

patients were missed, then a case review of those patients should be reviewed and discussed.

Strengths and Limitations

The strength within this doctoral project was that it used an algorithm in order to address the need of primary care providers involvement as well as nurses and medical assistants. The algorithm is easy to follow and comes with a manual on how to use the practice guideline. Recommendations for future projects will address issues that may cause medication nonadherence and alternatives for patients who cannot tolerate statins. Another recommendation will be, to involve a larger amount of nurse practitioners, physicians and other medical personnel as well as provisions for patient feedback.

My plan is to disseminate this work to both clinics in the practice since each had experienced the practice problem. The algorithm should be posted in all exam rooms and placed on clip boards of all medical assistants. Other clinical personnel such as the medical office manager should have those materials as well. It is then left for the stake holder to push implementation. Suggestions of quarterly chart audits was also recommended. Limitations was getting the staff together. This will also be a challenge during the time to educate other staff members before implementation of the guideline.

Section 5: Dissemination Plan

Dissemination Plan

The issue of underprescription of statins to help prevent heart disease for those patients at risk continues to be a problem in the healthcare setting. The findings and work from this project will be disseminated to provide awareness of this issue in primary care. Based on the nature of this project, the audiences and venues that will be appropriate for project dissemination consist of primary care providers (nurse practitioners, physicians, physician assistants) who are medically trained to diagnose. Registered nurses should be used as patient advocates who will alert the primary care providers when there is a need for statin therapy. This project is appropriate for an outpatient primary care setting as well as cardiology practices and even hospital inpatient units who discharge patients to home.

Analysis of Self

In this section, I provide an analysis of myself in the role of a nurse practitioner, scholar, and project manager. As a practitioner, I will address a practice area that has been underserved. In this practitioner role, I noticed that this project increased my awareness of the need to ensure evidence-based practice in primary care not only to promote statin use for the prevention of heart disease but also to promote preventive medicine. As a scholar, I found that this project gave me skills and insight I needed to render evidence-based practice to support positive health outcomes in the primary care sector. In the role of project manager, I fully understood the importance of interdisciplinary communication.

The completion of this project resulted in the support of the clinical practice guideline for implementation. The challenge was getting the expert panels together for the three sessions. The solution was for me to take time off work and to adapt to their schedules. To gain insights, I developed a PowerPoint presentation and open-ended questions for the expert panel.

Summary

Clinical practice guidelines are important to maintain continuity of quality care as it relates to statin therapy and the prevention of heart disease. This doctoral project sought to develop a clinical practice guideline that would promote the use of statins to help prevent heart disease, and approval from the expert panel for implementation was achieved. Implementation was not achieved and was not a part of this project but plans for implementation were discussed.

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Appendix A: Literature Matrix

Using the GRADE system, each entry on the list is ranked accordingly:

Author(s)	Year	Publication	Brief Overview	Level of Evidence
Gamboa, C. M., Safford, M. M., Levitan, E. B., Mann, D. M., Yun, H., Glasser, S. P., ... & Muntner, P.	2014	*The American journal of the medical sciences*	Theoretical explanation of the statin underuse and low prevalence of LDL-C control and the risk of coronary heart disease in adults.	VII
Meid, A. D., Quinzler, R., Freigofas, J., Saum, K. U., Schöttker, B., Holleczek, B., ... & Haefeli, W. E.	2015	*PLoS one*	A cohort study on the underuse of medication with the elderly.	IV
Chou, R., Dana, T., Blazina, I., Daeges, M., & Jeanne, T. L.	2016	*Journal of geriatric cardiology*	A systematic review of statins for the prevention of heart disease.	I
Pedro-Botet, J., Climent, E., Chillarón, J. J., Toro, R., Benaiges, D., & Flores-Le Roux, J. A	2015	*Journal of geriatric cardiology*	Theoretical explanation for statin use and CVD prevention in the elderly.	VII
Go, A. S., Mozaffarian, D., Roger, V. L., Benjamin, E. J., Berry, J. D., Blaha, M. J., ... & Fullerton, H. J.	2014	*Circulation*	Statistics on heart disease and stroke prevalence.	VI
LeFevre, M. L.	2014	*Annals of internal medicine*	Theoretical explanation on behavioral counseling to promote healthful diet and physical activity for cardiovascular disease prevention in adults with cardiovascular risk.	VII

Gurzick, M., & Kesten, K. S	2010	*Journal of Professional Nursing*	Discussed the importance of clinical guidelines in healthcare.	VI
Quinn, G. R., Ranum, D., Song, E., Linets, M., Keohane, C., Riah, H., & Greenberg, P. (2017).	2017	*The Joint Commission Journal on Quality and Patient Safety*	Discussed missed diagnosis of cardiovascular disease in primary care using malpractice claims data.	V
Müller, M. K., Dedes, K. J., Dindo, D., Steiner, S., Hahnloser, D., & Clavien, P. A.	2009	*Langenbeck's archives of surgery*	Studied the impact of clinical guideline post-surgery.	II
Hayman, L. L., Berra, K., Fletcher, B. J., & Miller, N. H	2015	global cardiovascular nursing leadership forum	The role of nursing in heart disease prevention.	VII
Thomas, J. J., Hart, A. M., & Burman, M.	2014	*The Journal for Nurse Practitioners*	Describes the importance of behavioral theories to NP-healthcare delivery in primary care	VII
Benjamin, E. J., Blaha, M. J., Chiuve, S. E., Cushman, M., Das, S. R., Deo, R., ... & Jiménez, M. C.	2017	*Circulation*,	Discussed the prevalence through statistics on heart disease and stroke.	V
Lubna, S. R.	2014	*Conference*	Used a meta-analysis to predict and discuss risk factors for coronary heart disease.	I
Gander, J., Sui, X., Hazlett, L. J., Cai, B., Hébert, J. R., & Blair, S. N	2014	*Preventing chronic disease*	Studied cardiovascular risk in men.	I
Pencina, M. J., Navar, A. M., Wojdyla, D., Sanchez, R. J., Khan, I., Elassal, J., ... & Sniderman, A. D.	2019	*Circulation*	Observational cohort showing the importance of major risk factors of cardiovascular disease.	IV

Lawal, A. K., Rotter, T., Kinsman, L., Machotta, A., Ronellenfitsch, U., Scott, S. D., ... & Groot, G.	2016	*BMC medicine*	Theoretical explanation for what is a clinical guideline and its importance.	V11
Grimsmo, A., Løhre, A., Røsstad, T., Gjerde, I., Heiberg, I., & Steinsbekk, A.	2018	*Scandinavian journal of primary health care*	Studied the importance of clinical guidelines use in primary care using a mixed method exploratory design.	V
Short, V. L., Ivory-Walls, T., Smith, L., & Loustalot, F	2014	*Epidemiology Research International*	Reviewed human surveys on cardiovascular health in the Mississippi Delta region using address based sampling.	VI
Yusuf, S., Bosch, J., Dagenais, G., Zhu, J., Xavier, D., Liu, L., ... & Avezum, A.	2016	*New England Journal of Medicine*	A double blind randomized study that studied the importance in lowering LDL levels with statins for prevention of CVD.	II
Lloyd-Jones, D. M., Morris, P. B., Ballantyne, C. M., Birtcher, K. K., Daly, D. D., DePalma, S. M	2016	*Journal of the American College of Cardiology*	Theoretical explanation on the role of healthy life style changes a long with statins for CAD prevention.	VII
McNaughton, R. J., & Shucksmith, J.	2014	*Journal of Public Health*	Qualitative study on why patients who are at high risk for CVD are non-compliant.	VI
Tehrani, J., Michell, V., & Pan, Y. C.	2018	Springer	Studied the correlation between clinical guidelines and reducing medical errors using a systematic approach.	I
Sheppard, J. P., Fletcher, K., McManus, R. J., & Mant, J	2014	*Br J Gen Pract*,	A cross sectional study showing missed CVD diagnosis in primary care.	II
Johnson, K. B., Blaisdell, C. J., Walker, A., & Eggleston, P	2000	*Pediatrics*	A randomized control trial on the usefulness of a clinical guideline for patients admitted in the hospital for asthma management.	I

Panella, M., Marchisio, S., & Di Stanislao, F	2003	*International Journal for Quality in Health Care*	Studied the importance of clinical guidelines and its overall outcome and the positive effects in providing quality healthcare.	IV

Literature Matrix Key with level I Ranked the Highest

Systematic review or meta-analysis	A production of evidence randomized controlled studies	Level I
Randomized controlled trial	that subjects are placed in a control group	Level II
Controlled trial without randomization	A trial with subjects being randomly placed in a control group	Level III
Case-control or cohort study	A comparison of subjects that have a certain problem with those who don't have the problem. Cohort is observational	Level IV
Systematic review of qualitative or descriptive	Assembles evidence from studies that are qualitative or descriptive.	Level V
Qualitative or descriptive study Qualitative	Gathers info on reasoning behind certain behaviors. Descriptive studies surroundings and the who what when	Level VI
Expert opinion or consensus	Personal opinion of the author or researcher.	VII

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Appendix B: Statin use Clinical Guideline Curriculum

Learning Outcome(s): NPs will properly prescribe statins as a preventive measure in the primary care setting.			
Topical Content Outline	Time frame	References	Teaching method/learner engagement and Evaluation method
What are statins Cholesterol lowering medications in patients at risk for developing coronary artery disease	15 minutes	Jones et al., 2016	PowerPoint
CAD CAD is the buildup of plaque in the arteries of the heart which restricts the necessary blood flow to the heart).	30 minutes	Gander et al., 2014	PowerPoint Question answer sessions
How to use the clinical guideline In a primary care setting, a clinical guideline can be used to screen and identify those at risk for CAD and treat them with statin therapy to help prevent the development of coronary artery disease. A clinical guideline improves the quality of health and outcomes for patients with various diseases	30 minutes	Lawal et al., 2006.	Picture Case studies
Questions	15 Minutes		Brief discussion with participants.

Appendix C: Tips for Using the Statin use Guideline in Primary Care

Part I. The initial visit

- It is important to gather important data such as patient's medical history, family history, vital signs and physical assessment of the patient.
- Next, routine labs should be collected with specific attention to hemoglobin A1c (HgA1c) level and low density lipoprotein (LDL). HgA1c is a blood test that measures glucose concentration over a three month period (Silva, Ana Paula, et al 2013).
- A two week follow up appointment will be given to the patient to review the patients' results.

Part II. Follow up visit

The patient arrives for their two weeks follow up appointment.

- If the LDL is greater than or equal to 190, statin therapy should be started.
- If not then next we need to look to see if the HgA1c is greater than 6.4 or if the patient has already been diagnosed previously as a diabetic and LDL is 70-189. A statin should be considered if this is the case.
- If LDL is low and patient is not a diabetic then the risk for cardiovascular disease should be calculated using QRISK3. The QRISK3 estimates a person's risk for developing heart disease within the next ten years. The website where you can find the QRISK3 calculation is https://qrisk.org. Pending on patient's individual QRISK scores will determine the need for statin to be initiated to those individuals with a normal LDL and HgA1c level.

Appendix D: Open-Ended Questions for Expert Panel

Round 1:

1. After hearing the presentation and reviewing the practice guideline for statin use in primary care, what are your immediate impressions?
2. What barriers or obstacles do you see if you were to implement the practice guideline?
3. What revisions would you like to see before implementation?

Round 2:

1. What concerns do you have about the implementation plan?
2. How will you monitor and measure the impact of the practice guideline on care in the future?
3. How will you know that the practice guideline is having an impact on preventive care at the primary care practice?

Round 3:

1. Do you have any additional concerns that you would like to see addressed? If so, please state them now. If not, process to the next question.
2. Do you approve the practice guideline for full implementation?
3. What start date do you recommend?