ASPIRIN AND STATIN USE FOR PRIMARY PREVENTION OF CARDIOVASCULAR DISEASE

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Natalie Jean Carriveau

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Natalie Jean Carriveau

The Supervisory Committee certifies that this ***disquisition*** complies with North Dakota State University's regulations and meets the accepted standards for the degree of

DOCTOR OF NURSING PRACTICE

SUPERVISORY COMMITTEE:

Dean Gross, Ph.D., FNP-BC
Chair

Mykell Barnacle, DNP, FNP-BC

Lisa Montplaisir, Ph.D.

Tara Brandner, DNP, FNP-C

Approved:

3/1/2022
Date

Carla Gross, Ph.D.
Department Chair

ABSTRACT

Cardiovascular disease (CVD) is the leading cause of morbidity and mortality in the United States and aspirin and statins are well-known medications associated with CVD prevention. There are well-known benefits of aspirin for secondary prevention of CVD, but aspirin's role in primary prevention remains controversial. The decision to start aspirin for primary prevention is individualized to the specific patient and situation. Statins are a drug used as first-line therapy in cholesterol management, though there is a complicated relationship with adherence due to real and/or perceived safety issues associated with statin use. The decision to start statins needs to be determined on an individualized basis.

The United States Preventive Services Task Force (USPSTF) has level B recommendations for low-dose aspirin (81 mg) and level B recommendation for statins in primary prevention of CVD. However, preliminarily updated recommendations for aspirin use in late 2021 are proposing the decision to change aspirin use to a level C recommendation. In addition, the American Heart Association (AHA) and American College of Cardiology (ACC) developed a calculator in 2013 to determine a patient's 10-year CVD risk. The guidelines coupled with the risk calculator offers providers a valuable decision-making tool. However, despite available guidelines and the calculator, aspirin and statin prescription and adherence remains suboptimal.

The purpose of the project was successful adoption of the 2016 USPSTF guideline on aspirin and statin use for primary prevention of CVD by North Dakota State University (NDSU) staff participating in a NDSU Health Screening. The screening collected participant data, recorded data into the calculator, and provided recommendations based off the USPSTF guidelines for participants to discuss with their primary care provider (PCP).

Evaluations were performed through use of post-implementation surveys. Results demonstrated proper participant use of aspirin and statins according to USPSTF guidelines, with a majority expressing awareness of the guidelines. Participants reported a positive viewpoint of the calculator and intent to provide results to their PCP. Conclusively, the project supports use of the 2016 USPSTF guidelines regarding the use of aspirin and statins for primary prevention of CVD along with the risk calculator in health screenings and primary care.

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There are many individuals who have aided in the successful completion of my dissertation. I would like to extend recognition and my deepest gratitude to my committee chair, Dr. Dean Gross. If not for his seemingly endless knowledge and patience during this project, this dissertation would not have been nearly as successful as it was. I am forever appreciative of having had such a phenomenal mentor during my time in this program. I would also like to extend my appreciation to my other committee members: Dr. Mykell Barnacle, Dr. Lisa Montplaisir, and Dr. Tara Brandner. Their feedback, guidance, and expertise were vital to the success of this dissertation project.

DEDICATION

I would like to dedicate this dissertation to my family and friends. I would first like to thank my husband, Jason. If I could give him an honorary doctoral degree, I would. His unwavering support, positivity, and confidence in me was exactly what I needed when I had a difficult time seeing it in myself. I'm not sure how I would have done this without him, and I am glad I didn't have to. Now let's go take the dogs on a really long walk.

I would also like to thank my parents, Doug and Vicky, for always supporting me throughout all of my educational endeavors and life in general. I credit them for my work ethic and desire to care for others with integrity and compassion because I learned it from them. I would also like to thank my siblings, Jeni, Denise, and Adam, for their support, as always.

I do not know how I became so fortunate to be surrounded by so many compassionate, caring, and supportive friends and family. My appreciation for everything they have all given me is truly overwhelming and not overseen. As I finish this educational journey, if you find yourself reading this dedication know that you contributed somewhere along the way and for that I am thankful.

TABLE OF CONTENTS

LIST OF TABLES

LIST OF FIGURES

LIST OF ABBREVIATIONS

CVD .....Cardiovascular Disease

ASCVD .....Atherosclerotic Cardiovascular Disease

USPSTF .....United States Preventive Services Task Force

AHA .....American Heart Association

ACC .....American College of Cardiology

NSAID .....Nonsteroidal Anti-inflammatory

MI.....Myocardial Infarction

GI .....Gastrointestinal

CHAPTER 1: INTRODUCTION

Background and Significance

Cardiovascular disease (CVD) is the leading cause of morbidity and mortality in the United States (Xu et al., 2020). The American Heart Association (AHA) reports that 121.5 million people, or approximately 48% of Americans, have at least one form of CVD (AHA, 2019). The AHA (2019) estimated that CVD costs reached $351.2 billion in the United States in 2014-2015, with total direct medical costs projected to increase to $749 billion by 2035.

Aspirin inhibits cyclooxygenase-1 (COX-1), which is known as a potent vasoconstrictor, and thereby decreases platelet aggregation, reducing thromboembolic potential and prolonging bleeding time (Smith et al., 2019). These effects can carry health benefits but can also increase potential for risks. The benefits of low-dose aspirin in patients as secondary prevention with previous myocardial infarction (MI), stroke, or transient ischemic attack (TIA) is supported by numerous studies and hundreds of thousands of patients (Gaziano et al., 2018). The role of aspirin as primary prevention for CVD has remained controversial, despite 30 years of randomized trials (Gaziano et al., 2018).

The potential benefits of using aspirin for the primary prevention of CVD are complicated by the fact that aspirin invariably increases risk for major gastrointestinal (GI), intracranial bleeding, and hemorrhagic stroke, depending on the patient's medical history and other factors (Bibbins-Domingo, 2016a). Risk factors for complications include higher dose and duration of aspirin use, history of GI ulcers or upper GI pain, bleeding disorders, renal failure, severe liver disease, concurrent anticoagulant or nonsteroidal anti-inflammatory drug (NSAID) use, uncontrolled hypertension, male sex, and older age (United States Preventive Services Task Force [USPSTF], 2016). Ultimately, the decision to place a patient on aspirin for primary

prevention of CVD is an individualized one made to the specific patient and situation (Bibbins-Domingo, 2016a).

As dyslipidemia plays a key role in the development and mortality of CVD, the common lipid-lowering drugs known as statins have become the first-line therapy used to lower high plasma cholesterol (Li et al., 2019). Statins are a class of lipid-lowering medications that function by inhibiting the enzyme 3-hydroxy-3-methyl-glutaryl coenzyme A reductase, which is involved in the rate-limiting step in the production of cholesterol (USPSTF, 2017). Statins reduce levels of total cholesterol and LDL and, to a lesser extent, triglycerides, plus hold the added benefit of anti-inflammatory and plaque stabilization effects (USPSTF, 2017). High blood cholesterol levels are associated with increased risk of CVD events and deaths and use of statins is associated with a significant reduction in that risk (Yang et al., 2017).

Though the benefits of statin therapy for primary prevention of CVD is evident, risks remain. Statins come with potential adverse effects including myopathy, new-onset diabetes mellitus, and hemorrhagic stroke (Collins et al., 2016). Most notoriously, muscle symptoms such as myalgias and rhabdomyolysis are common contributors to discontinuation of statin therapy, which is estimated to occur in 10% of patients in the United States (Newman et al., 2018). Individuals who discontinue statins early have an increased risk of MI and CVD death (Newman et al., 2018). Other potential risks, such as an increased risk of any cancer, cognitive harms, cataracts, or renal dysfunction, have limited data to support them as tangible risks (Chou et al., 2016).

Currently, the USPSTF recommends the initiation of low- to moderate-dose statins in adults aged 40-75 years without a history of CVD who have one or more risk factors and a calculated 10-year CVD event risk of 10% or greater (Bibbins-Domingo, 2016b). Limited

information is available about use of high-dose statins in a primary prevention population, and as such, the decision about dose should be based on shared decision-making between patients and providers (USPSTF, 2017). An important consideration to make is that the most directly applicable body of evidence for patients without a history of CVD demonstrates benefits with use of low- and moderate-dose statins (USPSTF, 2017). As a result, the use of statins for primary prevention of CVD needs to be determined on an individual basis.

Problem Statement

According to Bibbins-Domingo (2016a), nearly 40% of adults over 50 years of age use aspirin for primary and secondary prevention of CVD. Data from the 2017 National Health Interview Survey shows that among adults aged 40 years or older without CVD, 23.4% report taking daily aspirin for prevention of CVD and of these, 22.8% did so without a provider's recommendations (O'Brien et al., 2019). Among patients who are eligible for aspirin therapy and were at an increased risk of CVD, only 41% reported that they were told by a provider to take aspirin (Bibbins-Domingo, 2016a). Similarly, 41.8% of U.S. adults eligible for statin use were actually taking the medication (Ngo-Metzger et al., 2018). Despite the cardiovascular benefits of statins, studies show that after 3 years less than 40% of patients continued taking statins for primary prevention and less than 45% for secondary prevention (Spence & Dresser, 2016).

Current recommendations and guidelines related to aspirin administration for primary prevention of CVD varies among associations. The American College of Cardiology/American Heart Association (ACC/AHA) recommends low-dose aspirin (75-100 mg) as a consideration for select adults 40 to 70 years of age who are at higher risk for CVD but not an increased risk of bleeding (Marquis-Gravel et al., 2019). The ACC/AHA does not recommend low-dose aspirin for those at an increased risk of bleeding of any age as well as those over the age of 70 years

(Marquis-Gravel et al., 2019). The American Diabetes Association recommends aspirin 75-162 mg daily for patients with diabetes mellitus at increased risk for CVD (Marquis-Gravel et al., 2019). The American Stroke Association recommends the use of low-dose aspirin for CVD prevention in adult whose risk is high and benefits outweigh risks of treatment (Bibbins-Domingo, 2016a). Currently, the US Food and Drug Administration recommends against the routine use of aspirin for primary prevention of CVD, and as a result does not provide guidance on labels in relation to dose for CVD prevention (Smith et al., 2019).

The fear of myopathies and other statin-induced adverse events play a key role in discontinuation of statin therapy, strengthened by patient information leaflets and internet information emphasizing the negative effects, as well as provider warning of development of muscle-related symptoms (Newman et al., 2019). Statins can effectively decrease the occurrence of angina, nonfatal and fatal MI, coronary revascularization, ischemic stroke, and cardiovascular mortality (Bibbins-Domingo, 2016b; Li et al., 2018). However, patients and providers may discontinue statins simply due to the fear of side effects, which may or may not be truly related to the treatment, thus increasing their risk of CVD-related morbidity and mortality (Newman et al., 2019).

Guidelines among associations for aspirin as primary prevention of CVD are not consistent, making difficult or unclear direction for providers to follow recommendations. Hesitance by providers and patients to initiate or continue statins for primary prevention of CVD due to the potential adverse events creates difficulty in following the guidelines available. As a result, adherence and prescription rates are sub-optimal. The USPSTF has guidelines in place regarding the use of aspirin and statins for the primary prevention of CVD. In addition, the ACC and AHA have developed a calculator that helps determine a patient's 10-year CVD risk. The

calculator and guidelines aid providers in the decision to start, stop, or continue aspirin and statins for primary prevention based on risk. Due to the aforementioned lack of adherence and prescription by eligible adults to recommended medications, improved provider education and the risk calculator coupled with the 2016 USPSTF guidelines may be a beneficial tool for providers to use to identify those at risk of CVD and more accurately prescribe medications, specifically statins and aspirin, to reduce that risk.

Purpose

The purpose of the project is successful adoption of the 2016 USPSTF guideline on aspirin and statin use for primary prevention of CVD by North Dakota State University (NDSU) staff participating in a NDSU Health Screening. The benefits of appropriate primary CVD prevention for patients eligible for aspirin and/or statin therapy and the associated risks of those therapies according to the USPSTF guidelines are addressed by the project. The knowledge gained by the participants will allow for increased awareness of the USPSTF guidelines for patients on proper use of aspirin and/or statins for primary prevention of cardiovascular disease.

Awareness of the subject is key for NDSU staff to understand the significance of the proposed project. Once the staff have increased awareness and understanding of the subject, the guideline is more likely to be adopted by the providers. Ideally, the staff members' providers will have a positive viewpoint of the USPSTF guidelines and plan to implement into their patient's plan of care.

Objectives

I. Data will be gathered from participants 40 years of age and older at the NDSU Health Screening in July 2021 to corroborate whether participants are taking aspirin and/or statins per the USPSTF guidelines.

II. Participants in the Health Screening will report awareness and practice of the current USPSTF guidelines related to aspirin and statin use for primary prevention of CVD and the cardiovascular risk calculator by the ACC/AHA by July 2021 through post-survey completion.

III. Participants in Health Screening will report a positive viewpoint related to the cardiovascular risk calculator by the ACC/AHA by July 2021 through post-survey completion.

IV. Participants in the Health Screening will agree to provide data from NDSU Health Screening on adherence to USPSTF guideline recommendations to their primary care providers.

CHAPTER 2: THEORETICAL FRAMEWORK AND LITERATURE REVIEW

A systematic review by Guirguis-Blake et al. (2016) reported a significant reduction in nonfatal MI and nonfatal stroke with the use of aspirin. However, current evidence indicates that the benefits of aspirin use varies among individuals based off risk factors such as age, sex, and race/ethnicity (USPSTF, 2016). While research supports the potential for benefits of aspirin use, evidence confirms that aspirin also increases risk of GI bleed and hemorrhagic stroke (Bibbins-Domingo, 2016a). Recent studies have shown that variations in dosage and formulation may have a clinically significant effect on bleeding risk (Smith et al., 2019). Subsequently, provider and patients need to be diligent in assessing the individual's risks and benefits of aspirin for primary prevention.

Large scale evidence from randomized trials shows that statin therapy reduces the risk of major vascular events, including coronary deaths, MIs, strokes, and coronary revascularization procedures, by about 25% for each mmol/L reduction in low-density lipoproteins (LDL) cholesterol during each year that a statin continues to be taken (Collins et al., 2016). However, statins come with the potential adverse effects including myopathy, new-onset diabetes mellitus, and hemorrhagic stroke (Collins et al., 2016). Rates of long term adherence to statin therapy are not optimal, with approximately 10% of patients discontinuing statin use (Newman et al., 2019). Clinical decisions about medications involve more than evidence alone and individualized decision-making specific to the patient and their situation should always be the forefront consideration (Bibbins-Domingo, 2016b).

List of Definitions

Cardiovascular disease. A broad term that encompasses a number of atherosclerotic conditions that affect the heart and blood vessels, including coronary heart disease. This definition is used interchangeably with atherosclerotic cardiovascular disease.

Dyslipidemia. A value of LDL>130 mg/dL or HDL<40 mg/dL.

Myalgia. Muscle pains or aches.

Myopathy. Muscle pain or weakness accompanied by a creatine kinase (CK) concentration >10 times the upper limit of normal (ULN).

Rhabdomyolysis. Severe form of myopathy, with CK typically >40 times ULN

Literature Review

Aspirin as Primary Prevention

CVD Risk and Risk Calculation

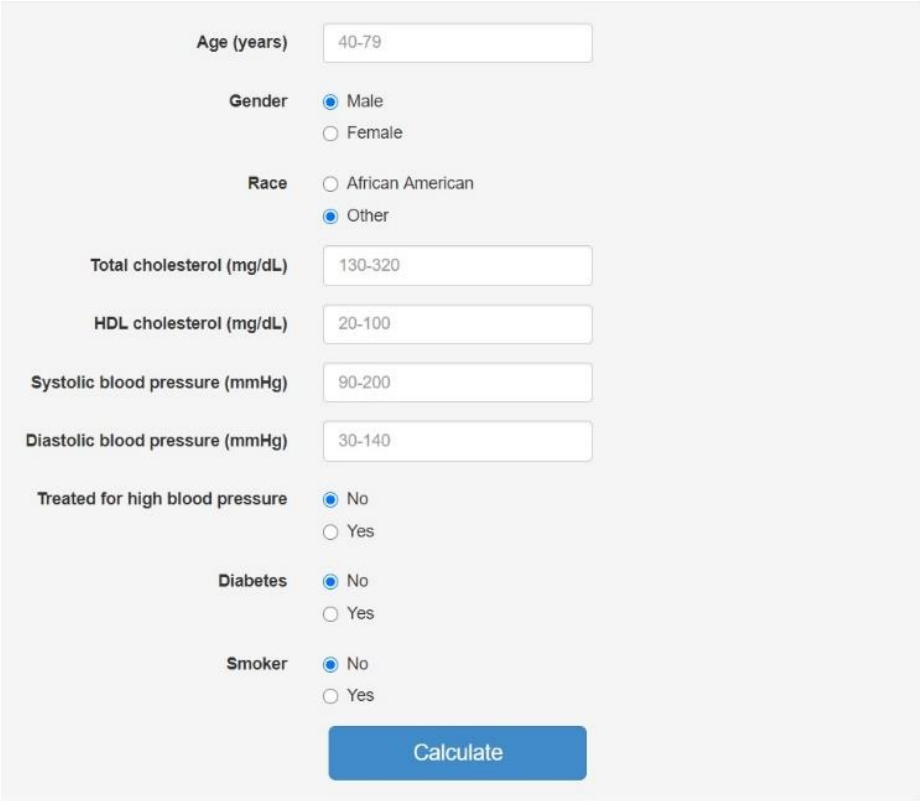
The USPSTF endorses the use of aspirin for the primary prevention of CVD in sex-, age-, and outcome-specific recommendations (Guirguis-Blake et al., 2016). The primary risk factors for CVD include older age, male sex, race/ethnicity, abnormal lipid levels, high blood pressure, diabetes, and smoking (USPSTF, 2016). A meta-analysis suggested that aspirin reduces MI risk in men and reduces the risk of ischemic stroke in women, while the effect on mortality is neutral among the genders (Marquis-Gravel et al., 2019). While there is consistent evidence suggesting enhanced effect on MI in older age groups, specifically women aged 65 years or older (Guirguis-Blake, 2016), caution is paramount due to the overall significant risks associated with those 70 years of age and older receiving aspirin (McNeil et al., 2018). Studies show that use of low-dose aspirin (81 mg) led to a 12% lower risk of serious vascular events in adults with diabetes mellitus and CVD benefits consistent with the benefits of those without diabetes mellitus (Bowman et al.,

2018). A cohort study by Fernandez-Jiminez et al. (2019) suggests that black patients are less likely to take aspirin for primary prevention of CVD and that low-dose aspirin use is not associated with decreased incidence of ischemic cardiac death as is seen in white patients.

The USPSTF calculates a patient's 10-year risk of developing CVD utilizing a risk calculator developed by the ACC/AHA (see Figure 1). This risk calculator utilizes pooled cohort equations to predict the 10-year risk for firsthand occurrence of hard atherosclerotic cardiovascular disease (ASCVD) events, which are defined as nonfatal MI, coronary heart disease death, and fatal or nonfatal stroke (USPSTF, 2016). The USPSTF selected this tool because of the broader focus on CVD outcomes, combining both cerebrovascular and cardiovascular outcomes versus strictly cardiovascular outcomes of earlier tools (Bibbins-Domingo, 2016a). Furthermore, external validation in various U.S. populations and reasonable performance in studies along with the use of cohorts that allowed for sex- and race-specific equations strengthened the tool for CVD risk estimation (Bibbins-Domingo, 2016a).

Figure 1

ACC/AHA Cardiovascular Risk Calculator



Note. A still image of the ACC/AHA risk calculator (Ahead Research, 2020)

The accuracy of the ACC/AHA risk calculator has come into question with concern that risk equation substantially overestimates actual CVD risk and delivers suboptimal accuracy in those with and without diabetes (Rana et al., 2016). However, an evaluation by Nguyen et al. (2019) exhibits a good overall quality of CVD risk calculation in adults 65 years of age and older. Ultimately, the ACC/AHA acknowledges the inherent limitations of over- and under-estimation of the 10-year CVD risk calculator and reiterate the importance of using the risk calculator as a decision-making tool that spurs the clinician-patient discussion regarding preventive CVD interventions (Arnett et al., 2019).

The 10-year risk calculation requires input of variables including age, total cholesterol, high-density lipoprotein (HDL) cholesterol, systolic blood pressure (SBP) and whether SBP is treated or untreated, diabetes mellitus status, and current smoking status (Arnett et al., 2019). The USPSTF then calculates recommendations for adults based off the 10-year risk of having a cardiovascular event (see Figure 2). Utilizing the percentage risk of a cardiovascular event in the next 10 years, providers may use these recommendations as a guideline in decision-making and weighing risks and benefits of placing a patient on aspirin for primary prevention. The USPSTF guideline recommends that this 10-year calculation be completed every 4 to 6 years for those who are considered low risk and free from CVD, and to consider completing the calculation less frequently in older individuals (over age 79) or those with limited life expectancy (Arnett et al., 2019).

Recommendations for aspirin as primary prevention of cardiovascular disease have been evolving over the past several decades. In 1997, the AHA did not recommend aspirin use for primary prevention as part of the original publication, citing the need for further research (Meyer et al., 2018). However, in 2002, major studies completed in the preceding years prompted the USPSTF, along with the AHA, to recommend aspirin 75-100 mg/day or 325 mg every other day for primary prevention, particularly in high-risk individuals with a 5-year CVD risk greater than or equal to 3% (Meyer et al., 2018). By 2009, the USPSTF refined their recommendations to include all men aged 45 to 79, to reduce occurrence of MI, and women aged 55 to 70, to reduce occurrence of stroke, as long as the patient's benefits outweighed the risks of bleeding (Meyer et al., 2018).

Figure 2

USPSTF Recommendations

Population	Adults aged 50 to 59 years with a ≥ 10% 10-year CVD risk	Adults aged 60 to 69 years with a ≥ 10% 10-year CVD risk	Adults younger than 50 years	Adults aged 70 years or older
Recommendation	Initiate low-dose aspirin use. Grade: B	The decision to initiate low-dose aspirin use is an individual one. Grade: C	No recommendation. Grade: I (insufficient evidence)	No recommendation. Grade: I (insufficient evidence)
Risk assessment	Primary risk factors for CVD are older age, male sex, race/ethnicity, abnormal lipid levels, high blood pressure, diabetes, and smoking. Risk factors for GI bleeding with aspirin use include higher aspirin dose and longer duration of use, history of GI ulcers or upper GI pain, bleeding disorders, renal failure, severe liver disease, and thrombocytopenia. The USPSTF used a calculator derived from the ACC/AHA pooled cohort equations to predict 10-year risk for first atherosclerotic CVD event.			
Preventive medication	Aspirin's anticlotting effect is useful for primary and secondary CVD prevention because it potentially decreases the accumulation of blood clots that form as a result of reduced blood flow at atherosclerotic plaques, thereby reducing hypoxic damage to heart and brain tissue. The mechanisms for inhibition of adenoma or colorectal cancer development are not yet well understood but may result from aspirin's anti-inflammatory properties.			
Treatment and dosage	A reasonable approach consistent with the evidence is to prescribe 81 mg per day (the most commonly prescribed dose in the United States), and assess CVD and bleeding risk factors starting at age 50 years and periodically thereafter, as well as when CVD and bleeding risk factors are first detected or change.			
Balance of benefits and harms	The benefits of aspirin use outweigh the increased risk of bleeding by a moderate amount.	The benefits of aspirin use outweigh the increased risk of bleeding by a small amount.	The evidence on aspirin use is insufficient and the balance of benefits and harms cannot be determined.	The evidence on aspirin use is insufficient and the balance of benefits and harms cannot be determined.
Other relevant USPSTF recommendations	The USPSTF has made recommendations on smoking cessation and promoting a healthful diet and physical activity, as well as screening for carotid artery stenosis, coronary heart disease, high blood pressure, lipid disorders, obesity, diabetes, peripheral artery disease, and colorectal cancer. These recommendations are available on the USPSTF website (http://www.uspreventiveservicestaskforce.org).			

Note. A summary of the USPSTF recommendation statement (USPSTF, 2016)

With the current 2016 recommendations, the USPSTF advises initiating low-dose aspirin as primary prevention of CVD and colorectal cancer (CRC) in adults aged 50 to 59 years who have a 10% or greater 10-year CVD risk, who are not at an increased risk for bleeding, have a life expectancy of at least 10 years, and are willing to take a low-dose aspirin daily for 10 years (USPSTF, 2016). This is graded as a B recommendation, with the USPSTF recommending to offer the service, as there is high certainty that the net benefit is moderate or there is moderate certainty that the net benefit is moderate to substantial (USPSTF, 2018).

The decision to initiate low dose aspirin as primary prevention of CVD and CRC in adults age 60 to 69 years who have a 10% or greater 10-year CVD risk should be an individualized one (USPSTF, 2016). Persons not at an increased risk of bleeding, have a life expectancy of at least 10 years, and are willing to take low-dose aspirin daily for at least 10 years are more likely to benefit from aspirin (USPSTF, 2016). Additionally, persons who place a higher value on the potential benefits than the potential harms may elect to initiate low-dose aspirin (USPSTF, 2016). This is graded as a C recommendation, in which the USPSTF recommends selectively offering the service to individual patients based on professional judgement and patient preferences, with at least moderate certainty that the net benefit is small (USPSTF, 2018).

Evidence is insufficient to assess the balance of benefits and harms of initiating aspirin use for the primary prevention of CVD and CRC in adults aged 70 years or older (USPSTF, 2016). This is an I statement, with the USPSTF concluding that evidence is lacking, of poor quality, or conflicting, and the balance of benefits and harms cannot be determined (USPSTF, 2018). Many adults aged 70 years or older are at an increased CVD risk because of their age and experience higher incidences of MI and stroke and could see substantial benefits (Bibbins-Domingo, 2016a). However, the relationship between older age and GI bleed are well-established and significant (Bibbins-Domingo, 2016a). The complexity of risk factors combined with the decreased CRC prevention observed contributes to the difficulty in assessing balance of benefits and harms (Bibbins-Domingo, 2016a).

The USPSTF concludes that the evidence of aspirin use to prevent CVD and CRC in adults younger than 50 years is insufficient to assess the balance of benefits and harms and also designate as an I statement (Bibbins-Domingo, 2016a). The risk for CVD events is lower in

adults aged 50 years or younger, but those in this age group who have an increased 10-year CVD risk may gain significant benefit from aspirin use, though precisely how much is unknown (Bibbins-Domingo, 2016a).

The magnitude of the health benefits is dependent on an individual's baseline CVD risk, CRC prevention, risk for bleeding, and general balance of benefits and harms (USPSTF, 2016). The decision about the risk at which potential benefits outweigh the potential harms is an individualized one and needs to be tailored based off of that unique individual's perceived benefits of reducing their CVD risk but increased likelihood of a bleeding event (Bibbins-Domingo, 2016a). Overall, the USPSTF determined the greatest net benefit to be gained is by adults aged 50 to 59 years whose 10-year CVD risk is 10% or greater, and recommends that persons in this age and risk group start taking aspirin (Bibbins-Domingo, 2016a). Adults aged 60 to 69 years may also benefit from starting aspirin, although the net benefits are smaller due to the increased risk for GI bleeding and decreased benefit from CRC prevention in this age group (Bibbins-Domingo, 2016a).

Bleeding Risk and Safety of Use

Risk factors for GI bleeding with aspirin use include higher dose and longer duration of use, history of GI ulcers or upper GI pain, bleeding disorders, renal failure, severe liver disease, and thrombocytopenia (USPSTF, 2016). Other risk factors that increase bleeding risk include concurrent anticoagulation or nonsteroidal anti-inflammatory (NSAID) use, uncontrolled hypertension, male sex, and older age (USPSTF, 2016).

Evidence shows that the risk for GI bleeding, with and without aspirin use, increases with age (USPSTF, 2016). NSAID therapy combined with aspirin use increases the risk for serious GI bleeding compared to aspirin use alone (USPSTF, 2016). Additionally, the rate of serious

bleeding among aspirin users is about 2 to 3 times greater in patients with a history of GI ulcer, and two times greater in men than women (USPSTF, 2016).

The USPSTF found adequate evidence that aspirin use in adults increases the risk of GI bleeding and hemorrhagic stroke (USPSTF, 2016). These risks are small in adults 50 years of age or younger and small to moderate in adults aged 60 to 69 years (USPSTF, 2016). In a prospective cohort study by Selak et al. (2019) designed to evaluate bleeding events associated with aspirin, 69% of bleeding events were gastrointestinal. In addition, of the most fatal bleeding events recorded, 57% were intracerebral (Selak et al., 2019). Among men and women, each additional year of age is associated with an estimated relative increase of 4% in 5-year risk for major bleeding with a mean estimated 5-year bleeding risk of 1.3% (Selak et al., 2019). A trial evaluating adults 70 years of age or older without life-limiting chronic illnesses was stopped prematurely based on futility; this study did not show any benefit of aspirin use for primary prevention and demonstrated higher major bleeding rates and higher all-cause mortality associated with aspirin use, calling into question the use of aspirin for those 70 years or older (Marquis-Gravel et al., 2019). The relationship between aspirin use and bleeding is well established (USPSTF, 2016). As a result, informed decision-making regarding individual risk factors related to both CVD and bleeding risk needs to be made amongst provider and patient.

Treatment and Dosage

The optimal dose of aspirin to prevent CVD events is not known, though the pragmatic approach consistent with evidence is to prescribe 81 mg per day, which is most commonly prescribed in the United States (USPSTF, 2016). The risk of GI bleeding may increase with the dosage (Bibbins-Domingo, 2016a). Some studies have shown increased risk of bleeding with daily doses of aspirin greater than 300 mg while others have shown no significant increase in

rates for bleeding with differing doses, though a large, randomized trial showed that low-dose aspirin led to a lower risk of serious vascular events (Bowman et al., 2019). A dose-escalating pharmacodynamic study suggests that twice-daily 81 mg aspirin dosing is associated with better platelet inhibition, though this dosing continues to be studied in trials (Marquis-Gravel et al., 2019).

Enteric coating does appear to demonstrate lower rates of gastric mucosal injury, although there is limited data on whether the effect is clinically significant (Smith et al., 2019). Furthermore, enteric coating is associated with decreased absorption and thus lower bioavailability, effectively diminishing the benefits of the formulation (Marquis-Gravel, 2019). Another bleeding mitigation currently being investigated is the concurrent use of proton pump inhibitors to limit the risk of significant GI bleeding and therefore shift the risk-benefit ratio toward an overall benefit of aspirin as primary prevention of CVD (Zheng & Roddick, 2019). While potential bleeding risk mitigation efforts are encouraging, further investigation into their effectiveness is paramount and continues to be underway.

Statins as Primary Prevention

Benefits and CVD Risk

CVD is a broad term that encompasses a number of atherosclerotic conditions that affect the heart and blood vessels which results in coronary heart disease, manifesting as MIs, and cerebrovascular disease, and strokes (USPSTF, 2017). Statins are a class of lipid-lowering medications that inhibit the production of cholesterol, reducing levels of total cholesterol and LDL, as well as triglycerides to a lesser extent (USPSTF, 2017). Additionally, statins play a role in reducing inflammation and stabilizing plaque (Bibbins-Domingo, 2016b).

Risk factors associated with the development of CVD events include dyslipidemia, diabetes, hypertension, and smoking (USPSTF, 2017). For the purpose of the USPSTF recommendations, dyslipidemia is defined as an LDL level greater than 130 mg/dL or a high-density lipoprotein cholesterol (HDL) level less than 40 mg/dL (USPSTF, 2017). Many participants enrolled in trials of statin use for the prevention of CVD had an LDL level of 130-190 mg/dL, with an LDL >190 mg/dL excluding the participant from the trial (USPSTF, 2017). The ACC/AHA designates hypertension as a SBP ≥130 mmHg or a DBP ≥80 mmHg (Whelton et al., 2018).

Nonmodifiable risk factors include older age, male sex, and race or ethnicity (USPSTF, 2017). Other risk factors, such as family history of primary coronary artery disease, have not been demonstrated to improve risk prediction in a clinically meaningful way (USPSTF, 2017). An important note is the calculated 10-year CVD event risk calculator is heavily influenced by age, with 41% of men and 27% of women aged 60 to 69 years without a CVD history as having a 10-year CVD event risk of 10% or greater (USPSTF, 2017). Furthermore, many older adults, particularly those 65 to 79 years of age, may meet recommendations for treatment despite the absence of dyslipidemia, diabetes, hypertension, or smoking (USPSTF, 2017). Consequently, decisions about initiating statin use in this age group should be based on individualized decision-making between clinicians and patients about their potential harms and benefits.

A meta-analysis by Li et al. (2018) found that statins can effectively decrease the occurrence of angina, nonfatal and fatal MI, any coronary heart events, coronary revascularization, and any cardiovascular events. In similar findings, Bibbins-Domingo (2016b) found that use of low-to-moderate dose statins were associated with a reduced risk of all-cause mortality, cardiovascular mortality, ischemic stroke, MI, and composite cardiac outcome.

However, there were no significant differences in CVD deaths and all-cause mortality among statin users or placebo (Li et al., 2018). Collins et al. (2016) found that effective low-cost statin regimens reduced LDL cholesterol by 50%, as well as a 25% reduction of major vascular events with each 1 mmol/L reduction in LDL cholesterol with statin therapy.

Among study populations, the proportion of CVD events prevented was similar across age, sex, race, ethnicity, lipid level, and other risk factor categories (Bibbins-Domingo, 2016b). Relative risk estimates among those classified as higher or lower CVD event risk had similar relative risk reductions (Bibbins-Domingo, 2016b). However, the relative risk estimates can be justified in that the more likely persons in a certain population will have a heart attack or ischemic stroke, the greater the potential reduction in the number of CVD events with statin use will be in that population (Bibbins-Domingo, 2016b). Chou et al. (2018) found that there are similar composite cardiovascular outcomes in men and women. However, statins were associated with a lower risk of nonfatal stroke in men versus women, but an opposite pattern is observed for revascularization or hospitalization (Chou et al., 2018).

The USPSTF found adequate evidence that use of low- to moderate-dose statins reduces the probability of CVD events, manifested by MI and ischemic stroke, as well as mortality by at least a moderate amount in adults aged 40 to 75 years who have one or more CVD risk factors, as previously described, and a calculated 10-year CVD event risk of 10% or greater (USPSTF, 2017). This is graded as a B recommendation, with the USPSTF recommending to offer the service, as there is high certainty that the net benefit is moderate or there is moderate certainty that the net benefit is moderate to substantial (USPSTF, 2018).

The USPSTF found adequate evidence that use of low- to moderate-dose statins reduces the probability of CVD events and mortality by at least a small amount in adults aged 40-75

years who have one or more risk factor, and a calculated 10-year CVD event risk of 7.5% to 10% (USPSTF, 2017). This is graded as a C recommendation, in which the USPSTF recommends selectively offering the service to individual patients based on professional judgement and patient preferences, with at least moderate certainty that the net benefit is small (USPSTF, 2018). The decision to initiate therapy in this population should reflect the patients' specific circumstances and their preferences for a potential small benefit relative to the potential harms and inconvenience of taking a lifelong daily medication (Bibbins-Domingo, 2016b).

The USPSTF found inadequate evidence to conclude whether initiating statin use in adults age 76 or older who are not already taking a statin is beneficial in reducing the incidence of CVD events and mortality (USPSTF, 2017). This is an I statement, with the USPSTF concluding that evidence is lacking, of poor quality, or conflicting, and the balance of benefits and harms cannot be determined (USPSTF, 2018). Adults 76 years and older were not included in any randomized trials, thus making it difficult, if not impossible, to assess the balance of benefits and harms of initiating statin use for primary prevention in this population (Bibbins-Domingo, 2016b).

Screening for dyslipidemia in adults aged 21 to 39 years is found to have insufficient evidence that there exists an effect on short- or long-term cardiovascular outcomes, finding no studies that evaluated the effects of screening versus no screening, treatment versus no treatment, or delayed versus earlier treatment in this age group (USPSTF, 2017). Consequently, the USPSTF recommends neither for nor against screening for dyslipidemia in this age group (USPSTF, 2017). The USPSTF recognizes that more research is needed to address the efficacy of screening and safety of long-term statin use in this population (Bibbins-Domingo, 2016b). Similarly, a separate recommendation statement is also available finding insufficient evidence to

assess the balance of benefits and harms of screening for dyslipidemia in children and adolescents (USPSTF, 2017).

Safety of Use

According to the Centers for Disease Control and Prevention, more than 25% of US adults over the age of 40 take a statin, which translates to more than 25 million men and women (Newman et al., 2019). Despite the cardiovascular benefits of statins, long-term adherence is sub-optimal with discontinuation of statin therapy estimated to occur in 10% of patients (Newman et al., 2019). Spence and Dresser (2016) observed that after 3 years, less than 40% of patients continued taking statins for primary prevention. Furthermore, even high-risk patients' continuation in taking statins was approximately 50% after 2 years (Spence & Dresser, 2016). Patients may discontinue statins simply due to the fear of side effects, which may or may not be truly related to the treatment, thus increasing their risk of MI and CVD death (Newman et al., 2019).

The only excesses of adverse events that have been reliably demonstrated to be caused by statin therapy are myopathy and diabetes mellitus, along with probable hemorrhagic stroke (Collins et al., 2016). Typically, treatment of 10,000 patients for 5 years of statin use would be expected to cause approximately 5 new cases of myopathy, 50-100 new cases of diabetes, and 5-10 hemorrhagic strokes (Collins et al., 2016). Statin therapy was not associated with an increased risk of any cancer, cognitive harms, cataracts, or renal dysfunction (Chou et al., 2016). One observational study claimed absolute increase in developing cataracts but has been unable to be replicated and has been subsequently disproven many times over (Collins et al., 2016).

As is the case for most drug adverse events, the incidence of myopathy combined with the rare occurrence of rhabdomyolysis tends to increase with statin dose increase (Newman et al.,

2019). Most drugs that interact with statins increase the plasma concentration of the statin and statins' active metabolites, equivalent to taking a larger dose and thereby increasing the risk of myopathy or rhabdomyolysis (Newman et al., 2019). Other risk factors associated with development of myopathy and rhabdomyolysis are not well defined, but older individuals appear to be more vulnerable, as well as those with hypothyroidism, preexisting muscle disease, female sex, diabetes mellitus, East Asian ancestry, and renal disease (Newman et al., 2019). Nguyen et al. (2018) add small body frame, frailty, and high-dose statin treatment as factors that increase myopathy risk. The excess risk of myopathy with statins versus placebo is <0.1% in large, long-term randomized controlled trial with all currently marketed statins at up to maximum recommended doses (Newman et al., 2019). The greatest risk of myopathy occurring is in the first year of therapy, after a dose increase, or with the addition of an interacting drug (Newman et al., 2019).

A complicating factor with myopathies with statin use is the potential for bias against statins. Of note, the risk of myopathy and rhabdomyolysis is prominent information leaflets, internet information on statin adverse effects may be exaggerated or emphasized as negative, and clinicians often warn patients to report muscle symptoms if they develop during treatment (Newman et al., 2019). A meta-analysis of randomized controlled trials in a broad array of patient types demonstrated that muscle adverse effects actually caused by statin occurred in no more than 1% of treated patients (Newman et al., 2019). Another study, supporting that statin intolerance depends on patient expectations, compared placebo with statin use and exhibited no difference in muscle symptoms among statin and placebo-allocated patients during the blind phase, but showed a higher rate of adverse events in the statin group in the unblinded phase (Newman et al., 2019). There could be many reasons for this cause, but one plausible

explanation for this is known as the nocebo effect. The nocebo effect is a normal neuropsychological phenomenon that is the cause of subjective, adverse events that result from expressed or internal expectations of harm from a therapy, and has more recently been gaining attention in the field of cardiovascular medicine (Newman et al., 2019). This effect does not imply abnormality in patients, and the patients may very well be experiencing myalgia, but current evidence indicates a relatively low chance of clinical myalgia. Furthermore, an impartial and unbiased mind needs to be present when prescribing statins and facing any potential adverse effects.

Evidence has shown that statins increase the risk of incidence of diabetes by 9-28% (Spence & Dresser, 2016). This excess of diabetes diagnoses appeared shortly after initiation of statin therapy, chiefly among those who had risk factors for diabetes and did not appear to get larger as treatment continued (Collins et al., 2016). Yang et al. (2017) argues that individuals taking statins who develop diabetes would become diabetic regardless because of the major risk factors they may have, suggesting that the date of diagnosis might simply be accelerated by taking statins. This is supported by a meta-analysis that also suggests that patients with pre-diabetes and metabolic syndrome simply accelerated the onset of diabetes mellitus (Newman et al., 2019). While the clinical relevance of the excess diabetes is unclear, the cardiovascular benefits associated with statin therapy are substantial and paramount to take into consideration (Collins et al., 2016).

Observational studies have shown a negative association between patients with a combination of low cholesterol and high blood pressure and rates of hemorrhagic strokes (Collins et al., 2016). Other studies show an increased risk of hemorrhagic stroke and higher high-density lipoproteins (Newman et al., 2019). However, a meta-analysis of more than 40

studies found no association between statin treatment and increased risk of intracerebral hemorrhage (Newman et al., 2019). Conflicting evidence supporting increased risk of hemorrhagic stroke is outweighed by the overall reduction of stroke associated with statin use, including those with hypertension or previous history of stroke (Collins et al., 2016).

Substantial evidence exists demonstrating the benefit of statin therapy for primary prevention of CVD in adults younger than 75 years of age (Singh et al., 2018). Extrapolation of efficacy and safety data from younger population onto those older than 75 years of age should be done cautiously, closely considering comorbidity, polypharmacy, potential side effects, and limited life expectancy (Mortenson & Falk, 2018). Risk-benefit ratio in the elderly may tip in favor of withholding statin therapy due to health conditions and limited life expectancy (Mortenson & Falk, 2018). Interestingly, strong evidence shows that older age predicts increased adherence to statins (Hope et al., 2019). Ultimately, there is a critical evidence gap relating to the benefits and risks of initiating statins in adults aged 80 or older with multiple chronic conditions (Singh et al., 2018). As a result, patient preferences are critically important for well-informed decision-making that focuses on patient values in relation to quality of life and longevity (Mortenson & Falk, 2018).

Among those eligible for statin use as primary prevention, almost 42% were using statins (Ngo-Metzger et al., 2018). A systematic review by Hope et al. (2019) shows strong evidence indicating better adherence to statins in those with traditional CVD risk factors, particularly those of older age, male gender, diagnosis of diabetes, diagnosis of hypertension, and higher socioeconomic status. Alternatively, female sex, Hispanic ethnicity, uninsured status, and living in the Southern region of the United States is associated with decreased odds of taking statins (Ngo-Metzger et al., 2018). Approaches to limit adverse events includes limiting or reducing the

dose, alternate daily dosing, and adding additional therapies such as ezetimibe, bile acid sequestrants, and fibrates (Spence & Dresser, 2016). Rosenson et al. (2017) suggest the implementation of clinical tools, such as questionnaires designed to facilitate the clinical diagnosis of statin-induced myalgias. Other suggestions for clinical practice include discontinuation and rechallenging with the same or a different statin (Rosenson et al., 2017). One could also suggest investigation into pharmacogenomics and how they uniquely respond to medications. It is important to note that lifestyle change should be considered first-line therapy for lowering LDL and CVD risk and should always play a key role when considering CVD risk and lowering the risk in patients.

Treatment and Dosage

The ACC/AHA has stratified statins into three categories: low-, moderate-, and high-intensity dose (Collins et al., 2016). As an example, low intensity demonstrates a <30% reduction in LDL cholesterol with simvastatin 10 mg daily (Collins et al., 2016). Moderate intensity demonstrates a 30% to <50% reduction with simvastatin 20-40 mg daily, atorvastatin 10-20 mg daily, or rosuvastatin 5-10 mg daily (Collins et al., 2016). Finally, high intensity demonstrates a ≥50% reduction with atorvastatin 40-80 mg or rosuvastatin 20-40 mg daily (Collins et al., 2016). In adults age 40 to 75 years of age, use of low- or moderate-dose statins was associated with a reduced risk of all-cause mortality, cardiovascular mortality, ischemic stroke, and heart attacks (USPSTF, 2017). A table depicting statins in low-, moderate-, and high-dose categories can be seen in Figure 3.

Figure 3

ACC/AHA Statin Regimens Used in Trials

	Dose, mg[a]		
Statin	Low	Moderate	High
Atorvastatin		10-20	40-80
Fluvastatin	20-40	40 twice daily	
Fluvastatin extended release		80	
Lovastatin	20	40	
Pitavastatin	1	2-4	
Pravastatin	10-20	40-80	
Rosuvastatin		5-10	20-40
Simvastatin	10	20-40	

Note. A summary of name, dose, and intensity of statins (Bibbins-Domingo, 2016b)

Limited information is available about use of high-dose statins in a primary prevention population, and the harms of statin use can only be bounded as small for low- and moderate-dose statins (Bibbins-Domingo, 2016b). Use of high-dose statins versus low-dose statins would expect to see proportional reductions in cholesterol (Collins et al., 2016). Different statins are noted to have different potencies, with newer agents such as atorvastatin and rosuvastatin able to produce larger reductions in cholesterol than older agents (Collins et al., 2016).

Randomized controlled trials evaluating statins in the prevention of CVD largely use low- and moderate-dose statins and showed no clear differences in estimates of effect when stratified according to statin dose (USPSTF, 2017). Collins et al. (2016) note that irrespective of the statin used, doubling of the dose produces an extra reduction of about 6 percentage points in LDL cholesterol. High-dose statins have been linked to significantly increased rates of myopathies and diabetes, though they are also associated with a significant reduction in LDL cholesterol by at least 2 mmol/L in those at highest risk (Collins et al., 2016). As a result, intensive statin therapy should be focused on patients at higher risk of vascular events rather than just those with high

cholesterol concentrations (Collins et al., 2016). There may be clinical circumstances that warrant consideration of high-dose statins, but decisions about dose should be based on shared decision-making between patient and clinician (Bibbins-Domingo, 2016b).

The most directly applicable body of evidence for patients without a history of CVD demonstrates benefits with the use of low- to moderate-dose statins, with a notable gap in evidence in the use of high-dose statins as primary prevention of CVD (USPSTF, 2017). The USPSTF concludes that any point in assessment where net benefit of statin use shifts from small to moderate for a population requires judgement, and recommends that decision to initiate use should reflect shared decision-making that weighs the benefits and harms, the uncertainty about risk prediction, and individual patient preferences, including long-term use of a daily medication (USPSTF, 2017).

Theoretical Framework

Iowa Model

The Iowa Model of Evidence-Based Practice to Promote Quality Care was used to facilitate the implementation of USPSTF guidelines on aspirin and statins for primary prevention of CVD. Permission for use was obtained from the University of Iowa Hospitals and Clinics (see Appendix C). The model provides guidance in making decision about clinical practice that affect patient outcomes and does so by outlining a multiphase change process with feedback loops (Melnyk & Fineout-Overholt, 2019). The model integrates questions, strategies, and instructions to guide decision-making through each feedback loop (See Appendix D).

I. Identify Triggering Issues and Opportunities: The USPSTF released recommendations in 2016 regarding aspirin and statin use for the primary prevention of CVD. Among patients eligible for aspirin therapy at an increased risk of CVD,

about 41% were told by a physician to take aspirin (Bibbins-Domingo, 2016a). The National Health and Examination Survey (NHANES) for 2013-2014 found that, of US adults eligible for statin therapy (CVD risk >7.5%), just 30% were currently taking statins (AHA, 2018). These statistics demonstrate that a large number of adults who could benefit from aspirin and/or statin therapy were not properly taking or being prescribed these medications and could benefit from implementation of USPSTF recommendations in the primary care setting.

II. Organizational Priorities: Staff Leadership at NDSU were spoken to and informed of the intent to implement a health screening for staff members to screen and evaluate USPSTF guidelines for aspirin and statin use for primary prevention. Leadership expressed interest in promoting and participating in a NDSU health screening and provision of USPSTF recommendations.

III. Forming a Team: The team consisted of the co-investigator and support personnel. My role as co-investigator will be to facilitate and implement the guidelines during the NDSU Health Screening followed by the evaluation of results following the implementation period. The supervisory committee for the project included Dean Gross as chair from the School of Nursing, Mykell Barnacle from the School of Nursing, Lisa Montplaisir as North Dakota State University (NDSU) graduate appointee, and Tara Brandner as a nurse practitioner (NP) and outside expert.

IV. Assemble, Appraise, and Synthesize Research: A literature review and synthesis of information and research was conducted. This information supported the indication for change in practice. The literature review assessed aspirin's associated risks of bleeding and its effect on CVD risk. The risk factors associated with statins, including

myalgias, stroke, and diabetes, were addressed as well as the effect of statins on CVD risk. The ACC/AHA risk calculator used by the USPSTF aids in determining the 10-year CVD risk. In calculating this risk, the USPSTF advises initiating low-dose aspirin as primary prevention of CVD and CRC in adults aged 50 to 59 years who have a 10% or greater 10-year CVD risk, who are not at an increased risk for bleeding, have a life expectancy of at least 10 years, and are willing to take a low-dose aspirin daily for 10 years (USPSTF, 2016). The USPSTF found adequate evidence that use of low- to moderate-dose statins reduces the probability of CVD events, manifested by MI and ischemic stroke, as well as mortality by at least a moderate amount in adults aged 40 to 75 years who have one or more CVD risk factors, as previously described, and a calculated 10-year CVD event risk of 10% or greater (USPSTF, 2017).

V. Design and Pilot the Practice Change: Project outcomes and baseline data will be collected. After supervisory committee and site approval, the USPSTF guidelines for aspirin and statin use for primary prevention will be initiated at the NDSU Health Screening starting July 2021 and the outcomes of the practice change were evaluated starting in July 2021.

VI. Integrate and Sustain the Practice Change, Disseminate Results: Objective two sought for participants to report a positive viewpoint related to the implementation of the USPSTF guidelines and to sustain use into the future. After completion of the project in July 2021, results are anticipated to demonstrate the participants' intent to continue use in the future. Once results are collected and data analysis complete, dissemination of the results will begin.

Diffusion of Innovations Theory

Implementation of the USPSTF guidelines of aspirin and statins for primary prevention of CVD were guided the Diffusion of Innovations theory. Everett Rogers developed this theory to help disseminate health behavior interventions for practical use (Pender et al., 2019). This framework describes the process of innovation diffusion and the various stages involved in adopting a new idea (Pender et al., 2019). Diffusion is considered a process through which an innovation, or new idea, is communicated through certain channels, over time, and among a group or community (Pender et al., 2019). In this project, the USPSTF guidelines represent the innovation that is to be adopted and the flyers, e-mails to staff listserv, and in-person communication are the forms of communication used to diffuse the information to the group of providers.

There are five adopter categories described in this theory: innovators, early adopters, early majority, late majority, and laggards. Innovators are out-of-the-box thinkers and readily recognize innovative opportunities. Early adopters are highly influential in organizations and encourage others to adopt innovations. The early majority are individuals who follow the lead of the early adopters in implementing the innovation. The late majority spends additional time watching how the innovation is progressing and are more cautious in its adoption. Laggards are fairly steeped in tradition and have much difficulty with change (Melnyk & Fineout-Overholt, 2019). In order to successfully implement an innovative change, it is crucial to be able to identify appropriate adopters.

According to the Diffusion of Innovations theory there are five stages, called the innovation decision process, in which individuals progress through while they are evaluating an innovation for adoption. These stages are knowledge, persuasion, decision, implementation, and

confirmation (Pender et al., 2019). To begin the innovation decision process, a lack of awareness regarding USPSTF guidelines on aspirin and statins for primary prevention was identified as potentially applicable to NDSU staff members. For the first stage, the introduction of knowledge of the USPSTF guidelines will be presented to the NDSU staff participants at the NDSU Health Screening. For the second stage, persuasion, potential adopters evaluated the innovation and formed either a positive or negative attitude toward the USPSTF guidelines.

There are several characteristics that can affect the speed of adoption during the second stage, including relative advantage, compatibility, complexity, trialability, and observability. Relative advantage is the degree to which adopting the USPSTF guidelines, or innovation, is perceived to be better than the staff members' current medication regimen. Whether the innovation is truly an advantage does not matter, but whether the participants believe it to be better. Another component that may affect adoption is compatibility, which explains whether the participants perceive the innovation fitting with their existing values and past experiences (Pender et al., 2019). In this example, the participants who may experience a change in their medication regimen will evaluate if potentially taking one or more new medications is feasible and something they are willing to do for the foreseeable future. Complexity of the innovation also plays a role in adoption. Whether the innovation is easy or difficult to understand plays a key role, with a more easily understood innovation more likely to be adopted than a complex innovation. Clear education, reassurance, and easy-to-understand instructions will be key in making the innovation easy to understand for the participants. Trialability is the extent to which the innovation can be experimented with and can be considered tentative for a period of time (Pender et al., 2019). Lastly, observability is the degree to which the results are visible to others (Pender et al., 2019). These final two components can be challenging with health changes, as

changes in medication regimens in participants may take months to years to see benefits. Additionally, in the case of the abstract nature of health behavior changes like primary prevention, the participant may prevent the development of CVD but would never see the disease state they successfully prevented, resulting in a difficulty perceiving the benefit of the changes made.

In the third stage of decision, the staff members and their providers determined their intent to adopt and utilize the USPSTF recommendations provided to the participant at the health screening through shared decision-making. In the final two stages, implementation and confirmation, the participants and their providers decided whether they will sustain the USPSTF guidelines in their participants' plan of care.

CHAPTER 3: METHODS

Project Implementation

The practice improvement project took place at a co-investigator-initiated health screening for NDSU staff members in July 2021. Advertisement of the health screening was made on campus via flyers, e-mail to staff listserv, and in-person communication by NDSU Staff Senate leaders. NDSU staff members were encouraged to sign up for 30–45-minute time slots prior to arrival to the health screening, though walk-ins were welcomed to participate. Clinical Laboratory Improvement Amendments (CLIA) training was obtained by the co-investigator and principal investigator to comply with laboratory testing regulations when using the CardioChek Plus machine.

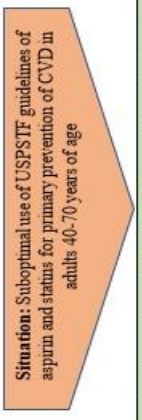
The health screening was provided to all participating NDSU staff a USPSTF screening in concurrence with the ACC/AHA risk calculator, cholesterol profile, blood glucose, oxygen saturation, body fat analysis, hand grip strength test, blood pressure, weight, height, and PHQ-9/GAD-7. Participants were encouraged to provide a copy to the co-investigator of their recent cholesterol profile and/or blood glucose if they had been obtained within one year of the health screening date. Results were highlighted upon completion of the health screening and the participants were encouraged to share the information with their primary care provider (PCP) as soon as possible via electronic messaging or at an in-person clinic visit.

With the intention to provide data/results to participants and not to render care, a mitigation strategy to address abnormalities in values and results was developed. A participant SBP ≥130 mmHg or DBP ≥80 mmHg would prompt encouragement to contact their PCP as soon as possible in accordance with ACC/AHA hypertension guidelines. Additionally, threat of a hypertensive crisis is characterized by a SBP >180 mmHg and/or DBP >120 mmHg (Whelton et

al., 2018) and requires prompt treatment by emergency personnel and would prompt the participant to seek care in the emergent setting. In accordance with standards of medical care by the American Diabetes Association (ADA), a blood glucose value of <70 mg/dL required the participant to ingest 15-20 g of carbohydrates or urgent treatment, whichever was more readily available (ADA, 2020). A blood glucose value >180 mg/dL would prompt the participate to seek care with their PCP as soon as possible, while a blood glucose value >240 mg/dL would require emergent care per ADA recommendations (ADA, 2020). A logic model (see Figure 4) was used to explain how interventions were used to meet the desired objectives.

Figure 4

Logic Model/Setting



Inputs	Outputs		Outcomes	
	Activities	Participation	Short	Long
NDSU DNP student & committee members NDSU GSO & SNA members NDSU Staff Leadership USPSTF guidelines ACC/AHA risk calculator Time to collect data and enter into ACC/AHA risk calculator & interpret results Time to counsel participants on results Supplies: Cardiochek Plus machine, O2 sat probe, blood pressure cuff, scale, stadiometer, thermometer, caliper, dynamometer Aldevron Tower rooms 340a, 350, and exam room 10	Flyers, e-mail to staff listserv, and in-person communication to NDSU Staff Members Health screening fair at NDSU for NDSU Staff members Health information brochures of healthy lifestyles, diets, activities Qualtrics post-implementation surveys Recommendation letters received by participants to provide to PCPs Follow-up e-mail evaluating communication with PCPs	Participants ages 40-70 years of age who are Staff members at NDSU NDSU GSO & SNA members	Improved participant understanding of USPSTF guidelines Improved participants understanding of ACC/AHA risk calculator Positive viewpoint of ACC/AHA risk calculator Contact between participants and their PCP with results of health fair data Participants taking aspirin and/or statin appropriately according to USPSTF guidelines	Participants taking aspirin and/or statins appropriately according to USPSTF guidelines and fewer CVD events Enhanced communication between participants and their PCPs

The health screening occurred in Aldevron Tower on the 3rd floor using the assessment lab 340a exam rooms and the multipurpose room 350 to provide adequate space for all the health screening stations. Cholesterol blood samples were done in the 350 multipurpose room on the third floor using portable room dividers to maintain privacy to provide a quiet, comfortable space for a blood draw. This location was selected due to its location, space, furniture, and proximity to the home of NDSU School of Nursing.

Sample/Sample Size/Recruitment

Participants selected for this project were adult staff members of NDSU 40-75 years of age in adherence with the USPSTF age guidelines. Recruitment was performed by contacting the NDSU Staff Senate sitting president on April 6, 2021. Support and need for the service was expressed by the then-Staff Senate sitting president (see Appendix E). Communication and promotion in their respective departments regarding the health screening will be made by the members of Staff Senate and chair of the campus engagement committee. The project goal was for 30 potential adults 40 years of age or older who were also current NDSU staff members to participate in this project due to availability of point-of-care test kit availability, with the potential of more staff members attending the health screening without collecting cholesterol values and applying the data to USPSTF guidelines. Adults less than 40 years of age were not eligible to participate in the project due to current USPSTF guidelines and recommendations but were welcome to participate in the health screening excluding cholesterol screening. Volunteer assistance from three members of the NDSU Graduate Student Organization (GSO) and Student Nurses' Association (SNA) were utilized to assist with obtaining participant data apart from blood glucose and cholesterol, which were obtained by the co-investigator and principal investigator after receiving CLIA training.

Facilitators to the project included Staff Senate sitting president and members, the chair of the campus engagement committee, and volunteer NDSU GSO/SNA members. Potential barriers identified included a perceived lack of benefit by potential participants, fear of blood, fear of finger stick, perceived or actual lack of time to attend the health screening, and lack of communication about pertinent results between the participant and their PCP. These issues were addressed with ample education leading up to and during the health screening on benefits of following USPSTF guidelines and appropriate medication adherence, encouragement and therapeutic communication for those fearing blood products, flexible and encompassing hours coupled with efficient data collection to accommodate busy staff members, and education on the importance of thorough communication with PCPs.

Evaluation/Outcomes/Data Analysis

For the first objective, data were gathered from participants 40 years of age and older at the NDSU Health Screening on July 27th, 2021 to corroborate whether participants were taking aspirin and/or statins per the USPSTF guidelines. Data were collected and recorded into the ACC/AHA risk calculator and evaluated whether the participant was currently taking aspirin, statins, or both, and whether USPSTF recommendations supported use of these medications according to their risk with a copy of results provided to each participant. Data were collected regarding percentages of participants who do, or do not, take aspirin and/or statin appropriately. The data collected helped to denote the significance of the proposed project in the population of adults over the age of 40. Once the lab values and other measurements were collected, the USPSTF guidelines were applied to participants in the health screening. Data calculations were completed the week of the health screening on July 27th, 2021. Once completed, these

calculations and recommendations were provided to the participant via a participant-provided e-mail.

For the second and third objective, participants completed a Qualtrics online post-implementation survey (see Appendix H) within 72 hours to evaluate their knowledge and current practice related to aspirin or statin use in their medication regimen in accordance with the USPSTF guidelines, and viewpoint related to the ACC/AHA cardiovascular risk calculator, respectively. The surveys included a four-point Likert scale that reflected evaluation of the objectives.

For the fourth objective, the participants were provided an e-mailed version of their health information with abnormalities highlighted. The participants were advised to contact and share findings with their PCP. A one-month and three-month follow-up e-mail evaluated contact made with their provider and if any changes were made in their care based off guideline recommendations (see Appendix G).

Protection of Human Subjects

The potential risk for participants in the NDSU health screening were a point-of-care finger-prick test to collect a desired 40uL of blood (1-2 drops) from the individual as well as exposure to their own blood sample during the collection process of cholesterol and glucose values. To minimize this risk, the procedure was a clean procedure with designated waste receptacles along with education on the process and obtaining the least amount of blood possible while collecting an adequate amount to successfully perform the test. Potential benefits of the project included increased knowledge about personal CVD risk and steps to ensure optimal treatment, increased knowledge of personal health information, enhanced communication between participants and their PCP, and possible improvement of CVD risk if appropriate

USPSTF recommendations are followed. Verbal consent was obtained through a consent form from each participant (see Appendix F).

Data were gathered from 28 NDSU staff participants 40 years of age and older at the health screening at Aldevron Tower on July 27th, 2021, with the potential of more staff members attending the health screening without collecting cholesterol values and applying the data to USPSTF guidelines. All data collection took place on that day and in subsequent post-implementation survey responses. Participant information used for each calculation was not included in the evaluation of the project and was only be used for generation of total percentages. The participants and their personal information were not jeopardized. Application for Expedited Review status through North Dakota State University's IRB was submitted and approved in May 2021 and approved in June 2021 (see Appendix A).

CHAPTER 4: RESULTS

After implementation, the project was evaluated to determine whether the objectives were achieved. The project was implemented on July 27, 2021. Data were collected from the health screening on July 27, 2021. Data were collected from post-implementation surveys in early September 2021 and late October 2021. Once the data were collected, analysis began. Quantitative data were analyzed to determine the results of the project. A total of 28 individuals participated in the health screening. The average participant was 55 years of age, with 25% of participants identifying as male and 75% identifying as female. The average CVD risk calculated was 4.96%, with an average total cholesterol of 175 mg/dL, average HDL of 55 mg/dL, and average triglyceride of 185 mg/dL. For the complete spreadsheet of values of participants, see Appendix I.

Presentation of Findings

To recap, the objectives of the project include:

I. Data will be gathered from participants 40 years of age and older at the NDSU Health Screening in July 2021 to corroborate whether participants are taking aspirin and/or statins per the USPSTF guidelines.

II. Participants in the Health Screening will report awareness and practice of the current USPSTF guidelines related to aspirin and statin use for primary prevention of CVD and the cardiovascular risk calculator by the ACC/AHA by July 2021 through post-survey completion.

III. Participants in Health Screening will report a positive viewpoint related to the cardiovascular risk calculator by the ACC/AHA by July 2021 through post-survey completion.

IV. Participants in the Health Screening will agree to provide data from NDSU Health Screening on adherence to USPSTF guideline recommendations to their primary care providers.

A post-implementation survey was provided to each participant upon receipt of their personal health screening data to evaluate their understanding and viewpoints of the USPSTF guidelines and the ACC/AHA cardiovascular risk calculator. The post-implementation survey consisted of a four-point Likert scale composed of five questions related to the project objectives. The one-month and three-month follow-up e-mails were sent to evaluate if participants contacted their provider and any changes made in their care based off guideline recommendations. The health screening was evaluated with labs, measurements, and vital signs obtained during the screening. Data were collected from 28 participants over the age of 40 and were collected on an Excel spreadsheet to assist with analysis. The following sections include the project results presented in relation to the objectives they addressed.

Objective One

Objective one, to corroborate whether participants are taking aspirin and/or statins per the USPSTF guidelines, was evaluated through use of collected data and recorded into the ACC/AHA risk calculator based off their own personal risk. Four (14%) of the participants were on aspirin and qualified per the USPSTF guidelines. One participant (4%) qualified for aspirin use but was not currently taking aspirin. None of the participants were on aspirin and did not qualify per the guidelines. Lastly, 23 (82%) of the participants were not on aspirin and did not qualify to be taking aspirin per the guidelines.

Results showed that five (18%) participants were on statins and qualified for statin use per the guidelines. Three (11%) of the participants were not on statins and qualified to use statins

per the guidelines. No patients were on statins that did not qualify for their use. Lastly, 20 (71%) of the participants were not on statins and did not qualify per the guidelines. See Table 1 for an illustration of these findings.

Table 1

Aspirin/Statins Health Screening Results

Aspirin/Statins and Status	# Participants	% Participants
Participants on aspirin and qualify	4	14%
Participants not on aspirin and qualify	1	4%
Participants on aspirin and do not qualify	0	0
Participants not on aspirin and do not qualify	23	82%
Participants on statins and qualify	5	18%
Participants not on statins and qualify	3	11%
Participants on statins and do not qualify	0	0
Participants not on statins and do not qualify	20	71%
Total # of participants	28	

Objective Two

Objective two, to report awareness and practice of the current USPSTF guidelines on aspirin and statin use and of the ACC/AHA cardiovascular risk calculator, was evaluated through the use of a four-point Likert scale on a post-implementation survey. The statements provided on the survey to evaluate the second objective included:

I. I am knowledgeable about aspirin use for primary prevention of CVD

II. I am knowledgeable about statin use for primary prevention of CVD

III. I feel that using the USPSTF guidelines are beneficial for aiding decision making of aspirin and/or statin use

IV. I am knowledgeable about the cardiovascular risk calculator produced by the ACC/AHA

One (8%) participant stated they “strongly disagree” and one (8%) stated they “disagree” with the statement “I am knowledgeable about aspirin use for primary prevention of CVD”. Eight (67%) participants stated they “agree” and two (17%) of the participants stated “strongly agree” with the statement “I am knowledgeable about aspirin use for primary prevention of CVD”.

Next, five (42%) participants stated they “disagree”, six (50%) of the participants stated they “agree”, and one (8%) participant stated they “strongly agree” with the statement “I am knowledgeable about statin use for primary prevention of CVD”. A total of 11 (92%) of the participants state they “agree” and one (8%) participant stated they “strongly agree” with the statement “I feel that using the USPSTF guidelines are beneficial for aiding decision making of aspirin and/or statin use”.

Lastly, two (17%) of the participants stated they “strongly disagree”, six (50%) of the participants “disagree”, and four (33%) participants “agree” with the statement “I am knowledgeable about the cardiovascular risk calculator produced by the ACC/AHA”. See Table 2 for an illustration of these findings.

Objective Three

Objective three, to report a positive viewpoint related to the ACC/AHA cardiovascular risk calculator, was evaluated through the use of a four-point Likert scale on a post-implementation survey. The statement provided on the survey to evaluate the third objective stated, “I feel that using the ACC/AHA risk calculator is beneficial”. In total, 10 (83%) of the participants stated they “agree” and two (17%) “strongly agree” with the statement “I feel that using the ACC/AHA risk calculator is beneficial”. See Table 2 for an illustration of these findings.

Table 2

Post-Implementation Survey Results

Statement	Strongly Disagree	Disagree	Agree	Strongly Agree
I am knowledgeable about aspirin use for primary prevention of CVD	1 (8%)	1 (8%)	8 (67%)	2 (17%)
I am knowledgeable about statin use for primary prevention of CVD	0	5 (42%)	6 (50%)	1 (8%)
I feel that using the USPSTF guidelines are beneficial for aiding decision making of aspirin and/or statin use	0	0	11 (92%)	1 (8%)
I am knowledgeable about the cardiovascular risk calculator produced by the ACC/AHA	2 (17%)	6 (50%)	4 (33%)	0
I feel that using the ACC/AHA risk calculator is beneficial	0	0	10 (83%)	2 (17%)
Total Responses	3 (5%)	12 (20%)	39 (65%)	6 (10%)

Objective Four

The fourth objective, to have participants provide data from the health screening to their primary care providers, was evaluated through one- and three-month post-implementation surveys. The statements provided on the survey to evaluate the fourth objective included:

I. Did you communicate the health screenings result to your PCP?

II. Were any changes made in your medication list based off the results of the health screening recommendations?

III. If you answered ‘yes’ to the previous question, briefly explain what changes were made.

In the one-month follow-up survey, four (29%) of the participants had stated “Yes” and 10 (71%) of the participants had stated “No” to the question “Did you communicate the health screening results to your PCP”. Additionally, 14 (100%) participants stated “No” to the question “Were any changes made in your medication list based off the results of the health screening

recommendations. Free text responses included the following: “If you had recommended that I talk with my doctor about the results, I would have. The wonderful thing is that I didn't need to. Good luck with your research!”; “I will at my next yearly visit”; “My results from the screening was that I am healthy so I didn't find it necessary to disuse [*sic*] it with my doctor”; and “My annual physical is at the end of September and I plan to discuss the screening results with my PCP then”. See Table 3 for an illustration of the results.

Table 3

One-month Follow-up Survey

Question	Yes	No
Did you communicate the health screening results to your PCP?	4 (29%)	10 (71%)
Were any changes made in your medication list based off the results of the health screening recommendations?	0	14 (100%)
Total Responses	4 (14%)	24 (86%)

Upon completion of the one-month follow-up survey results, the primary investigator and co-investigator concluded that a one-month period of time to contact, schedule an appointment, and be seen by a provider may not be an adequate amount of time to carry out the request. As a result, an IRB amendment was sought and approved to complete a three-month follow-up survey (see Appendix A).

In the three-month follow-up survey, three (21%) of the participants stated “Yes” and 11 (79%) participants stated “No” to the question “Did you communicate the health screening results to your PCP”. When asked “Were any changes made in your medication list based off of the results of the health screening recommendations”, 14 (100%) participants responded “No”. Free text responses included the following: “My next appointment isn't until February. I will discuss then”; “I was already on medication for high blood pressure, diabetes, and cholesterol,

they're being continued"; "Based on your screening, I had no reason to followup [*sic*] with my doctor"; and "In February I go in for a blood test then she will notify me of results. If quiting [*sic*] smoking and changing eating habits doesn't work then we are going to put me on crestor [*sic*]". See Table 4 for an illustration of the results.

Table 4

Three-month Follow-up Survey

Question	Yes	No
Did you communicate the health screening results to your PCP?	3 (21%)	11 (79%)
Were any changes made in your medication list based off the results of the health screening recommendations?	0	14 (100%)
Total Responses	3 (11%)	25 (89%)

CHAPTER 5: DISCUSSION AND RECOMMENDATIONS

Summary

The purpose of the project was successful adoption of the 2016 USPSTF guideline on aspirin and statin use for primary prevention of CVD by NDSU staff participating in a NDSU Health Screening. The project included a co-investigator led health screening comprising of a USPSTF-guided screening in concurrence with the ACC/AHA risk calculator, cholesterol profile, blood glucose, oxygen saturation, body fat analysis, hand grip strength test, blood pressure, weight, height, and PHQ-9/GAD-7. Data were collected and recorded into the ACC/AHA risk calculator and evaluated whether the participant was currently taking aspirin, statins, or both, and whether USPSTF recommendations supported use of these medications according to their risk with a copy of results provided to each participant. Objectives one and three were met with objectives two and four being partially met. Results of the project indicated proper participant use of aspirin and statins according to the USPSTF guidelines with a majority reporting awareness of the guidelines used in the project. Participants also reported a positive viewpoint of the cardiovascular risk calculator and the intent to provide data from the health screening to their PCP. The results of each objective have been interpreted and discussed below.

Objective One

Objective one was for data to be gathered from participants 40 years of age and older at the NDSU Health Screening to corroborate whether participants were taking aspirins and/or statin per the USPSTF guidelines. The objective was evaluated through successful implementation and completion of the health screening with application of the data to the ACC/AHA risk calculator and relevant USPSTF guidelines. Aspirin guidelines were well-followed, with four (14%) of the participants on aspirin that qualified for the use of aspirin and

just one (4%) participant who qualified to be taking aspirin but was not currently taking the medication. The majority of participants (82%) did not take aspirin and did not qualify, with no participants taking aspirin when they should not have been.

Statin use according to guidelines was slightly less objectively well-followed, with five (18%) participants taking statins who qualified. An additional three participants (11%) qualified for statin use but were not currently taking a statin. A significant number (71%) of participants were not on statins and did not qualify. Notably, a large majority of participants (89%) were observed to be taking statins correctly per the USPSTF guidelines. A conclusion can be reasonably inferred that objective one was met, with participants in the health screening taking aspirin and statins correctly per the USPSTF guidelines.

Objective Two

Objective two was for participants in the health screening to report awareness and practice of current USPSTF guidelines related to aspirin and statin use for primary prevention along with awareness and practice of the cardiovascular risk calculator through post-survey completion. The objective was evaluated with a four-point Likert scale on the post-implementation survey. Two (16%) participants selected “strongly disagree” or “disagree” with the statement “I am knowledgeable about aspirin for primary prevention of CVD”. Ten participants (84%) responded “agree” or “strongly agree” to the same statement. Next, five participants (42%) selected “disagree” to the statement “I am knowledgeable about statin use for primary prevention of CVD”. A majority of participants (58%) stated they either “agree” or “strongly agree” to the same statement. Though not a strong majority agreed that they were knowledgeable of statin use for primary prevention of CVD, a majority was established, nonetheless.

When responding to the statement "I am knowledgeable about the cardiovascular risk calculator produced by the ACC/AHA", eight participants (67%) stated they either "strongly disagree" or "disagree" with the statement. Another four (33%) participants stated they "agree" with the statement. Responses are sufficient to state that participants were aware of the current practice of USPSTF guidelines for aspirin and statin use for primary prevention of CVD. However, the objective data supports that participants are unable to state the same about awareness and practice of the cardiovascular risk calculator. As a result, objective two was partially met. It is essential to note that, though it is not necessary for patients to be fully informed on what the USPSTF guidelines and risk calculator are, it is imperative that patients are seeking care and discussing their risk with their PCP. This further supports the need for patients to be knowledgeable of what the guidelines and risk calculator are and why their CVD risk is important to discuss with their PCP.

Objective Three

Objective three sought a positive viewpoint related to the cardiovascular risk calculator through post-survey completion. A four-point Likert scale was used to evaluate the objective. When responding to the statement "I feel that using the ACC/AHA risk calculator is beneficial", no participants disagreed with the statement and all (100%) of the participants selecting "agree" or "strongly agree" with the statement. From the results of the post-implementation survey, it is reasonable to make the conclusion that objective three was met.

Objective Four

Objective four was for participants in the health screening to agree to provide data and recommendations per the USPSTF guidelines to their primary care providers. Evaluation was made with a "Yes" or "No" response. A second free-text response prompted "Were any changes

made in your medication list based off the results of the health screening recommendations". In the one-month follow-up survey, four participants (29%) had stated "Yes" and 10 (79%) stated "No" to the question "Did you communicate the health screening results to your PCP". Though intended to confer any changes made to the participant medication list based off the health screening recommendations provided, participants used the free-text option to provide feedback and rationalization for why they did not communicate findings to their provider. Responses included, "If you had recommended that I talk with my doctor about the results, I would have. The wonderful thing is that I didn't need to"; "I will at my next yearly visit"; "My results from the screening was that I am healthy so I didn't find it necessary to disuse it with my doctor"; and "My annual physical is at the end of September and I plan to discuss the screening results with my PCP then".

In the three-month follow-up survey including the same evaluation tools as the one-month follow-up survey, three (21%) participants selected "Yes" and 11 (79%) selected "No" when prompted "Did you communicate the health screening results to your PCP". In the free-text response inquiring "Were any changes made in your medication list based off the results of the health screening recommendations", participants again used the free-text response section as an opportunity to provide feedback on why they did not discuss findings with their PCP. Responses included, "My next appointment is not until February. I will discuss then"; "I was already on medication for high blood pressure, diabetes, and cholesterol, they're being continued"; "Based on your screening, I had no reason to follow-up with my doctor"; and "In February I go in for a blood test then she will notify me of results. If quiting [*sic*] smoking and changing eating habits doesn't work then we are going to put me on crestor".

During the health screening, the co-investigator made verbal contact with every participant and discussed when results were expected and were strongly encouraged to contact their PCP regarding their results, regardless of whether any changes were recommended, as conveyed in the objective. Subsequently, each participant verbalized understanding of the expectation upon completion of the health screening. If one were to follow the objective strictly and be evaluating whether participants agreed to provide data and results from the health screening with their PCP, one may reasonably state that objective four was met. However, if the metric used to predict whether the objective was met or not met was whether participants followed through and communicated the results to their PCP, one would be prudent to state that the objective was not met as intended, as the majority of the participants in the one-month (71%) and three-month follow-up survey (79%) did not report communicating results from the health screening to their PCP. As a result of the combination of agreement to contact their PCP regarding results but lack of follow-through with completing that communication, the objective is concluded as partially met.

Discussion

Applying the findings of the project to existing literature, participants generally followed the currently published 2016 USPSTF guidelines for both aspirin and statins as primary prevention of CVD as noted in earlier discussion. As a caveat, the USPSTF is currently re-evaluating the recommendations for both aspirin and statin use. Of note, preliminarily updated recommendations for aspirin use to prevent CVD released in late 2021 are now proposing the decision to initiate low-dose aspirin use for adults ages 40-59 years with a 10% or greater 10-year CVD as an individual one (USPSTF, 2021). This is graded as a C recommendation, previously a B recommendation, in which the USPSTF recommends selectively offering the

service to individual patients based on professional judgement and patient preferences, with at least moderate certainty that the net benefit is small (USPSTF, 2018). For adults age 60 years or older, the USPSTF is recommending against initiating low-dose aspirin use for the primary prevention of CVD (USPSTF, 2021). This is graded as a D recommendation, previously a C recommendation, in which the USPSTF recommends against the service with moderate or high certainty that the service has no net benefit or that the harms outweigh the benefits (USPSTF, 2018).

A study by Boakye et al. (2021) found that there has been a slight decline in aspirin use for the last decade, albeit not significant, with approximately 1 in 4 adults in the United States 40 years of age or older without a history of CVD events reporting aspirin use for primary prevention of CVD (Boakye et al., 2021). Of concern, almost half of adults aged 70 years or older without preexisting CVD reported primary prevention aspirin use (Boakye et al., 2021). The authors of the study found that among individuals without any self-reported conventional CVD risk factor, males, adults 70 years of age or older, and individuals with healthcare coverage were more likely to report primary prevention with aspirin use (Boakye et al., 2021). These findings stray from those of this project, where the vast majority of participants (96%) were taking aspirin according to the current guidelines. Applying the updated recommendations to this population, 86% of participants were noted to not be taking aspirin as primary prevention and were already in accordance with what would become the updated recommendations.

Though underway, no preliminary USPSTF recommendations are currently available for statins as primary prevention of CVD. Findings in this project demonstrated that 63% of those who qualified for statin use were currently being treated with statins. This is modestly improved from findings previously discussed in chapter two, where Ngo-Metzger et al. (2018) reported

42% of adults eligible for statin use were actually taking statins. Yourman et al. (2021) provided compelling literature for support of adherence to statins with a meta-analysis that reported length of time to benefit from reduction of adverse cardiac events for adults aged 50-75 treated with statins at 2.5 years, meaning benefits were seen after an average of 2.5 years of treatment with statins. Addressing the uncertainty about harms of statins, meta-analyses have generally shown that adverse event rates are similar in participants randomized to statin or placebo, suggesting no significant increase in adverse events with statins (Yourman et al., 2021), which is consistent with literature discussed in chapter two despite common rhetoric found when discussing statins and adverse events.

Evaluation of Theoretical Framework

As discussed in chapter two, the Iowa Model of Evidence-Based Practice was used to help facilitate implementation of the 2016 USPSTF guidelines regarding aspirin and statins for primary prevention of CVD at the NDSU Health Screening. The problem-solving steps and feedback loops associated with the model helped aid in decision-making within the project (Melnyk & Fineout-Overholt, 2019). A challenge encountered with the use of this model is the sustainability of the practice change, as the project will not be monitored past the three-month evaluation period and thus unable to verify sustainability by participants. However, one could infer from positive participant viewpoints of the guidelines and risk calculator used in this project that sustainability of the guidelines is quite possible.

Additionally, the Diffusion of Innovations theory was utilized to aid in implementation of the 2016 USPSTF guidelines. This theory was helpful when developing and evaluating the practice improvement project. As previously discussed, there are five categories that are described in the theory, ranging from innovators to laggards. Through discussion with

participants during the health screening, inferences could be made regarding which of those categories each participant may fit into. Furthermore, the theory discusses the five stages of innovation that participants progress through, including knowledge, persuasion, decision, implementation, and confirmation (Pender et al., 2019). The first stage of knowledge was easily addressed due to the lack of knowledge of USPSTF guidelines noted among NDSU staff.

During the second stage, persuasion, adopters are influenced by several factors, including relative advantage, compatibility, complexity, trialability, and observability (Pender et al, 2019). Relative advantage and compatibility could be seen through the effort of discussing the results with participant PCPs. In communicating the results, one could extrapolate that the participant had considered the advantages and compatibility of aspirin and statins with their lifestyle and deemed it worthy to pursue.

However, the final three characteristics of complexity, trialability, and observability are quite difficult to apply to the findings of this project as they are simply unverifiable unless further evaluations were made. While in-person education was provided to participants at the time of the screening, one could argue that more education beyond a several minute discussion at the health screening is necessary and likely expected from their PCP as well. Trialability is unable to be verified as any medication trials would occur with a PCP after completion of the project, and observability is challenging as previously discussed due to the abstract nature of health behavior changes and the perceived benefit of preventing a disease that may never occur due to that behavior change.

In the third stage of decision, participants and their providers are to determine their intent to adopt and utilize the USPSTF recommendations and taking part in shared decision-making. If one were to use the results of the post-survey implementation to decide whether the third stage

was successfully followed by participants, the conclusion is not positive with 71% of participants in the one-month follow-up survey and 79% in the three-month follow-up survey having actually communicated the health screening results to their provider.

The final two stages of implementation and confirmation are also unable to be verified due to the completion of follow-up evaluations being made prior to any reported changes made by participants. The one-month and three-month follow-up surveys conveyed that no participants had made any changes to their medication regimen. However, one participant did report lifestyle changes being trialed prior to addition of medications, which could be considered proof of implementation and confirmation of the use of the guidelines. Generally, completion of the final three stages of innovation are unable to be verified in this project. As a result, prudent consideration should be made in future similar projects whether, although helpful, the Diffusion of Innovations theory is the best theory to utilize for optimal project guidance.

Recommendations

Use of health screenings to identify those at risk of CVD is recommended for future practice. Use of the USPSTF guidelines related to aspirin and statin use for primary prevention of cardiovascular disease and the ACC/AHA risk calculator are recommended to be continued in future health screenings based on relatively positive project outcomes and supporting literature. Continued use of guidelines and tools, such as the risk calculator, are recommended to continue to improve medication adherence and prescription in the effort to reduce cardiovascular risk.

Implications for Practice of Health Screening

Results of the project support continued implementation of health screenings as a form of preventive care. Data from the health screening revealed several implications for practice in primary care. First and foremost, average CVD risk of participants was calculated as 4.96%,

which is well below the USPSTF's recommended value to consider aspirin and/or statins at a 10% calculated CVD risk. This indicates that the average participant in the health screening was theoretically reducing their CVD risk to a satisfactory level, though whether that is optimal needs to be individualized for each patient.

The average body mass index (BMI) of participants was 30.8 kg/m^2, which falls within the obesity range (Centers for Disease Control and Prevention [CDC], 2021). This further solidifies that, though the average CVD risk was more than acceptable, an all-encompassing view by providers on the patient values is necessary. The results of this health screening indicate that a continued focus on healthy and active lifestyle to reach a healthy weight and BMI is also essential. Next, blood pressure in participants demonstrated an exemplary average SBP of 120 mmHg, but an average DBP of 80 mmHg which technically classifies as hypertension (Whelton et al., 2018). Though not all participants were classified as hypertensive, a focus on trends of blood pressures is imperative in reducing risk of CVD, as blood pressure and whether the patient is being treated are used in the calculation of a patient's CVD risk. Average PHQ-9 in participants was 3 and average GAD-7 was 2. This indicates low self-reported rating of symptoms of depression and anxiety, though important to note is the use of PHQ-9 and GAD-7 is a screening tool and does not replace a thorough assessment and interview of patients in primary care.

Average blood glucose of participants was ~110 mg/dL, which is quite satisfactory with the assumption that these values were not fasting. Regardless, regular monitoring of blood glucose values is imperative in primary prevention of CVD, as diabetes is also a factor taken into consideration when calculating a patient's CVD risk. Finally, average HDL of participants was exemplary at 55 mg/dL. However, average total cholesterol (175 mg/dL) and triglycerides (185

mg/dL) indicated slight elevation compared to preferred values of total cholesterol of <170 mg/dL and triglycerides <150 mg/dL (Arnett et al., 2019). These values support a continual focus by PCPs on fostering and encouraging a healthy diet and active lifestyle. These interventions continue to be an integral step in managing and reducing CVD risk and should always be considered by PCPs when managing CVD risk whether a patient is on aspirin and/or statins or not.

Implications for Practice of USPSTF Guidelines

Results of the project support the need for continued use of the 2016 USPSTF guidelines regarding the use of aspirin and statins for primary prevention of CVD in health screenings and primary care. The literature review of this project displayed the need for improved adherence to guidelines. New guideline recommendations heeding the warning of taking aspirin as primary prevention of cardiovascular disease is further complicated by a long-standing presence in healthcare of aspirin as a champion of primary prevention of CVD despite multitudes of research negating that sentiment. As a result, continued and diligent education on the potential safety issues of aspirin as primary prevention of CVD is perhaps even more important in light of the newly developing changes anticipated in the 2021 USPSTF guidelines.

Statins as primary prevention of cardiovascular disease have their own complicated relationship with adherence due to the real and/or perceived safety issues associated with statin use. Despite the many benefits associated with continued statin use, adherence is still suboptimal which is supported by results of this project. Continued support and use of the USPSTF guidelines for statins as primary prevention of cardiovascular disease remains to be important and is recommended for future practice in health screenings and primary care.

Finally, use of the ACC/AHA risk calculator was extremely beneficial in calculation of individual risk of CVD through data generated from the health screening and in guidance of recommendations for potential lifestyle changes and medications in primary prevention of cardiovascular disease. The results of this project show a need for increased knowledge and education on what the risk calculator is and how the calculator can be used as a beneficial tool in decision-making between patient and provider. This is further solidified by the overwhelmingly positive viewpoint conveyed in post-implementation surveys regarding the use of the ACC/AHA risk calculator. As a result, further and increased use of the risk calculator is recommended in future practice for both health screenings and primary care.

Implications for Future Research of Health Screening

There are several ways the use of the health screening can be expanded in future research. Along with the use of the values needed for the ACC/AHA risk calculator, a health screening can be tailored to evaluate a near endless variety of health metrics that a future researcher may desire. Application of the average blood pressure may be expanded to evaluate whether participants are being accurately treated according to the USPSTF guidelines on hypertension management along with aspirin and/or statins. Lifestyle questions addressing average activity or diet may be considered as an addition to a health screening and be used as another element to discuss with a PCP in order to optimally manage CVD risk. Overall, the use of a health screening is an exceedingly useful tool to collect data, evaluate health risks, and provide opportunities for education for any patient. In conclusion, the use of a health screening has multitudes of opportunities of expansion for future researchers in the evaluation of CVD risk.

Implications for Future Research of USPSTF Guidelines

There are various ways this project could be expanded for further research. First, an increase in the number of participants screened could be beneficial in obtaining a more accurate depiction of the general public's CVD risk. In order to do so, the broadening of a screening beyond NDSU staff into the general public could certainly generate more data and the expansion into more than one business day could promote increased attendance.

An intriguing study by Chien et al. (2019) determined primary drivers that motivated people to participate in health screenings for chronic diseases. Key factors for increased participation in health screenings included higher education level, married status or participants who lived with others, the female sex, and age greater than 60 years old (Chien et al, 2019). In this study, those with a higher education level were more motivated to take part in a health screening than their lower educated counterparts, which implied that higher education had an effect on knowledge of chronic disease and enhanced willingness to participate in health screenings (Chien et al., 2019). Chien et al. (2019) also noted that those from remote districts, those with a lower education level, and those who lived alone were less likely to attend a health screening. Reviewing this study can find extremely relatable points to adults in rural Midwest populations. As a result, future projects could consider expanding the population beyond NDSU campus into a more rural setting versus the relatively urban setting used in this project to obtain a more accurate depiction of the rural North Dakota population.

Several factors addressing the implementation process of the health screening could be considered for future research. One factor for consideration is the sign-up process for participation in the health screening. As discussed in the project design, an informational e-mail and flyers were distributed with details of the project and what made participants eligible to

participate. One key factor of this project is the participant age being 40 years or older due to insufficient research available on adults younger than 40 years of age. Despite those points being made in the information distributed, adults younger than 40 years of age were able to sign up for slots to participate in the health screening. A suggestion for future practice is a multi-step sign-up form that inquires age and disqualifies participants younger than 40 years of age from progressing on to signing up for participation in the cholesterol portion of the health screening with the opportunity to continue to participate in all of the remaining stations of the health screening.

Another factor that proved to be somewhat deficient in this project was the communication of results, whether there were recommended changes or not, with the participants' primary care provider. A suggestion for future research is stressing the expectation of clear and thorough communication, regardless of results, be made between participants and their PCPs after completion of the health screening when participants are provided with their results. A final factor for consideration in future research is increased education on the guidelines, what the guidelines mean and how they may apply to the participant, and what the ACC/AHA risk calculator is and how the calculator works. Follow-up survey results from this project indicated a considerable opportunity for improvement in participant understanding of the guidelines and risk calculator. As a result, improved education beyond informal discussion, such as a brief, formal education session during the health screening, could improve participant understanding of the guidelines and risk calculator and aid in the improvement of overall participant outcomes.

Dissemination

The final step within the feedback loops is dissemination of results. Dissemination of results is important for advanced practice nurses to continue to enhance knowledge and strive to continue to improve through evidence-based practice (Melnyk & Fineout-Overhold, 2019). This project was presented via peer reviewed poster presentation at the annual North Dakota Nurse Practitioner Association (NDNPA) Pharmacology Conference in September of 2021. The project results will also be presented at the Spring 2022 NDSU College of Health Professions Poster Presentation. Further anticipated dissemination by the co-investigator will be submission of a manuscript for publication to *The American Journal of Nursing* in the spring of 2022. Journals of interest include those that are focused on nurse practitioners, cardiovascular health, rural health, and primary care. Other opportunities for dissemination include the NDSU Graduate School's 2022 Three Minute Thesis Competition and publication in NDSU's Thesis & Dissertation database.

Strengths and Limitations

There were several noted strengths and limitations during this project. The first strength noted in this project was an overwhelming amount of interest and support among NDSU staff and staff leadership. The response rate to signing up for the health screening was so immediate with little advertisement made that demand could have possibly necessitated doubling the number of spaces available, if resources had allowed. A project like this has the ability to be implemented on a much larger scale to serve a larger number of individuals with the proper amount of time and resources.

The second strength of this project was an extremely positive response to the USPSTF guidelines and risk calculator used in this project. Not only did survey responses indicate a

positive participant viewpoint of the guidelines and risk calculator, but personal communication with participants expressed enthusiasm during and after the screening for the health screening, guidelines, and risk calculator. It is reasonable to consider this enthusiasm would continue to endure on to future projects.

A final strength of this project was the response rates obtained in the follow-up surveys. Though estimates and ranges vary among different companies and organizations for what constitutes an average response rate, typically the figure falls between 20% and 30% (Qualtrics, n.d.). Response rates for this project varied from 43% up to 50%, which is excellent and shows a more encompassing view of the opinions and beliefs of the participants of this health screening.

There were several limitations to consider for this project. The first limitation was the cost-prohibitive nature of the health screening. While interest abounded, the simple matter of being self-funded was prohibitive of the number of participants screened. With each lipid panel test strip costing $15 each, a self-funded project would become financially difficult with a larger number of participants unless further funding was obtained. Human error always being a factor when utilizing a device, such as the Cardiochek Plus for obtaining lipid values, the added pressure of absolute perfection was noted due to the high cost of the testing strips. Though the screening advertised the ability to bring in lipid panel results from the previous year to calculate participant CVD risk, no participants chose that option and could be encouraged further for increased participation with lower cost.

The second limitation noted was the sign-up process to participate in the health screening. As previously discussed, the USPSTS guidelines are only applicable to adults 40 years of age or greater due to insufficient research available on adults younger than 40 years of age. The sign-up website used was rather simple, with no verification of the participants' age when they were

signing up for a time slot during the health screening. In fact, several participants who signed up for the health screening were under the age of 40 years and, as a result, the guidelines were not applicable to them. These participants were educated on the age guidelines and were invited to participate in the remainder of the health screening, though this resulted in available time slots that were eventually filled by other participants of the proper age. Improvements in the sign-up could be made by making a more intuitive, multi-step process for signing up to assist with vetting participants based on age and possibly medication regimen and whether they are already taking aspirin and/or statins.

A third limitation to this project was evident during the evaluation and follow-up process. As previously discussed in chapters four and five, participant communication with their PCP was low. Various responses for not having communicated results to the PCP existed, which reflects the necessity for further clarity to participants on the importance of communicating results regardless of whether new recommendations were made. This also provides a limitation in that there was not a proper feedback loop from the co-investigator to the participant, to the provider, and back to the co-investigator. As a result, relatively little feedback was obtained in that respect, making difficulty in evaluating application to theories used and application to primary care providers. Another portion of the process that acted as a limitation was the follow-up period being no longer than three months. Though current technology allows ease of communication for patients and providers, the capability and desire are not there for all patients. As a result, participants may elect to wait to discuss results with their PCP at their annual exam. With three months being used as a follow-up window, participants may have already had their annual exam with no intent to see their PCP for a possibly extended period of time.

A final limitation noted for this project was verification of participant health status. The participant medications, medical history, and social history were taken from the participants with no ability to verify reliability against a medical chart. Participants may not have disclosed smoking status, aspirin use for secondary prevention, diabetic status, or any of the risk factors noted in the risk calculator to increase CVD risk and inadvertently skewed their actual risk results. With the design of this project, there was no way to verify reliability of information provided beyond the participant's personal provision of their medical and social history. As a result, the prospect of not having had accurate risk calculations is a likely possibility.

Conclusion

With 89% of the nurse practitioner population in primary care and more than 75% actively practicing NPs providing primary care, NPs are a vital part of the U.S. primary care workforce (American Association of Nurse Practitioners, n.d.). The American Association of Nurse Practitioners (AANP) has developed Standards of Practice to provide an overview and insight of what qualities demonstrate exemplary nurse practitioners. While extensive, one of the standards focus on quality assurance and research as a basis for practice (AANP, 2019). Furthermore, continued competence is essential with application of current evidence-based practice and utilization of best practice standards (AANP, 2019).

This practice improvement project utilized evidence-based research and guidelines available to all NPs and applied them to individuals in the community. Moreover, the project is a real example of how our practice as primary care providers should look with the application of guidelines, research, and education to our patients. The NP combines roles of provider, mentor, advocate, educator, and researcher and interprets and conveys that information to individuals, families, colleagues, and legislators (AANP, 2019). With CVD remaining as the leading cause of

morbidity and mortality in the U.S., focus and continued consideration of application of guidelines utilized in this project will continue to raise up the profession and provide impactful, holistic care to our patients as NPs continue to lead the way in primary prevention of CVD.

REFERENCES

Ahead Research. (2020). ACC/AHA ASCVD Risk Calculator. Retrieved from http://www.cvriskcalculator.com/

American Association of Nurse Practitioners. (n.d.). *Nurse practitioners in primary care* [Report]. https://www.aanp.org/advocacy/advocacy-resource/position-statements/nurse-practitioners-in-primary-care

American Association of Nurse Practitioners. (2019). *Discussion paper: Standards of practice for nurse practitioners* [Report]. https://www.aanp.org/advocacy/advocacy-resource/position-statements/standards-of-practice-for-nurse-practitioners

American Diabetes Association. (2020). Standards of medical care in diabetes-2021 abridged for primary care providers. *Clinical Diabetes*, *39*(1), 14–43. Retrieved April 23, 2021, from https://doi.org/10.2337/cd21-as01

American Heart Association. (2019). Heart disease and stroke statistics-2019 update: A report from the American Heart Association. *Circulation*, *139*(10), e56-e528. http://dx.doi.org/10.1161/CIR.0000000000000659

American Heart Association. Center for Health Metrics and Evaluation (CHME). (2018). Data Visualizations. https://aha2017chme.wpengine.com/data-visualization/, accessed on 12/03/2020.

Arnett, D. K., Blumenthal, R. S., Albert, M. A., Buroker, A. B., Goldberger, Z. D., Hahn, E. J., Himmelfarb, C., Khera, A., Lloyd-Jones, D., McEvoy, J., Michos, E. D., Miedema, M. D., Muñoz, D., Smith, S. C., Virani, S. S., Williams, K. A., Yeboah, J., & Ziaeian, B. (2019). 2019 ACC/AHA guideline on the primary prevention of cardiovascular disease.

Journal of the American College of Cardiology, *74*(10), e177–e232. https://doi.org/10.1016/j.jacc.2019.03.010

Bibbins-Domingo, K. (2016a). Aspirin use for the primary prevention of cardiovascular disease and colorectal cancer: U.S. Preventive Services Task Force recommendation statement. *Annals of Internal Medicine*, *164*(12), 836. https://doi.org/10.7326/m16-0577

Bibbins-Domingo, K. (2016b). Statin use for the primary prevention of cardiovascular disease in adults. *JAMA*, *316*(19), 1997–2007. https://doi.org/10.1001/jama.2016.15450

Boakye, E., Uddin, S., Obisesan, O. H., Osei, A. D., Dzaye, O., Sharma, G., McEvoy, J., Blumenthal, R., & Blaha, M. J. (2021). Aspirin for cardiovascular disease prevention among adults in the United States: Trends, prevalence, and participant characteristics associated with use. *American Journal of Preventive Cardiology*, *8*, 1-8. https://doi.org/10.1016/j.ajpc.2021.100256

Bowman, L., Mafham, M., Wallendszus, K., Stevens, W., Buck, G., Barton, J., Murphy, K., Aung, T., Haynes, R., Cox, J., Murawska, A., Young, A., Lay, M., Chen, F., Sammons, E., Waters, E., Adler, A., Bodanksy, J., Farmer, A.,...Armitage, J. (2018). Effects of aspirin for primary prevention in persons with diabetes mellitus. *New England Journal of Medicine*, *379*(16), 1529–1539. https://doi.org/10.1056/nejmoa1804988

Capodanno, D., & Angiolillo, D. (2016, November 15). Aspirin for primary cardiovascular risk prevention and beyond in diabetes mellitus. *Circulation*, *134*(20), 1579-1594. http://dx.doi.org/10.1161/CIRCULATIONAHA.116.023164

Centers for Disease Control and Prevention. (2021, June 7). *Adult body mass index*. Overweight & obesity. https://www.cdc.gov/obesity/adult/defining.html

Chien, S.-Y., Chuang, M.-C., Chen, I.-P., & Yu, P. H. (2019). Primary drivers of willingness to continue to participate in community-based health screening for chronic diseases. *International Journal of Environmental Research and Public Health*, *16*(9), 1–10. https://doi.org/10.3390/ijerph16091645

Chou, R., Dana, T., Blazina, I., Daeges, M., & Jeanne, T. L. (2016). Statins for prevention of cardiovascular disease in adults. *JAMA*, *316*(19), 2008–2024. https://doi.org/10.1001/jama.2015.15629

Collins, R., Reith, C., Emberson, J., Armitage, J., Baigent, C., Blackwell, L., Blumenthal, R., Danesh, J., Smith, G., DeMets, D., Evans, S., Law, M., MacMahon, S., Martin, S., Neal, B., Poulter, N., Preiss, D., Ridker, P., Roberts, I.,...Peto, R. (2016). Interpretation of the evidence for the efficacy and safety of statin therapy. *The Lancet*, *388*(10059), 2532–2561. https://doi.org/10.1016/s0140-6736(16)31357-5

Fernandez-Jimenez, R., Wang, T. J., Fuster, V., & Blot, W. J. (2019). Low-dose aspirin for primary prevention of cardiovascular disease: Use patterns and impact across race and ethnicity in the southern community cohort study. *Journal of the American Heart Association*, *8*(24). https://doi.org/10.1161/jaha.119.013404

Guirguis-Blake, J. M., Evans, C. V., Senger, C. A., O'Connor, E. A., & Whitlock, E. P. (2016). Aspirin for the primary prevention of cardiovascular events: A systematic evidence review for the U.S. Preventive Services Task Force. *Annals of Internal Medicine*, *164*(12), 804. https://doi.org/10.7326/m15-2113

Hope, H. F., Binkley, G. M., Fenton, S., Kitas, G. D., Verstappen, S. M., & Symmons, D. M. (2019). Systematic review of the predictors of statin adherence for the primary prevention

of cardiovascular disease. *PLOS ONE*, *14*(1), 1–38. https://doi.org/10.1371/journal.pone.0201196

Li, M., Wang, X., Li, X., Chen, H., Hu, Y., Zhang, X., Tang, X., Miao, Y., Tian, G., & Shang, H. (2019). Statins for the primary prevention of coronary heart disease. *BioMed Research International*, *2019*, 1–15. https://doi.org/10.1155/2019/4870350

Marquis-Gravel, G., Roe, M. T., Harrington, R. A., Muñoz, D., Hernandez, A. F., & Jones, W. (2019). Revisiting the role of aspirin for the primary prevention of cardiovascular disease. *Circulation*, *140*(13), 1115–1124. https://doi.org/10.1161/circulationaha.119.040205

McNeil, J. J., Wolfe, R., Woods, R. L., Tonkin, A. M., Donnan, G. A., Nelson, M. R., Reid, C. M., Lockery, J. E., Kirpach, B., Storey, E., Shah, R. C., Williamson, J. D., Margolis, K. L., Ernst, M. E., Abhayaratna, W. P., Stocks, N., Fitzgerald, S. M., Orchard, S. G., Trevaks, R. E.,...Murray, A. M. (2018). Effect of aspirin on cardiovascular events and bleeding in the healthy elderly. *New England Journal of Medicine*, *379*(16), 1509–1518. https://doi.org/10.1056/nejmoa1805819

Melnyk, B. M. & Fineout-Overholt, E (2019). Evidenced-based practice in nursing and healthcare: A guide to best practice (4th ed.). Philadelphia, PA: Wolters Kluwer.

Meyer, J., Arps, K., Blumenthal, R., & Martin, S. (2018, September 28). *New data on aspirin use in the era of more widespread statin use*. American College of Cardiology. https://www.acc.org/latest-in-cardiology/articles/2018/09/28/08/08/new-data-on-aspirin-use-in-the-era-of-more-widespread-statin-use

Mortensen, M., & Falk, E. (2018). Primary prevention with statins in the elderly. *Journal of the American College of Cardiology*, *71*(1), 85–94. https://doi.org/10.1016/j.jacc.2017.10.080

Newman, C. B., Preiss, D., Tobert, J. A., Jacobson, T. A., Page, R. L., Goldstein, L. B., Chin, C., Tannock, L. R., Miller, M., Raghuveer, G., Duell, P., Brinton, E. A., Pollak, A., Braun, L. T., & Welty, F. K. (2019). Statin safety and associated adverse events: A scientific statement from the American Heart Association. *Arteriosclerosis, Thrombosis, and Vascular Biology*, *39*(2), e38–e79. https://doi.org/10.1161/atv.0000000000000073

Ngo-Metzger, Q., Zuvekas, S. H., & Bierman, A. S. (2018). Estimated impact of us preventive services task force recommendations on use and cost of statins for cardiovascular disease prevention. *Journal of General Internal Medicine*, *33*(8), 1317–1323. https://doi.org/10.1007/s11606-018-4497-4

Nguyen, K. A., Li, L., Lu, D., Yazdanparast, A., Wang, L., Kreutz, R. P., Whipple, E. C., & Schleyer, T. K. (2018). A comprehensive review and meta-analysis of risk factors for statin-induced myopathy. *European Journal of Clinical Pharmacology*, *74*(9), 1099–1109. https://doi.org/10.1007/s00228-018-2482-9

Nguyen, Q., Odden, M. C., Peralta, C. A., & Kim, D. (2020). Predicting risk of atherosclerotic cardiovascular disease using pooled cohort equations in older adults with frailty, multimorbidity, and competing risks. *Journal of the American Heart Association*, *9*(18), 1–13. https://doi.org/10.1161/jaha.119.016003

O'Brien, C. W., Juraschek, S. P., & Wee, C. C. (2019). Prevalence of aspirin use for primary prevention of cardiovascular disease in the United States: Results from the 2017 National Health Interview Survey. *Annals of Internal Medicine*, *171*(8), 1–6. https://doi.org/10.7326/m19-0953

Pender, N. J., Murdaugh, C.L., & Parsons, M.A. (2019). Health promotion in nursing practice (8th ed). Hudson, NY: Pearson Education.

Qualtrics. (n.d.). *How to increase survey response rates*. Retrieved November 30, 2021, from https://www.qualtrics.com/experience-management/research/tools-increase-response-rate/

Rana, J. S., Tabada, G. H., Solomon, M. D., Lo, J. C., Jaffe, M. G., Sung, S., Ballantyne, C. M., & Go, A. S. (2016). Accuracy of the atherosclerotic cardiovascular risk equation in a large contemporary, multiethnic population. *Journal of the American College of Cardiology*, *67*(18), 2118–2130. https://doi.org/10.1016/j.jacc.2016.02.055

Rosenson, R. S., Baker, S., Banach, M., Borow, K. M., Braun, L. T., Bruckert, E., Brunham, L. R., Catapano, A. L., Elam, M. B., Mancini, G., Moriarty, P. M., Morris, P. B., Muntner, P., Ray, K. K., Stroes, E. S., Taylor, B. A., Taylor, V. H., Watts, G. F., & Thompson, P. D. (2017). Optimizing cholesterol treatment in patients with muscle complaints. *Journal of the American College of Cardiology*, *70*(10), 1290–1301. https://doi.org/10.1016/j.jacc.2017.07.752

Selak, V., Jackson, R., Poppe, K., Wu, B., Harwood, M., Grey, C., Pylypchuk, R., Mehta, S., Kerr, A., & Wells, S. (2019). Predicting bleeding risk to guide aspirin use for the primary prevention of cardiovascular disease. *Annals of Internal Medicine*, *170*(6), 357. https://doi.org/10.7326/m18-2808

Siu, A. L. (2015). Screening for high blood pressure in adults: U.S. Preventive Services Task Force recommendation statement. *Annals of Internal Medicine*, *163*(10), 778–786. https://doi.org/10.7326/m15-2223

Singh, S., Zieman, S., Go, A. S., Fortmann, S. P., Wenger, N. K., Fleg, J. L., Radziszewska, B., Stone, N. J., Zoungas, S., & Gurwitz, J. H. (2018). Statins for primary prevention in older

adults-moving toward evidence-based decision-making. *Journal of the American Geriatrics Society*, *66*(11), 2188–2196. https://doi.org/10.1111/jgs.15449

Smith, D. K., Demetriou, T., & Weber, C. (2019). Aspirin for primary prevention: USPSTF recommendations for CVD and colorectal cancer. *The Journal of Family Practice*, *68*(3), 146–151.

Spence, J., & Dresser, G. K. (2016). Overcoming challenges with statin therapy. *Journal of the American Heart Association*, *5*(1), 1–13. https://doi.org/10.1161/jaha.115.002497

United States Preventive Services Task Force. (2016). Aspirin use for the primary prevention of cardiovascular disease and colorectal cancer: Recommendation statement. *American Family Physician*, *94*(8), 660A–660F.

United States Preventive Services Task Force. (2017). Statin use for the primary prevention of cardiovascular disease in adults: Recommendation statement. *American Family Physician*, *95*(2), 108A–108G.

United States Preventive Services Task Force. (2018). *Grade definitions.* https://www.uspreventiveservicestaskforce.org/uspstf/grade-definitions#july2012

United States Preventive Services Task Force. (2021, October 12). *Aspirin use to prevent cardiovascular disease: Preventive medication*. https://uspreventiveservicestaskforce.org/uspstf/draft-recommendation/aspirin-use-to-prevent-cardiovascular-disease-preventive-medication#fullrecommendationstart

Whelton, P. K., Carey, R. M., Aronow, W. S., Casey, D. E., Collins, K. J., Dennison Himmelfarb, C., DePalma, S. M., Gidding, S., Jamerson, K. A., Jones, D. W., MacLaughlin, E. J., Muntner, P., Ovbiagele, B., Smith, S. C., Spencer, C. C., Stafford, R. S., Taler, S. J., Thomas, R. J., Williams, K. A.,...Wright, J. T. (2018). 2017

ACC/AHA/AAPA/ABC/ACPM/AGS/APhA/ ASH/ASPC/NMA/PCNA guideline for the prevention, detection, evaluation, and management of high blood pressure in adults: A report of the American College of Cardiology/American Heart Association task force on clinical practice guidelines. *Hypertension*, *71*(6), e13–e115. Retrieved April 16, 2021, from https://doi.org/10.1161/hyp.0000000000000065

Xu, J., Murphy, S., Kochanek, K., & Arias, E. (2020). *Mortality in the United States, 2018* [Data Brief]. Retrieved from National Center for Health Statistics: https://www.cdc.gov/nchs/data/databriefs/db355-h.pdf

Yang, Q., Zhong, Y., Gillespie, C., Merritt, R., Bowman, B., George, M. G., & Flanders, W. (2017). Assessing potential population impact of statin treatment for primary prevention of atherosclerotic cardiovascular diseases in the USA: Population-based modelling study. *BMJ Open*, *7*(1), 1–11. https://doi.org/10.1136/bmjopen-2016-011684

Yourman, L. C., Cenzer, I. S., Boscardin, W., Nguyen, B. T., Smith, A. K., Schonberg, M. A., Schoenborn, N. L., Widera, E. W., Orkaby, A., Rodriguez, A., & Lee, S. J. (2021). Evaluation of time to benefit of statins for the primary prevention of cardiovascular events in adults aged 50 to 75 years. *JAMA Internal Medicine*, 181(2), 179–185. https://doi.org/10.1001/jamainternmed.2020.6084

Zheng, S. L., & Roddick, A. J. (2019). Association of aspirin use for primary prevention with cardiovascular events and bleeding events. *JAMA*, *321*(3), 277–287. https://doi.org/10.1001/jama.2018.20578

APPENDIX A: IRB APPROVAL

NDSU NORTH DAKOTA STATE UNIVERSITY

06/23/2021

Dr. Dean A Gross
Nursing

IRB Approval of Protocol #IRB0003680, "Health Screening of NDSU staff with emphasis on Aspirin and Statin Use for Primary Prevention of Cardiovascular Disease"

Co-investigator(s) and research team:

- Dean A Gross
- Natalie Jean Carriveau

Approval Date: 06/23/2021
Expiration Date: 06/22/2024
Research site(s): The health screening will occur in Aldevron Tower on the 3rd floor using the assessment lab 340a, multipurpose room 350 as well as the exam rooms as needed (#10) to provide adequate space for all the health screening stations. Cholesterol blood samples will be done in the health assessment lab on the third floor in exam rooms 9/10 to provide a quiet, comfortable space for a blood draw (finger stick).
Funding Agency:
Review Type: Expedited category # 2,4

The above referenced protocol has been reviewed in accordance with federal regulations (Code of Federal Regulations, Title 45, Part 46, *Protection of Human Subjects*).

Additional approval from the IRB is required:

- Prior to implementation of any changes to the protocol.
- For continuation of the project beyond the approval period. A task will automatically generate for the PI and Co-PI 8 weeks prior to the expiration date. To avoid a lapse in approval, suspension of recruitment, and/or data collection, a report must be received, and the protocol reviewed and approved for continuation prior to the expiration date.

Other institutional approvals:

- Research projects may be subject to further review and approval processes.

A report is required for:

- Any research-related injuries, adverse events, or other unanticipated problems involving risks to participants or others within 72 hours of known occurrence.
- Protocol Deviations
- Any significant new findings that may affect risks to participants.

Thank you for cooperating with NDSU IRB procedures, and best wishes for a successful study.

NDSU has an approved FederalWide Assurance with the Department of Health and Human Services: FWA00002439.

RESEARCH INTEGRITY AND COMPLIANCE
NDSU Dept 4000 | PO Box 6050 | Fargo ND 58108-6050 | ndsu.research@ndsu.edu
Shipping Address: Research 1, 1735 NDSU Research Park Drive, Fargo ND 58102
NDSU is an EO/AA University

NDSU NORTH DAKOTA STATE UNIVERSITY

09/07/2021

Dr. Dean A Gross
Nursing

IRB Approval of Amendment to Protocol #IRB0003680 , "Health Screening of NDSU staff with emphasis on Aspirin and Statin Use for Primary Prevention of Cardiovascular Disease"

Co-investigator(s) and research team:

- Dean A Gross
- Natalie Jean Carriveau

Funding Agency:
The protocol amendment request and all included documentation for the above-referenced project have been reviewed and approved via the procedures of the North Dakota State University Institutional Review Board. Current protocol approval expires - 06/22/2024.

Thank you for cooperating with NDSU IRB procedures, and best wishes for a successful study.

NDSU has an approved FederalWide Assurance with the Department of Health and Human Services: FWA00002439.

RESEARCH INTEGRITY AND COMPLIANCE
NDSU Dept 4000 | PO Box 6050 | Fargo ND 58108-6050 | ndsu.research@ndsu.edu
Shipping Address: Research 1, 1735 NDSU Research Park Drive, Fargo ND 58102
NDSU is an EO/AA university

APPENDIX B: EXECUTIVE SUMMARY

EXECUTIVE SUMMARY

Aspirin and Statin Use for Primary Prevention of Cardiovascular Disease

Introduction

Cardiovascular disease (CVD) is the leading cause of morbidity and mortality in the United States. The benefits of low-dose aspirin (81 mg) in secondary prevention is well-established, but the role of aspirin as primary prevention for CVD remains controversial primarily due to risk of bleeding. Ultimately, the decision to place a patient on aspirin for primary prevention of CVD is an individualized one made to the specific patient and situation.

With dyslipidemia playing a key role in development and mortality of CVD, statins are a first-line therapy used to lower plasma cholesterol. Though benefits of statin therapy are evident, perceived and/or real risks and side effects contribute to statin discontinuation and nonadherence. As a result, the use of statins for primary prevention should be determined on an individual basis.

The United States Preventive services Task Force (USPSTF) has level B recommendations in place regarding the use of low-dose aspirin for primary prevention of CVD. The USPSTF also has level B recommendations in place for the use of statins for primary prevention of CVD. In addition, the American Heart Association (AHA) and American College of Cardiology (ACC) developed a calculator to determine a patient's 10-year CVD risk. The guidelines and CVD risk calculator offer providers a beneficial tool to determine accurate medication prescription. However, despite the USPSTF guidelines, appropriate medication prescription and adherence remain suboptimal.

Project Design

The purpose of the project was successful adoption of the 2016 USPSTF guideline on aspirin and statin use for primary prevention of CVD by North Dakota State University (NDSU) staff participating in a NDSU Health Screening.

The health screening was provided to all participating NDSU staff a USPSTF screening in concurrence with the ACC/AHA risk calculator, cholesterol profile, blood glucose, oxygen saturation, body fat analysis, hand grip strength test, blood pressure, weight, height, and PHQ-9/GAD-7. Data were collected and recorded into the ACC/AHA risk calculator and evaluated whether the participant was currently taking aspirin, statins, or both, and whether USPSTF recommendations supported use of these medications according to their risk with a copy of results provided to each participant. Participants

were encouraged to share the information with their primary care provider (PCP) as soon as possible. Evaluation was performed through post-implementation surveys at one- and three-month increments.

Project Results

Results of the project indicated proper participant use of aspirin and statins according to the USPSTF guidelines with a majority reporting awareness of the guidelines used in the project. Participants also reported a positive viewpoint of the cardiovascular risk calculator and the intent to provide data from the health screening to their PCP.

Recommendations

Continued and diligent education on the potential safety issues of aspirin as primary prevention of CVD is perhaps even more important in light of the newly developing changes anticipated in the 2021 USPSTF guidelines.

Despite the many benefits associated with continued statin use, adherence is still suboptimal which is supported by results of this project. Continued support and use of the USPSTF guidelines for statins as primary prevention of cardiovascular disease remains to be important and is recommended for future practice in health screenings and primary care.

Use of the ACC/AHA risk calculator was extremely beneficial in calculation of individual risk of CVD through data generated from the health screening and in guidance of recommendations for potential lifestyle changes and medications in primary prevention of cardiovascular disease. The results of this project show a need for increased knowledge and education on what the risk calculator is and how the calculator can be used as a beneficial tool in decision-making between patient and provider.

Conclusion

Results of the project support the need for continued use of the 2016 USPSTF guidelines regarding the use of aspirin and statins for primary prevention of cardiovascular disease in health screenings and primary care. Results of the project also support the continued use of health screenings as an aid in preventive care in relation to CVD. Healthcare providers in primary care will likely encounter patients inquiring about or requiring aspirin and/or statins for primary prevention of CVD, and with the use of evidence-based guidelines such as those provided by the USPSTF coupled with the ACC/AHA risk calculator, an impactful change can be made in primary prevention of CVD.

APPENDIX C: PERMISSION TO USE IOWA MODEL

Permission to Use The Iowa Model Revised: Evidence-Based Practice to Promote Excellence in Health Care

KC **Kimberly Jordan - University of Iowa Hospitals and Clinics <noreply@qemailserver.com>**

9/21/2020 12:54 PM

To: Carriveau, Natalie

You have permission, as requested today, to review and/or reproduce *The Iowa Model Revised: Evidence-Based Practice to Promote Excellence in Health Care.* Click the link below to open.

The Iowa Model Revised (2015)

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Citation: Iowa Model Collaborative. (2017). Iowa model of evidence-based practice: Revisions and validation. *Worldviews on Evidence-Based Nursing, 14(3), 175-182. doi:10.1111/wvn.12223*

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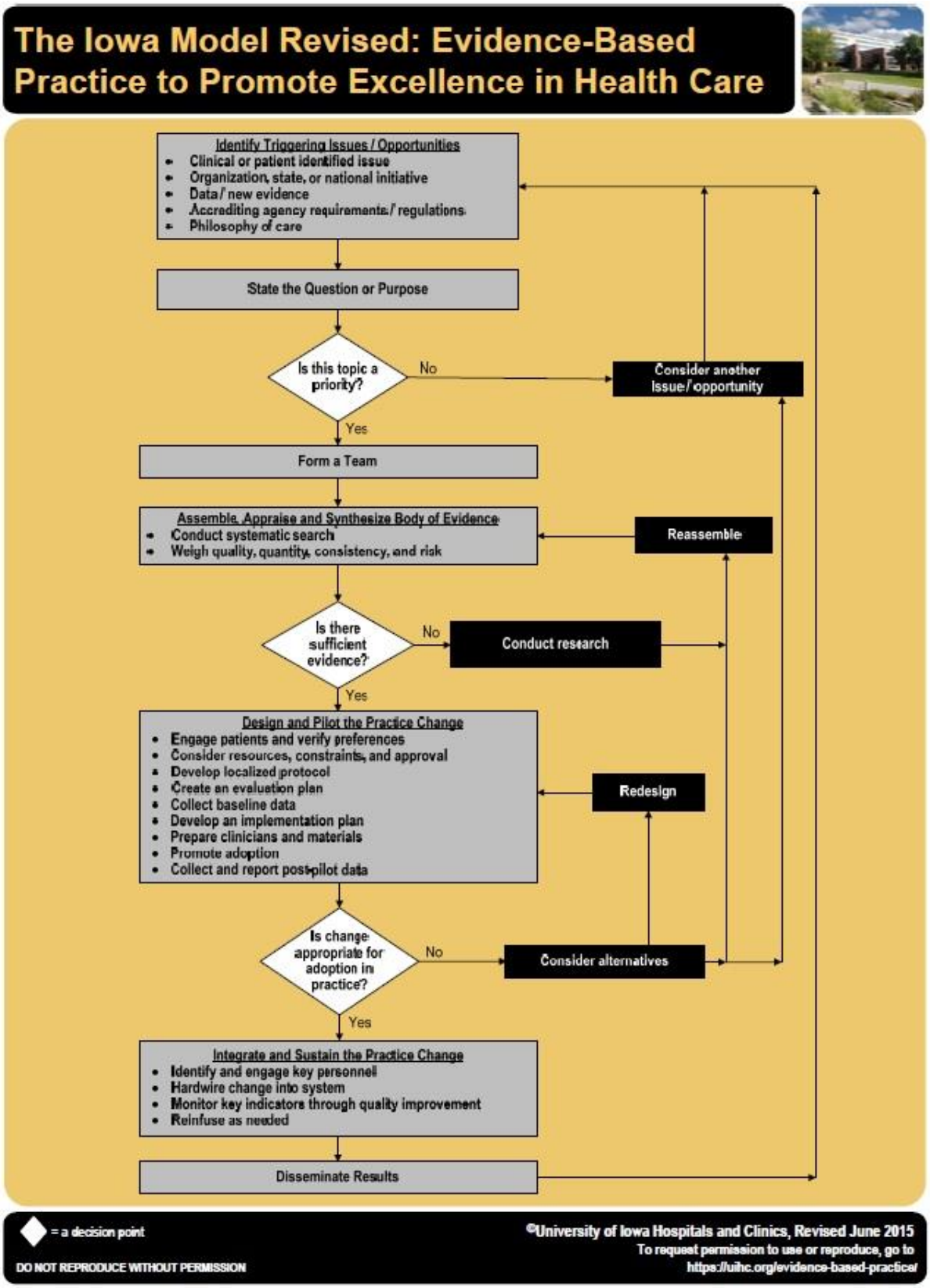
Please contact UIHCNursingResearchandEBP@uiowa.edu or 319-384-9098 with questions.

APPENDIX D: IOWA MODEL



APPENDIX E: LETTER OF SUPPORT

NDSU NORTH DAKOTA STATE UNIVERSITY

May 3, 2021

Re: NDSU Health Fair

To Whom It May Concern,

NDSU Staff Senate supports Natalie Carriveau's implementation of an NDSU Health Fair for the summer of 2021. We look forward to spreading the word and seeing our colleagues from across campus take advantage of this opportunity to learn more about their health.

Thank you,

Margaret Latterell
NDSU Staff Senate President

STAFF SENATE
NDSU Dept 1040 | PO Box 6050 | Fargo ND 58108-6050 | www.ndsu.edu/staff_senate

APPENDIX F: PARTICIPANT CONSENT FORM

School of Nursing
Aldevron Tower 540
Dept. #2670, P.O. Box 6050
Fargo, ND 58108-6050
(701) 231-7395

Aspirin and Statin Use for Primary Prevention of Cardiovascular Disease

This study is being conducted by: Dr. Dean Gross, Assistant Professor of Practice, Dean.Gross@ndsu.edu, 701-231-8355; and Natalie Carriveau, DNP Student, Natalie.Carriveau@ndsu.edu, 605-690-6086.

Key Information about this study:

This consent form is designed to inform you about the study you are being asked to participate in. Here you will find a brief summary about the study; however you can find more detailed information later on in the form.

- **Purpose of the study**: To provide a health screening to North Dakota State University (NDSU) staff members to determine if staff are following the 2016 USPSTF guidelines on aspirin and statin use for primary prevention of cardiovascular disease.
- **Inclusion Criteria:** NDSU Staff members that are 40 to 75 years of age
- **Exclusion Criteria:** Adults <40 years of age, adults >75 years of age, not a current NDSU staff member
- **Risks:** A point-of-care finger-prick test to collect a desired 40uL of blood (1-2 drops), as well as exposure to your own blood sample during the collection process of cholesterol and glucose values
- **Benefits:** Increased knowledge about personal cardiovascular disease risks and steps to ensure optimal treatment, increased knowledge of personal health information, enhanced communication between participants and their Primary Care Provider (PCP), and possible improvement of CVD risk if appropriate guideline recommendations are followed.
- **Time commitment:** Approximately 20 minutes
- **Compensation:** The study will cover the cost of a cholesterol/blood sugar screening ($15 per test) for the 1st 30 NDSU Staff participants
- **Privacy Concerns:** Privacy will be maintained via use of NDSU equipment and storing all information on a password-protected personal computer. No personal information will

be shared with any individuals not directly involved in the study. Information collected on paper forms will be logged into a password-protected personal computer accessible only to members of the study team. Paper forms will be shredded within 72 hours of the screening after information has been logged.

Why am I being asked to take part in this study?

You are a current NDSU staff member who is between the ages of 40 and 75 years.

What will I be asked to do?

You will be asked to review this consent form and verbally consent to participating in this health screening. The health screening includes a variety of stations, including cholesterol profile, blood glucose, oxygen saturation, body fat analysis, hand grip strength test, blood pressure, temperature, weight, height, and PHQ-9/GAD-7. Information from these stations will be entered into the American College of Cardiology/American Heart Association (ACC/AHA) risk calculator, which also asks for smoking status, if you're currently being treated for hypertension, diabetic status, and your race: African American or other. You will also be asked to provide your name, e-mail address, gender, age, and current use of statin or aspirin. The results from the ACC/AHA risk calculator will then be used with the USPSTF guidelines on aspirin and statin use and potentially generate recommendations from the guidelines. You will receive your results within 72 hours of the health screening with a short 5-minute survey to complete. You will then be asked to contact your PCP with the results. By September 2021 you will be asked to respond if your PCP made any changes to your medication regimen based off the health screening findings.

Where is the study going to take place, and how long will it take?

The health screening will be held on the 3rd floor of Aldevron Tower at 1455 14th Avenue N. Aldevron Tower is conveniently located directly north of the NDSU public parking lot E, providing easy access for all NDSU Staff. It will take approximately 20 minutes to complete the health screening.

What are the risks and discomforts?

Potential risks for participants in the NDSU health screening are a point-of-care finger-prick test to collect a desired 40uL of blood (1-2 drops) from the participant, as well as exposure to your own blood sample during the collection process of cholesterol and glucose values. This risk will be minimized through education on the process and obtaining the least amount of blood possible while collecting an adequate amount to successfully perform the test.

It is not possible to identify all potential risks in research; however, reasonable safeguards have been taken to minimize known risks. If new findings develop during the course of the study which may change your willingness to participate, we will tell you about these findings.

What are the expected benefits of this study?

Individual Benefits: Potential benefits gained by participants include increased knowledge about personal CVD risks and steps to ensure optimal treatment, increased knowledge of personal health information, enhanced communication between participants and their PCP, and possible improvement of CVD risk if appropriate guideline recommendations are followed.

Societal: Increased awareness/understanding of the USPSTF recommendations on the use appropriate use of aspirin and statins.

Do I have to take part in this study?

Your participation in this study is your choice. If you decide to participate in the study, you may change your mind and stop participating at any time without penalty or loss of benefits to which you are already entitled.

What are the alternatives to being in this study?

Instead of being in this study, you may choose not to participate.

Who will have access to my information?

Only Dean Gross and Natalie Carriveau will have access to identifiable information. Privacy will be maintained via the sole use of NDSU equipment and keeping all identifiable information on a password-protected personal computer. Information collected from paper forms will be logged into a password-protected computer accessible only to the primary and co-investigators, and paper forms will be shredded within 72 hours of the screening after information has been logged.

Once all information has been collected, data will be merged with those of other participants in the study. Data collected will not be associated with any personal information or shared with anyone not directly involved in the study. If you decide to withdraw from the study before it is completed, we will remove your information, shred all physical documents from your participation, and no additional information will be collected.

Can my participation in the study end early?
You may choose to stop your participation in the study at any time, for any reason.

Will I receive any compensation for participating in the study?
The study will cover the cost of a cholesterol/blood sugar screening ($15 per test) for the first 30 NDSU Staff participants.

What happens if I have abnormal results during the health screening?

All results will be e-mailed to each participant to be shared with their PCP. If you are injured during the course of this study, you should contact Dean Gross at 701-231-8355. Treatment secondary to the finger stick will be available. If you require further management of abnormal results, these must be provided by you and your third-party payer, such as private health insurance or Medicare. This does not mean that you are releasing or waiving any legal right you might have against the researcher or NDSU as a result of your participation in this study.

What if I have questions?

Before you decide whether you'd like to participate in this study, please ask any questions that come to mind now. Later, if you have questions about the study, you can contact Dean Gross at 701-231-8355 or Dean.Gross@ndsu.edu, or Natalie Carriveau at 605-690-6086 or Natalie.Carriveau@ndsu.edu.

What are my rights as a study participant?

You have rights as a study participant. All research with human participants is reviewed by a committee called the *Institutional Review Board (IRB)* which works to protect your rights and welfare. If you have questions about your rights, an unresolved question, a concern, or complaint about this study you may contact the IRB office at 701.231.8995, toll-free at 855-800-6717 or via e-mail (ndsu.irb@ndsu.edu).

Documentation of Consent:

You are freely making a decision whether to be in this practice improvement project. Participating in this health screening for cholesterol/blood glucose indicates that

1. you have read and understood this consent form
2. you have had your questions answered, and
3. you have decided to be in the project.

You will be given a copy of this consent form to keep.

_____ _____

Signature of researcher explaining study Date

_____

Printed name of researcher explaining study

APPENDIX G: ONE-MONTH/THREE-MONTH FOLLOW-UP E-MAIL TEMPLATE

To whom it may concern:

It has been approximately one month since your participation in the NDSU Health Screening to aid in the project of Natalie Carriveau, investigating aspirin and/or statins for primary prevention of cardiovascular disease. As previously discussed upon completion of the Health Screening, all participants were encouraged to discuss the results of the health screening with their primary care provider (PCP). It is now requested of you to complete a short survey inquiring whether you discussed the results with your provider and if any changes were made to your medication list based off those results.

Again, your participation in this project and following questions are completely voluntary and confidential but are appreciated and will aid in evaluating the results of this project. Any questions or concerns can be made via e-mail at natalie.carriveau@ndsu.edu or phone call at 701-231-8355.

Thank you,

Question 1:

Did you communicate the health screening results to your PCP? Yes/No

Question 2:

Were any changes made in your medication list based off of the results of the health screening recommendations? Yes/No

Question 3:

If you answered 'yes' to the previous question, briefly explain what changes were made:

APPENDIX H: POST-IMPLEMENTATION SURVEY

Post-Implementation Survey

Participants: Please fill out the following survey to assist this investigator in identifying current knowledge and practice related to aspirin and/or statin use in your current medication regimen, USPSTF guideline recommendations related to aspirin and statins use for primary prevention of cardiovascular disease (CVD), and the ACC/AHA cardiovascular risk calculator. Participation is completely voluntary, yet greatly appreciated.

1-Strongly Disagree, 2- Disagree, 3- Agree, 4-Strongly Agree

I am knowledgeable about aspirin use for primary prevention of CVD	-1- Strongly disagree	-2- Disagree	-3- Agree	-4- Strongly agree
I am knowledgeable about statin use for primary prevention of CVD	-1- Strongly disagree	-2- Disagree	-3- Agree	-4- Strongly agree
I feel that using the USPSTF guidelines are beneficial for aiding decision-making of aspirin and/or statin use	-1- Strongly disagree	-2- Disagree	-3- Agree	-4- Strongly agree
I am knowledgeable about the cardiovascular risk calculator produced by the ACC/AHA	-1- Strongly disagree	-2- Disagree	-3- Agree	-4- Strongly agree
I feel that using the ACC/AHA risk calculator is beneficial	-1- Strongly disagree	-2- Disagree	-3- Agree	-4- Strongly agree

APPENDIX I: HEALTH SCREENING RESULTS

Participant	Age	Risk	Sex	Height (")	Weight (lb)	BMI (kg/m2)	Blood pressure	Heart rate	Oxygen saturation (%)	Body fat percentage	Hand grip strength (lb)	PHQ-9	GAD-7	Blood glucose (mg/dL)	Total cholesterol (mg/dL)		Triglycerides (mg/dL)
1	46	0.5	F	66	147.8	23.9	110/75	55	95	32.4	69.2	0	0	104	184	61	51
2	68	16.4	F	58.25	226.2	46.9	125/80	85	95	-	52.2	0	0	102	138	47	247
3	47	0.6	F	54.25	177.4	30.0	115/95	77	97	38.2	75.4	0	1	89	154	52	195
4	41	0.7	M	68.25	213	32.1	122/82	87	94	30.5	99.0	2	4	97	168	58	59
5	54	1.4	F	68.25	223.8	33.8	115/80	61	97	42.6	65.0	2	2	118	201	56	166
6	65	7.7	F	64.5	138.2	23.6	125/75	88	96	36.5	55.6	0	0	92	172	81	81
7	52	4.7	M	74.25	299.0	38.4	127/82	96	96	35.3	105.6	9	0	148	100	25	195
8	44	9.5	F	67.125	213.2	33.4	124/78	67	97	39.6	89.6	2	1	103	195	42	228
9	64	4.5	F	68	144.2	22.0	116/74	66	98	27.2	77.8	8	5	106	194	44	135
10	64	3.7	F	69.5	131.2	19.1	122/72	60	98	27.7	54.8	0	0	101	174	73	71
11	55	1.4	F	69	170	25.1	110/85	74	98	34	62.4	0	0	117	157	45	326
12	61	4.7	F	62	239.2	43.8	138/92	92	92	-	43.6	2	0	156	207	49	229
13	64	3.5	F	64.75	126.4	21.2	120/80	58	98	31	52.0	1	0	95	191	88	118
14	54	1.1	F	70	162.6	23.3	106/70	57	97	32.4	65.6	2	1	95	220	68	296
15	60	16.0	F	65	237.6	39.5	138/78	83	97	49.6	59.8	-	-	218	151	55	158
16	50	4.6	M	70.5	203.2	28.7	140/60	90	97	24	103.8	3	6	129	183	39	218
17	63	2.7	F	65.625	176.4	28.8	108/72	66	95	40.1	83.8	2	0	95	244	97	105
18	65	15.9	M	68.375	191.7	29.1	122/84	77	97	23.6	90.8	-	-	103	227	60	179
19	46	0.7	F	60.125	164.6	32.1	122/88	61	97	40.6	63.2	3	1	96	176	54	107
20	53	3.9	M	72.625	256.4	34.3	132/88	94	95	29.6	136.0	19	15	106	101	36	268
21	42	2.7	M	66.875	160.6	25.3	112/80	66	95	21	98.2	1	1	108	173	45	202
22	57	1.1	F	62.5	178	32.0	136/80	80	95	40.4	77.6	2	1	98	138	64	170
23	45	0.6	F	71.875	212	28.9	108/74	58	98	38.8	62.2	-	-	100	191	54	101
24	63	19.7	M	71.5	233	32.0	124/80	57	96	34.6	69.6	0	0	102	146	41	365
25	44	1.2	F	62	176	32.2	130/82	89	97	36.71	58.8	1	3	97	134	34	298
26	66	5.6	F	68.25	195	29.6	122/80	66	67	39.8	79.0	9	7	102	261	80	252
27	43	0.7	F	61	232	43.8	106/80	87	98	46.7	66.6	8	2	101	149	39	298
28	61	3	F	64	172	29.2	120/80	60	99	40.2	69.2	1	0	95	182	55	72
Average	**55**	**4.96**	**F= 21, M=7**	**66.23**	**192.88**	**30.8**	**121/80**	**73.46**	**95.39**	**35.12**	**74.5**	**3.08**	**2**	**109.75**	**175**	**55**	**185**