

ASPIRIN USE FOR PRIMARY PREVENTION OF CARDIOVASCULAR DISEASE

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DOCTOR OF NURSING PRACTICE

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ABSTRACT

Cardiovascular disease (CVD) is a major cause of morbidity and mortality in the United States and aspirin is a well-known medication strongly associated with CVD prevention. Aspirin has undeniable benefits in the role of secondary prevention of CVD, however, the benefits are ambiguous when associated with primary prevention. The decision to start aspirin for primary prevention becomes complicated due to aspirin's effect on coagulation and the risk of gastric ulceration.

The United States Preventive Services Task Force (USPSTF) has level B recommendations in place regarding the use of low-dose aspirin (81 mg) for primary prevention of CVD. 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 guideline and CVD calculator offer healthcare providers an easy-to-navigate tool to determine proper patient use of aspirin. However, despite the USPSTF guideline, appropriate aspirin use remains suboptimal.

Successful adoption of the 2016 USPSTF guideline on aspirin use for primary prevention of CVD by providers in two rural North Dakota communities was the goal of this practice improvement project. The project began with education to providers and staff at the rural clinics regarding the USPSTF guideline and the ACC/AHA calculator. Following the educational session, implementation of the USPSTF guideline occurred for three months.

Evaluation was performed through the use of a post-implementation survey. Results of the project demonstrated increased knowledge and usage of the guideline and a positive viewpoint related to implementation of the guideline with the providers in both of the communities having plans to sustain use in future practice. Data were also collected at a health screening fair in one of the rural communities to validate whether patients were taking aspirin

per USPSTF guideline. Data gathered from the fair concluded only 59% of patients (41 out of 70) were taking, or not taking, aspirin appropriately according to the USPSTF guideline.

Conclusively, primary care providers would be well served by using the ACC/AHA calculator and 2016 USPSTF guideline with all patients 40-79 years of age to determine appropriate use of aspirin for primary prevention of CVD.

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DEDICATION

First of all, I would like to dedicate this dissertation to my wonderful and supportive husband, Bobby. We began our relationship at the very beginning of this program and his love, patience, encouragement, and belief in my abilities never wavered. I am forever grateful and blessed to have him by my side through all of the challenges and successes of life.

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LIST OF ABBREVIATIONS

CVD.....	Cardiovascular Disease
USPSTF.....	United States Preventive Task Force
AHA.....	American Heart Association
ACC.....	American College of Cardiology
NSAID.....	Nonsteroidal Anti-inflammatory Drug
MI.....	Myocardial Infarction
GI.....	Gastrointestinal
AMC.....	Ashley Medical Center
FMC.....	Family Medical Clinic
EHR.....	Electronic Health Records

CHAPTER ONE. INTRODUCTION

Background and Significance

Cardiovascular disease is the number one cause of morbidity and mortality in the United States (Lin, De Caterina, & Rodriguez, 2014). The American Heart Association estimates that 92.1 million Americans have at least one form of CVD, and that by 2030, that number will equal 43.9 percent of the United States adult population (American Heart Association [AHA], 2017). Additionally, the healthcare costs associated with caring for persons with CVD were projected around \$315 billion in 2010 (Bobbins-Domingo, 2016). With such a high prevalence and economic cost, being precautionary by taking a daily low-dose aspirin may seem admissible.

Aspirin is an over-the-counter, nonsteroidal anti-inflammatory drug (NSAID) that has analgesic, anti-inflammatory, and antipyretic effects on certain cells in the body (Gaziano & Greenland, 2014). Aspirin is commonly used for the primary and secondary prevention of CVD due to aspirin's irreversible, anti-thrombotic effect on platelets, observed as a prolonged bleeding time (Casado-Arroyo, Sostres, & Lanas, 2013). Secondary prevention is preventing a recurrent cardiovascular event in patients with a known history of CVD (Tsai, 2016). Primary prevention is preventing a cardiovascular event from happening in patients with no history of disease (Tsai, 2016).

Aspirin is an irreversible cyclooxygenase (COX)-1 inhibitor, and COX-1 is responsible for producing thromboxane A₂, which aggregates platelets (Gaziano & Greenland, 2014). Without thromboxane A₂, platelet aggregation is inhibited, which prevents the formation of a thrombus at a ruptured atherosclerotic plaque (Gaziano & Greenland, 2014). Without thrombus formation, the chance of vessel occlusion is decreased, thus preventing a cardiovascular event such as a myocardial infarction (MI) or stroke (Gaziano & Greenland, 2014).

Even with the evident benefits of aspirin for CVD prevention, the decision to start a patient on aspirin can be complicated for providers due to an increased bleeding risk. Platelet inhibition is beneficial to prevent vessel occlusion, but also has the potential to induce major vascular events, such as intracranial bleeding (Howard, 2014). As a COX inhibitor, aspirin can disrupt the mucosa of the gastrointestinal (GI) tract, as the inhibited COX-1 enzyme is in charge of producing prostaglandins that protect the delicate GI mucosa (Bobbins-Domingo, 2016). Without protection, the GI mucosa is vulnerable to damage capable of starting a major GI bleed (Bobbins-Domingo, 2016). A major GI bleed is defined as a bleed that requires transfusion, hospitalization, or leads to death (Bobbins-Domingo, 2016). A systematic review by Rodríguez, Martín-Pérez, Hennekens, Rothwell, and Lanas, (2016) found that long-term low-dose aspirin therapy led to an approximate 40% increased risk of having a GI bleed and 40% increased overall risk of having an intracranial hemorrhage. Thus, the benefit of aspirin is questioned with primary prevention, as the risk of developing a GI bleed or suffering a hemorrhagic stroke could offset the intended cardiovascular benefits (Casado-Arroyo et al., 2013).

The benefits of aspirin for secondary prevention are indisputable, as patients who have suffered from one or more CVD events are very high risk of having recurrent CVD events (Ittaman, VanWormer, & Rezkalla, 2014). Long-term aspirin therapy reduces the annual risk of having a subsequent CVD event by about 25% (Howard, 2014). However, the decision to place a patient on aspirin for primary prevention must be well thought out, as the benefits of preventing an initial CVD event may not outweigh the associated bleeding risks. There has to be a balance between the benefit of preventing a major vascular event and the risk of a having a major bleed (Gaziano & Greenland, 2014). The benefit versus risk of aspirin is dependent on a patient's risk

for bleeding, personal preference about taking aspirin, baseline CVD risk, and age, and should be an individualized decision made between the provider and patient (Bobbins-Domingo, 2016).

Problem Statement

According to the Agency for Healthcare Research and Quality (2016), close to 40% of older adults (50 years and older) use aspirin for primary or secondary CVD prevention. A National Health and Nutrition Survey found that 59% of patients, who were eligible for aspirin therapy for primary prevention, were not instructed by a healthcare provider to start taking aspirin (Agency for Healthcare Research and Quality [AHRQ], 2016). Also, an estimated 20% of patients taking a daily low-dose aspirin do so without a provider's recommendation due to aspirin's publicly perceived benefits, low cost, and over-the-counter availability, even though aspirin may not be appropriate for everyone (Howard, 2014). Low risk patients and patients not in the recommended age taking a daily aspirin is concerning, as taking a daily aspirin unnecessarily exposes them to the bleeding risks associated with the medication (Malayala & Raza, 2016). Patients not instructed to take aspirin when they are eligible is also concerning, as not taking aspirin puts them at risk of having a cardiovascular event, which may have been avoidable with a simple and inexpensive medication. In the 2016 USPSTF systematic evidence review of the major aspirin primary prevention clinical trials, aspirin was found to have reduced the incident of nonfatal MIs by 22%, cardiovascular mortality by 6%, and nonfatal strokes by 5% (Mora & Manson, 2016). Additionally, the U.S. Food and Drug Administration does not support the use of aspirin for primary prevention of CVD due to evidence from available data and aspirin's associated bleeding risks (Center for Drug Evaluation and Research, 2014). Therefore, the aspirin label does not provide any guidance for patients regarding aspirin's use for CVD

prevention, which is a concern for patients taking the medication without a provider's recommendation or those with limited education regarding the pills' risks (Howard, 2014).

The net benefits and recommendations regarding aspirin use for secondary prevention are well-known, however, primary prevention guidelines and recommendations vary (Brotons, Benamouzig, Filipiak, Limmroth, & Borghi, 2015). Along with varying guidelines, an overall benefit versus risk of aspirin use for primary prevention is unclear for many providers (Brotons et al., 2015). Tools that identify patients who are eligible to take aspirin for primary prevention are recommended to prevent the under use and overuse of aspirin and simplify clinical application (Guirguis-Blake, Evans, Senger, O'Connor, & Whitlock, 2016).

The USPSTF has a guideline in place regarding the use of low-dose aspirin for the primary prevention of CVD. In addition, the ACC and AHA developed a calculator to determine a patient's 10-year CVD risk. The calculator and guideline aid providers with the decision to start, stop, or continue aspirin for patients for primary prevention. However, despite the USPSTF's recommendations, many eligible patients do not receive a recommendation from their provider, and aspirin use remains suboptimal (Fiscella et al., 2014). Poor use of the USPSTF's recommendations may relate to lack of provider awareness, uncertainty of benefits, time restraints, and competing clinical demands (Fiscella et al., 2014). A study by Malayala and Raza (2016) found that providers are more likely to prescribe aspirin for primary prevention to patients of older age and who have obvious risk factors, rather than according to established guidelines. Providers seem to overlook younger patients who may be eligible to take aspirin, which puts them at an increased risk of not receiving appropriate primary prophylaxis (Malayala & Raza, 2016). Additional education to providers is needed in regard to aspirin use for primary prevention, the ACC/AHA CVD risk calculator, and the USPSTF's guideline regarding aspirin

use for primary prevention. Also, increased implementation of the USPSTF aspirin guideline is necessitated to properly guide providers when prescribing aspirin to patients for primary prevention.

Observation during clinical rotations at Ashley Medical Center (AMC) in Ashley, North Dakota and Family Medical Clinic (FMC) in Lisbon, North Dakota demonstrated that the providers did not routinely use the ACC/AHA risk calculator and USPSTF guideline regarding aspirin use for primary prevention of CVD. Also, their electronic health records (EHRs) did not embed the calculator and guideline into the patient charts, adding an additional challenge for providers using the USPSTF guideline. Through observance of practice and input from the providers at both clinics, a decision was made that implementation of the 2016 USPSTF guideline was necessary.

Purpose and Objectives

The purpose of the project was successful adoption of the 2016 USPSTF guideline on aspirin use for primary prevention of CVD by providers at AMC and FMC. The benefits of appropriate primary CVD prophylaxis for patients eligible for aspirin therapy and a reduced bleeding risk in patients who do not qualify for aspirin therapy according to the USPSTF guideline are addressed by the project. The knowledge gained by providers at AMC and FMC will allow for sustained adoption of the USPSTF guideline with patients at AMC and FMC properly taking aspirin for primary prevention of CVD.

Knowledge of the subject is important for the providers at AMC and FMC in order to understand the significance behind the proposed project. Once the providers have improved knowledge of the subject, the guideline is more likely to be implemented. Optimistically, the

providers will adopt a positive viewpoint of the USPSTF guideline with plans to implement the guideline in their future practice.

Project Objectives:

- I. Providers at AMC and FMC will report knowledge and usage of the current USPSTF guideline related to aspirin use for primary prevention of CVD and the cardiovascular risk calculator from the ACC/AHA by July of 2018.
- II. Providers at AMC and FMC will report a positive viewpoint related to implementation of the USPSTF guideline with plans to sustain usage in future practice by July of 2018.
- III. Data will be gathered from patients 40 years of age and older at AMC's health screening fair in April of 2018 to validate whether patients are taking aspirin per the USPSTF guideline.

CHAPTER 2. LITERATURE REVIEW

A systematic review by Guirguis-Blake et al. (2016), reported that out of 11 primary prevention trials, aspirin reduced the risk for nonfatal MI's by 22%. However, the extent of aspirin's potential benefit is dependent on a patient's overall CVD risk and the extent of aspirin's potential harm is dependent on a patients' risk factors for bleeding (U.S. Preventive Task Force [USPSTF], 2016). The benefits of aspirin may include prevention of MI's and ischemic strokes but may include the harms of GI bleeds and hemorrhagic strokes (Bobbins-Domingo, 2016). Providers must be mindful of their role in assessing aspirin's potential harms and benefits before making recommendations to their patients.

Bleeding Risk

Evidence has proven that older age and the male gender are associated with an increased bleeding risk, which is why the USPSTF considered both factors significant when determining a patient's risk for bleeding (USPSTF, 2016). Men are twice as likely as women to develop a major GI bleed (USPSTF, 2016). The USPSTF found the risk of bleeding to be small for patients aged 59 years and younger and small to moderate in patients aged 60 to 69 years (AHRQ, 2016). The USPSTF did not find enough evidence to determine the risk of bleeding for patients greater than 70 years of age (USPSTF, 2016).

Other risk factors for bleeding include a history of upper GI tract pain, history of GI ulcers, bleeding disorder, renal failure, severe liver disease, thrombocytopenia, concurrent anticoagulation use, NSAID use, and uncontrolled hypertension (Bobbins-Domingo, 2016). If a patient has a history of a GI ulcer, he or she is two to three times more likely to have a GI bleed with daily low-dose aspirin use (USPSTF, 2016). Concomitant use of corticosteroids and serotonin reuptake inhibitors with aspirin can also increase a patient's risk for bleeding (Khan,

2015). Patients who are hypertensive are also at an increased risk of experiencing a cerebral hemorrhage with use of aspirin (Khan, 2015). Additionally, providers need to be watchful of patients' medication lists with long-term aspirin use, as new medications that increase a patient's risk for bleeding may be added throughout time (Whitlock, Burda, Williams, Guirguis-Blake, & Evans, 2016).

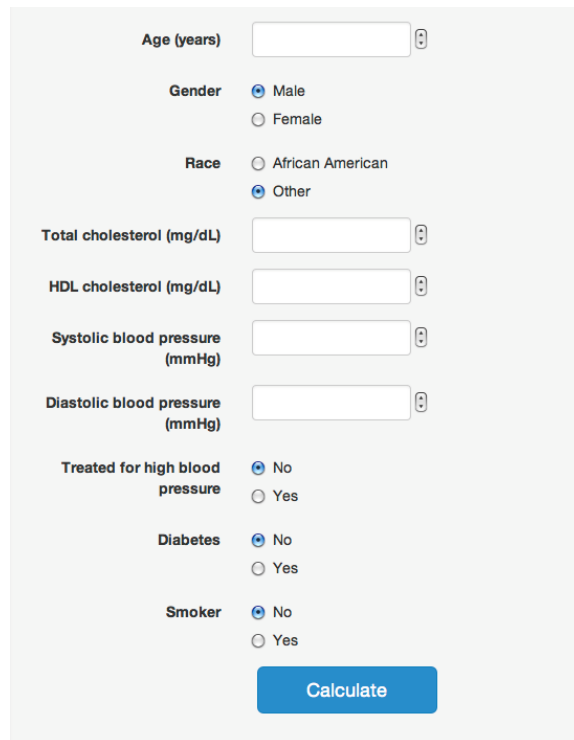
Currently there are no established tools that have been validated in clinical studies to determine a patient's bleeding risk when deciding to place a patient on aspirin for primary CVD prevention (Mora, Ames, & Manson, 2016). Providers need to determine a patient's individual baseline bleeding risk by assessing the patient's history and current medication regimen (Whitlock et al., 2016). Factors that increase a patient's chance of having a major bleed need to be well-thought-out before the decision is made to start or continue a patient on aspirin for primary prevention of CVD, as there is sufficient evidence demonstrating aspirin use increases patients' risks of having a major GI bleed or hemorrhagic stroke (Bobbins-Domingo, 2016).

CVD Risk and CVD Risk Calculation

The total amount of CVD risk reduction for patients taking aspirin is dependent on a patient's overall risk for having a primary cardiovascular event (USPSTF, 2016). CVD primary risk factors include increased age, male gender, race/ethnicity, high total cholesterol, low high-density lipoprotein cholesterol, high blood pressure, diabetes, and smoking (Bobbins-Domingo, 2016). Although the male gender has an increased risk of having an MI or stroke, women are at more of an increased risk of dying from these incidents (Ittaman et al., 2014). Studies also show that aspirin therapy is more likely to prevent a stroke in women and prevent a MI in men, which current guidelines take into consideration (Ittaman et al., 2014). Additionally, patients with diabetes are two to four times more likely to have a cardiovascular event due to increased

coronary thrombus formation, increased platelet reactivity, and decreased endothelial dysfunction (Ittaman et al., 2014).

The USPSTF calculates a patient's 10-year CVD risk with a calculator produced by the ACC and AHA (see figure 1). The ACC/AHA used pooled cohort equations to determine patient's 10-year risk of having a primary cardiovascular event, which is defined as a primary nonfatal MI, coronary heart disease death, or fatal/nonfatal stroke (USPSTF, 2016). The USPSTF chose the ACC/AHA calculator due to the calculator's wide focus on CVD outcomes, proof in various U.S. populations, and fair execution in studies (Bobbins-Domingo, 2016). The calculator is more racially and ethnically diverse than other known calculators, as race is included (African American or non-African American) into the equation and is found to be more accurate and efficient with identifying CVD risk than other risk calculators (Guirguis-Blake et al., 2016).



The image shows a digital form for calculating 10-year CVD risk. It includes the following fields and options:

- Age (years)**: A text input field with a clear button.
- Gender**: Radio buttons for Male and Female.
- Race**: Radio buttons for African American and Other.
- Total cholesterol (mg/dL)**: A text input field with a clear button.
- HDL cholesterol (mg/dL)**: A text input field with a clear button.
- Systolic blood pressure (mmHg)**: A text input field with a clear button.
- Diastolic blood pressure (mmHg)**: A text input field with a clear button.
- Treated for high blood pressure**: Radio buttons for No and Yes.
- Diabetes**: Radio buttons for No and Yes.
- Smoker**: Radio buttons for No and Yes.

A blue **Calculate** button is located at the bottom of the form.

Figure 1. 10-year CVD risk calculator produced by ACC/AHA (Ahead Research, 2013).

The 10-year risk calculation requires entering in the patient’s age, sex, race/ethnicity, total cholesterol level, high-density lipoprotein cholesterol level, systolic blood pressure, and whether the patient is a diabetic, a smoker, or on hypertension medication (AHRQ, 2016). After entering in the patient’s information, a percentage will generate regarding the patient’s 10-year risk of having a cardiovascular event. With the generated percentage, providers can then access the USPSTF’s guideline. The guideline provides a table summarizing the recommendations to help providers assess the benefits and risks of placing a patient on aspirin for primary prevention (see figure 2). The 10-year risk calculation is recommended every four to six years in patients who are free from heart disease with a low 10-year risk (Goff et al., 2013).

Population	Adults aged 50 to 59 y with a $\geq 10\%$ 10-y CVD risk	Adults aged 60 to 69 y with a $\geq 10\%$ 10-y CVD risk	Adults younger than 50 y	Adults aged 70 y 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-y risk for first atherosclerotic CVD event.			
Preventive Medication	Aspirin’s anticommuting 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/d (the most commonly prescribed dose in the United States), and assess CVD and bleeding risk factors starting at age 50 y 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 for bleeding by a moderate amount.	The benefits of aspirin use outweigh the increased risk for 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 Web site (www.uspreventiveservicestaskforce.org).			

Figure 2. Summary of evidence from the USPSTF recommendation statement (Bobbins-Domingo, 2016).

In 2002 the USPSTF provided recommendations stating providers should consider aspirin therapy for adults who are at an increased risk for CVD (Malayala & Raza, 2016). In 2009 the USPSTF determined there is a difference in the therapeutic benefit of aspirin for men and women, as women benefit more by reducing the risk of stroke and men benefit more by reducing

the risk of coronary artery disease (Malayala & Raza, 2016). In 2009 the USPSTF recommended aspirin for men aged 45 to 79 years and women aged 55 to 79 years when the potential benefits of CVD prevention outweigh the risks of bleeding (Malayala & Raza, 2016). In 2016 the USPSTF updated their recommendations to combine men and women in the same recommendation and narrowed the age range to 50 to 69 years (Malayala & Raza, 2016). The USPSTF's recommendations are largely consistent with recommendations from the AHA, American Stroke Association, American Diabetes Association, American Academy of Family Physicians, and the American College of Chest Physicians (Bobbins-Domingo, 2016).

The USPSTF found enough evidence to recommend that a daily low-dose aspirin should be initiated for primary prevention of CVD in patients 50 to 59 years of age who have a 10% or higher 10-year CVD risk, do not have a high bleeding risk, have a life expectancy of at least 10 years, and are agreeable to take a daily aspirin for 10 years or longer (USPSTF, 2016). This is a B recommendation from the USPSTF (USPSTF, 2016). A B recommendation affirms that the USPSTF recommends providing this service to patients, as there is a high certainty that the net benefit is moderate (AHRQ, 2016).

The USPSTF states the decision should be individualized on whether to start patients, 60 to 69 years of age with a 10% or higher 10-year CVD risk, on a low-dose aspirin for primary prevention of CVD (USPSTF, 2016). Patients who do not have a high bleeding risk, have a life expectancy of at least 10 years, and are agreeable to take a daily aspirin for 10 years or longer, are expected to benefit most (USPSTF, 2016). With the decision being individualized, those patients who place importance on receiving the potential benefits versus the potential harms, may decide to start aspirin therapy (USPSTF, 2016). This is a C recommendation from the USPSTF (USPSTF, 2016). A C recommendation affirms that the USPSTF recommends providing this

service to selected patients based off professional judgment and patient preference, as there is a moderate certainty that the net benefit is small (AHRQ, 2016).

There is currently not enough evidence to determine the benefit versus harms of starting aspirin for primary prevention of CVD in patients older than 70 years of age and younger than 50 years of age (USPSTF, 2016). This is an “I” statement from the USPSTF (USPSTF, 2016). An “I” statement declares that the USPSTF presumes there is insufficient evidence to accurately determine the benefit versus harms of a service (AHRQ, 2016).

As a person increases in age, their risk of CVD increases. However, as a person increases in age their risk of bleeding also increases significantly. Therefore, assessing the benefit versus risk of aspirin use for primary prevention in patients 70 years of age and older can be difficult (USPSTF, 2016). Patients who are 70 and older may benefit from a daily low-dose aspirin, but the potential harms of bleeding could be substantial (USPSTF, 2016). Also, older patients can have complex risk factors, use multiple medications, and have various illnesses that make assessing the benefit versus risk of aspirin complicated (USPSTF, 2016). A decision analysis assessing three systematic evidence reviews for the USPSTF did not find the benefits outweigh the risks for patients older than 70 with a 10-year CVD risk less than 20% (Dehmer, Maciosek, Flottemesch, LaFrance, & Whitlock, 2016). However, evidence is lacking regarding the proper age to discontinue aspirin after long-term use and it could be deceptive to use a model to make discontinuation decisions without better evidence to support such conclusions (Dehmer et al., 2016). One expert analysis states that aspirin for primary prevention should not be initiated in patients older than 70 years of age, but it is unclear whether those already taking aspirin for primary prevention should stop at the age of 70 (Meyer, Arps, Blumenthal, & Martin, 2018). A study was performed in Sweden related to aspirin discontinuation after long-term therapy

(Sundstrom et al., 2017). The study found that discontinuing aspirin after long-term therapy increased a patient's chance of having a cardiovascular event by more than 30% due to aspirin's rebound effect of increasing the blood's clotting tendencies (Sundstrom et al., 2017). However, the study failed to mention the risk to benefit equation for the lower-risk primary prevention population. Conclusively, providers need to have a discussion with patients who are 70 years and older and currently taking a daily aspirin for primary prevention about whether they should continue (USPSTF, 2016).

The potential benefit for patients younger than 50 years of age taking aspirin for primary prevention is possibly low due to only a small percent of patients younger than 50 have a greater than 10% risk (USPSTF, 2016). However, those patients who are younger than 50 with an increased CVD risk may benefit greatly from a daily low-dose aspirin (USPSTF, 2016). The USPSTF guideline can apply to patients over the age of 40 without known CVD and without a high risk of bleeding (USPSTF, 2016).

Overall, the USPSTF concluded that patients aged 50 to 59 years, who have a greater than 10% 10-year CVD risk, will have the largest net benefit from taking a daily low-dose aspirin (USPSTF, 2016). Patients aged 60 to 69 years may also have a large net benefit from taking a daily low-dose aspirin, but the net benefit is reduced due to their higher risk of having a GI bleed (USPSTF, 2016). However, the determination on whether the potential benefits of aspirin use outweigh the potential harms should be made individually, as some patients may rather take the risk of a bleed over the risk of a CVD event, or vice versa (USPSTF, 2016). Some patients who are more worried about having a cardiovascular event may choose to take aspirin at a lower CVD risk than patients who are more worried about having a major bleed (USPSTF, 2016). Also, patients who are adamant on avoiding long-term daily medication use may be poor

prospects for aspirin therapy (Bobbins-Domingo, 2016). Even with the decision ultimately up to the patient, patients with a high chance of benefit and low chance of bleeding should be well-informed and encouraged to take a daily low-dose aspirin, and patients with a low chance of benefit with a high chance of bleeding should be educated on the risks and discouraged from taking a daily low-dose aspirin (USPSTF, 2016).

Treatment and Dosage

The ideal dosage of aspirin for CVD prevention is unknown, as many primary prevention studies have shown benefit with dosages ranging from 75 to 100 per day and 100 to 325 every other day (USPSTF, 2016). However, an increased dosage may increase the risk of having a GI bleed, which is why the lowest dose should be considered (USPSTF, 2016). One study found that the optimal dose of aspirin was bodyweight dependent and that a low-dose aspirin is ineffective in individuals weighing more than 70 kg (Rothwell et al., 2018). The study may suggest that a more tailored dosing strategy is needed, however, the guidelines have not yet acquired this information. With the 81 mg aspirin being the most commonly prescribed dosage in the United States, prescribing 81 mg daily is most practical (USPSTF, 2016). The USPSTF, AHA, or ACC do not specify if a daily aspirin should be taken in the morning or at night or whether brand name versus generic are most beneficial; patient preference may take precedence. Additionally, studies do not prove that using enteric coated aspirin decreases the chance of having a GI bleed, as aspirin inhibits COX-1 in the blood, which reduce prostaglandins protecting the stomach (Howard, 2014).

The ideal timing in regard to initiation of patient monitoring is unknown, however, assessing CVD and bleeding risk starting at the age of 50, as well as when CVD and bleeding risk factors are initially discovered is most sensible (USPSTF, 2016). Generally, aspirin use is

contraindicated for patients with a known allergy or intolerance to aspirin and other NSAIDS, those at an increased risk for bleeding, and those with asthma, rhinitis, and nasal polyps (Casado-Arroyo et al., 2013). Aspirin has the potential to worsen asthma symptoms and possibly lead to an asthma attack in some patients.

Evidence is lacking regarding what advice should be given to patients who are already taking aspirin for primary prevention but are considered low-risk or out of the age range suitable for aspirin therapy. As already noted, a Swedish study found an increased risk of having a cardiovascular event after discontinuation of aspirin but fails to mention the associated bleeding risks (Sundstrom et al., 2017). The most practical advice is to have a risk versus benefit conversation with the patient and allow the patient to determine whether he or she would like to continue aspirin therapy for primary prevention.

Theoretical Framework

Iowa Model

The Iowa Model of Evidence-Based Practice to Promote Quality Care helped facilitate implementation of the USPSTF's guideline regarding aspirin use for primary prevention of CVD at AMC and FMC. Permission to use the model was obtained from the University of Iowa Hospitals and Clinics (see Appendix A). The model uses problem-solving steps with a series of feedback loops to guide providers when making clinical decisions that affect patient outcomes (Melnik & Fineout-Overholt, 2015). The model poses a series of questions, decision making points, and instructions that guide you through each feedback loop (see Appendix B).

- I. Problem and Knowledge Focused Triggers: The USPSTF released a new recommendation statement in 2016 regarding aspirin use for primary prevention of CVD. AMC and FMC had not yet implemented the USPSTF's guideline. Not implementing the

USPSTF's guideline was significant, as the AHRQ found that 59% of patients who were eligible for aspirin therapy for primary prevention were lacking a recommendation from their provider (AHRQ, 2016). Also, 20% of patients who take a daily aspirin do so without a provider's recommendation (Howard, 2014). A large number of patients were not receiving appropriate primary prophylaxis with aspirin therapy, and with proper implementation of USPSTF guideline, providers had the opportunity to ensure that their patients aspirin use is consistent with the intended health benefits (Lin, 2016).

II. Organizational Priorities: Healthcare providers at the AMC and FMC were spoken to and informed about the USPSTF guideline regarding aspirin use for primary prevention.

Providers at both AMC and FMC desired to implement the USPSTF guideline to adhere to current recommendations and improve patient care.

III. Forming a Team: The team consisted of the co-investigator, advanced practice nurses, staff nurses, and unit manager at AMC, and advanced practice nurse, physician assistant, staff nurses, and unit manager at FMC. My role as the co-investigator was to facilitate implementation of the guideline at AMC and FMC and evaluate the 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 Brander, a nurse practitioner (NP) from AMC.

IV. Assemble and Synthesize Relevant Research: A literature review and syntheses was completed, and there was adequate research to indicate a sufficient base of information to pilot the change in practice. The literature review assessed risk factors for bleeding and CVD risk factors. The ACC/AHA CVD risk calculator used by the USPSTF determines a

patient's 10-year CVD risk. The 10-year CVD risk has been used in conjunction with the USPSTF's guideline regarding aspirin use for primary prevention of CVD. Research by the USPSTF confirmed patients aged 50 to 69 years, who were not at an increased risk for bleeding, had the highest net benefit from aspirin use for primary prevention of CVD (USPSTF, 2016).

- V. Pilot the Change in Practice: Project outcomes were determined. Baseline data were collected. The USPSTF developed a guideline for practice regarding aspirin use for primary prevention of CVD. After committee and site approval, implementation of the guideline was determined to be initiated at AMC and FMC starting in April of 2018, and the outcomes of the change in practice were evaluated in July of 2018.
- VI. Integrate and Sustain the Practice Change and Disseminate Results: Objective two sought for providers to report a positive viewpoint related to implementation of the USPSTF guideline with plans to sustain usage in future practice. After completion of the project in July of 2018, results from the project were to indicate whether providers had plans to sustain use of the guideline in future practice. Once the results were collected and data analysis took place, dissemination of results began.

Diffusion of Innovations Theory

Implementation of the 2016 USPSTF guideline regarding aspirin use for primary prevention of CVD at AMC and FMC was guided by the Diffusion of Innovations theory. Everett M. Rogers developed the Diffusion of Innovations theory in 1962 to aid in the dissemination of new health behaviors into clinical practice (Pender, Murdaugh, & Parsons, 2015). The theory has been useful for facilitating evidence-based practice change, as the theory refers to a process that happens during the adoption of new ideas (Kaminski, 2011). Diffusion is

defined as a form of communication that occurs during the spread of new ideas, and innovation is defined as the idea that is believed to be new (Pender et al., 2015). The USPSTF guideline represents the new innovation to be adopted, and face to face interactions represent the form of communication used to diffuse the information.

Five adopter categories regarding the rate of adoption of new innovations are described by the theory. Innovators, early adopters, early majority, late majority, and laggards are the five adopter categories (Pender et al., 2015). Innovators are the first to seek out and adopt new ideas, are not intimidated by change, and are considered role models in the system. Early adopters hold the highest level of opinion and leadership within the system, which makes them the adopters to confer with before making a change. Early majority are cautious and rarely take the lead with adopting new ideas. Late majority have many uncertainties regarding new ideas, and usually only make a change after receiving pressure from others. Laggards slow down the diffusion of innovations, are often cynical of the new ideas, and want to rule out failure before adoption (Pender et al., 2015). Identification of the appropriate adopters at AMC and LMC was key to successful implementation the USPSTF guideline.

The Diffusion of Innovations theory includes a five-stage adoption process of information-seeking and information-processing (Kaminski, 2011). Before the process could begin, a prior condition was identified. Lack of knowledge and implementation of the USPSTF's guideline at AMC and FMC was identified as the prior condition. Knowledge was the first stage in the adoption process. The knowledge stage consisted of becoming aware of the USPSTF's guideline regarding aspirin use for primary prevention. Persuasion was the second stage of the adoption process. In the persuasion stage, a positive or negative viewpoint regarding the USPSTF's guideline was formed. Decision was the third stage of the adoption process. Providers

at AMC and FMC decided about whether to adopt and pilot the USPSTF's guideline. In conclusion, the fourth and fifth stages moved towards implementation and confirmation, where AMC and FMC providers decided whether to permanently adopt the USPSTF's guideline into practice.

Congruence of the Project to the Organization's Mission

The project demonstrated congruency with the mission statements at both AMC and FMC. Ashley Medical Center's mission statement is as follows: "Ashley Medical Center is a community service organization which provides preventative, curative, supportive and educational health care that meets the physical, emotional, and spiritual needs of the people they serve" (Ashley Medical Center, n.d.). By implementing the 2016 USPSTF's guideline related to aspirin use for primary prevention of CVD, AMC was directly supporting their mission to provide preventative, supportive, and educational health to meet the physical needs of the patients they serve. Part of FMC's mission statement is as follows: "All staff members and health care practitioners at FMC understand that all patients seeking care will be treated without regard to race, color, national origin, age, handicap status, sex or creed, and all patients seeking medical care at FMC will receive quality medical care without regard to ability to pay" (M. Kelsen, personal communication, October 10, 2017). By implementing the USPSTF's guideline related to aspirin use for primary prevention of CVD, FMC continued to treat patients regardless of their background or social history and improved the quality of care they gave their patients without regard to ability to pay.

CHAPTER 3. PROJECT DESIGN

Project Implementation

The project began on April 17th, 2018 at AMC and April 18th, 2018 at FMC with an educational session to the nurses, nurse aides, and providers regarding use of the ACC/AHA calculator and USPSTF guideline regarding aspirin use for primary prevention of CVD. There were two NPs from AMC and one NP and one physician assistant from FMC included in the project. The nurses, nurse aides, and providers were educated on how to enter patient information into the calculator, and the providers were educated on how to interpret the calculation and apply the calculation to the USPSTF guideline.

The calculator (<http://www.cvriskcalculator.com>) was “bookmarked” on Internet Explorers’ favorites list on the computers in each exam room and also on the providers’ personal computers for easy access. Each nurse or nurse aid who roomed the patient was expected to enter in the patient data into the calculator before the provider entered the room to see the patient. Patient information needed for each calculation included: age, gender, race, total cholesterol, HDL cholesterol, systolic blood pressure, diastolic blood pressure, if the patient was being treated for high blood pressure, if the patient was a smoker, and if the patient was a diabetic. The calculation was completed on patients 40 years of age and older during annual visits or hypertension, hyperlipidemia, and/or diabetes follow-up appointments. Ideally, the calculation was completed before the provider entered the room so that an interpretation could immediately be made by the provider who applied the results to the USPSTF recommendations. The calculation was recommended to be completed every four to six years in patients free of CVD and should be done annually with cholesterol screenings for those with high a CVD risk. Implementation of the project occurred from April 17-18 of 2018 to July 17-18 of 2018.

Data Collection

Data were collected to evaluate the first two objectives on July 17th, 2018 at AMC and July 18th, 2018 at FMC. The first objective was for providers at AMC and FMC to report knowledge and usage of the current USPSTF guideline and ACC/AHA cardiovascular risk calculator. The second objective was for providers at AMC and FMC to report a positive viewpoint related to implementation of the USPSTF guideline with plans to sustain usage in future practice. A post-implementation survey was provided to each provider for evaluation of the project. Surveys included a 4-point Likert scale that reflected evaluation of the proposed objectives.

For the third objective, data were collected from a health screening fair at AMC on April fifth and sixth of 2018. The third objective intended for data to be gathered from patients 40 years of age and older at the health screening fair at AMC in April of 2018 to validate whether patients were taking aspirin per the USPSTF guideline. The health screening fair allowed patients in the community to get a set of labs drawn, including a cholesterol screening, and get their blood pressure checked for a low cost of 40 dollars. Data were collected regarding the percentage of patients who qualify for aspirin therapy and are not taking aspirin, the percentage of patients who do not qualify for aspirin therapy and are taking aspirin, and the percentage of patients who take, or do not take, aspirin appropriately. The data collected helped to denote the significance of the proposed project in the rural community. Once the lab work was completed on all patients from the health screening fair, the USPSTF guideline was applied to 70 random patients over the age of 40. The allotted time to perform the calculations at AMC allowed the co-investigator to apply the calculation to 70 of the patients seen at the health screening fair. Patient information for the calculations was gathered from the health screening fair results and patient

charts. The data calculations were performed on April 17th, 2018 at AMC. Once the calculations were complete, the information was shared with the providers at AMC and distributed by mail to all patients with written recommendations regarding the results of the calculation.

Protection of Human Subjects

Both providers at AMC and FMC were included in the proposed project. The potential risk to the providers was failing to correctly implement the USPSTF guideline in relation to aspirin use for primary prevention of CVD. Failing to implement the USPSTF guideline correctly was a risk to the providers as the guideline properly guides providers when prescribing aspirin to patients for primary prevention. The risk was minimized through proper education of the USPSTF guideline and relaying the importance of the guideline's recommendations to the providers and staff at AMC and FMC. Potential benefits of the project included successful adoption of the USPSTF recommendations by providers at AMC and FMC, appropriate primary CVD prophylaxis for patients eligible for aspirin therapy, and a reduced bleeding risk in patients who do not qualify for aspirin therapy. Knowledge gained by providers at AMC and FMC allowed for sustained adoption of the USPSTF guideline with patients at AMC and FMC properly taking aspirin for primary prevention of CVD. Recruitment and informed consent was obtained through a consent form signed by each provider (see Appendix C) and each clinic manager signed a letter (see Appendix D and E) to the North Dakota State University's Institutional Review Board (IRB) indicating they were aware of the intent of the proposed project.

Data were also gathered from 70 patients 40 years of age and older at the health screening fair at AMC in April of 2018. All data collection took place at AMC and access to the patient information was provided by the patient's healthcare provider. Patient information used for each

calculation was not included in the evaluation of the project and was only used for generation of total percentages. The patients and their personal information was not jeopardized. Application for exempt status through North Dakota State University's IRB was submitted and approved in March of 2018 (see Appendix F).

CHAPTER 4. EVALUATION

Project evaluation involved assessment of whether project objectives were met. To evaluate implementation of the USPSTF guideline at AMC and FMC, a post-implementation survey was given to the providers at AMC and FMC (see Appendix G). The post survey contained six questions about provider knowledge at AMC and FMC related to aspirin use for primary prevention of CVD, the USPSTF's guideline, the cardiovascular risk calculator, provider usage of the current USPSTF guideline related to aspirin use for primary prevention of CVD, and provider viewpoint of USPSTF guideline with plans to sustain usage in future practice. A four-point Likert scale was used for outcome assessments on the post surveys. The Likert scale is an ordinal scale often used in medical education research to measure attitudes following an educational intervention (Sullivan & Artino, 2013). The scale was used by the providers to rate the degree to which they agree or disagree with the statements listed. The response choices on the Likert scale included strongly agree, agree, disagree, and strongly disagree.

To evaluate the health screening fair, labs and vital signs from the health screening fair along with information from patient charts were applied to the USPSTF guideline. Data were collected from 70 random patients who were 40 years of age and older. The ACC/AHA calculator was used to calculate each person's risk score. After the calculations were complete, the risk score was evaluated against the USPSTF guideline and the results were tallied on an excel spreadsheet (see Appendix H). A number and percentage were generated regarding the number of patients 40 years of age and older taking aspirin inappropriately, taking aspirin appropriately, not taking aspirin when aspirin is considered medically necessary, and taking aspirin when aspirin is considered medically necessary. Each patient evaluated with the USPSTF guideline received recommendations in the mail from their provider regarding their results.

Objective One

Objective one was to report knowledge and usage of the current USPSTF guideline and cardiovascular risk calculator from the ACC/AHA. The first objective was evaluated through use of the four-point Likert scale on the post-implementation survey. “I am knowledgeable about the USPSTF’s guideline related to aspirin use for primary prevention of CVD,” “I am knowledgeable about the cardiovascular risk calculator produced by the ACC/AHA,” and “I applied the USPSTF guideline to all patients over the age of 40 during annual visits or hypertension, hyperlipidemia, and/or diabetes follow-up appointments” were the statements provided on the survey to evaluate the first objective.

Objective Two

Objective two was to report a positive viewpoint related to implementation of the USPSTF guideline with plans to sustain usage in future practice. The second objective was evaluated through the use of the four-point Likert scale on the post-implementation survey. “I feel that using the USPSTF guideline will benefit my practice and my patients” and “I plan to sustain use of the USPSTF guideline in my future practice” were the statements provided on the survey to evaluate the second objective.

Objective Three

Objective three was to gather data from patients 40 years of age and older at the health screening fair to validate whether patients are taking aspirin per the USPSTF guideline. The third objective was evaluated by gathering labs and vital signs from the health screening fair and information from patient charts and applying the information to the USPSTF guideline.

Data Analysis

The data collected from the post-implementation survey and health screening fair were analyzed quantitatively. Post-implementation survey data analysis consisted of simple statistical tests with mean scores for each of the six Likert scale responses on the survey. The health screening fair was analyzed with numbers, percentages, and statistical tests. An expert statistician from NDSU was consulted to further assist with data analysis and descriptive statistics from the health screening fair. An excel spread sheet used to collect and document data was sent to the expert statistician for further analysis. Help from an expert statistician ensured correctness and validity of the data analyzed.

Evaluation Model

The Diffusion of Innovation theory and the five stages of adoption guided the evaluation process of the providers at AMC and FMC. Each stage of the adoption process was included in the post-implementation survey and allowed for evaluation of the providers at AMC and FMC regarding their knowledge, viewpoint, usage and plans for sustained adoption of the USPSTF guideline. Wong, Soon, Zed, and Norman (2014) developed a survey to assess the acceptability of an innovative contraception practice among rural pharmacists and used the Diffusion of Innovations theory as a guide. In the survey provided to the rural pharmacists, they used the Diffusion of Innovation theory to address adoption, change, and acceptability (Wong et al., 2014). The survey was effective in using the Diffusion of Innovations theory as a guide, as there was internal reliability of questions reflecting the readiness to adopt the new innovation (Wong et al., 2014). I found the survey developed by Wong, Soon, Zed, and Norman to be effective in providing guidance in the development of the post-implementation survey used in this project as they reported a similar process with use of the Diffusion of Innovation theory.

A logic model (see figure 3) was used to explain how interventions were used to meet the desired objectives. A prior situation of suboptimal use of the USPSTF guideline regarding aspirin use for primary prevention of CVD at AMC and FMC instigated use of the logic model. The logic model described the relationship between inputs, outputs, and short and long-term outcomes.

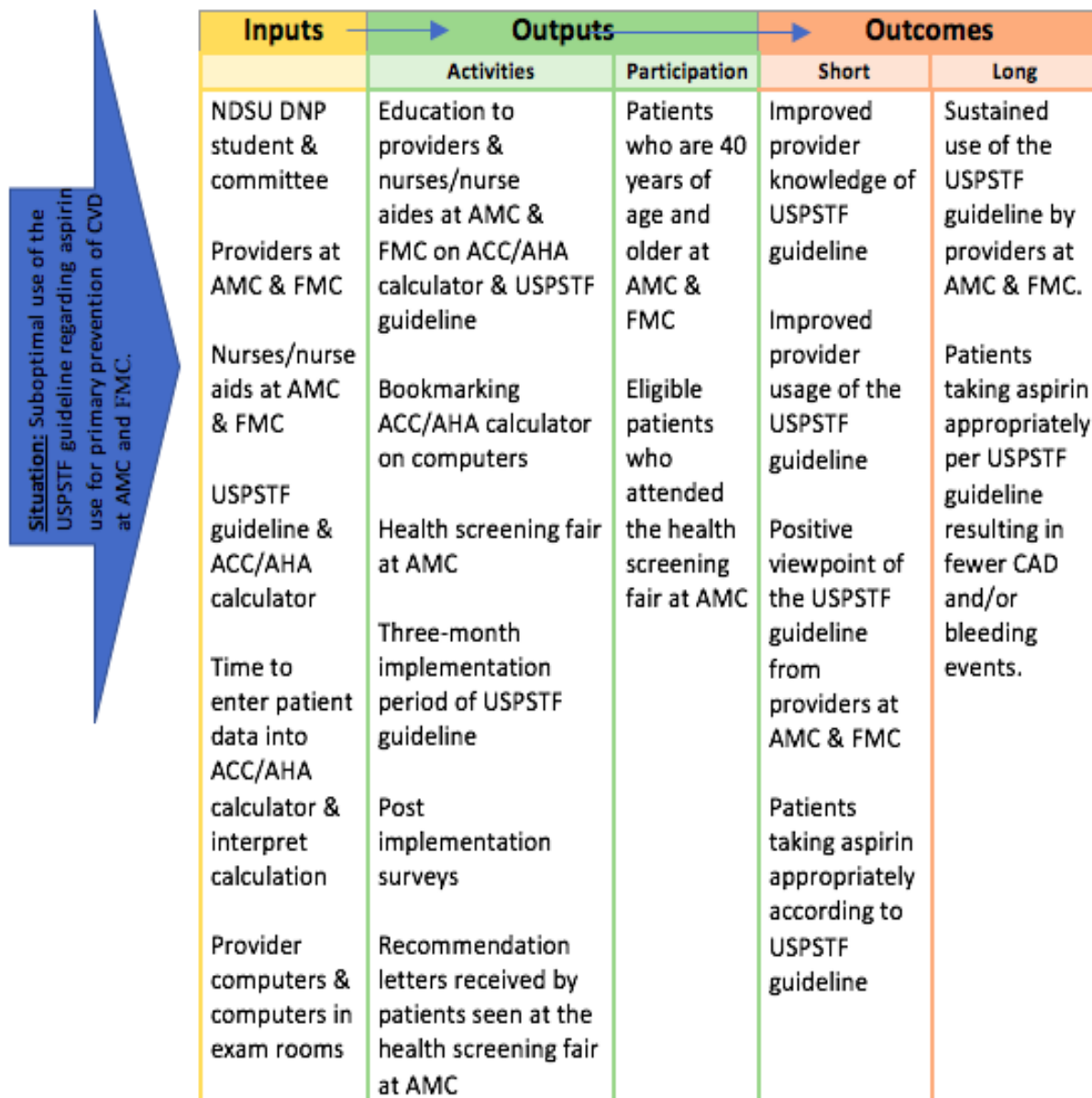


Figure 3. Logic Model

CHAPTER 5. RESULTS

After implementation, the project was evaluated to determine whether the objectives were achieved. The project was implemented from April of 2018 to July of 2018. In July of 2018 the data were collected from both AMC and FMC. Data were collected from the health screening fair at AMC in April of 2018. Once the data were collected, analysis began. Quantitative data were analyzed to determine the results of the project. Two NPs at AMC and one NP and physician assistant at FMC completed the post-implementation survey. All providers were female with greater than four years of experience and work full-time at the rural clinics involved in the project.

Presentation of Findings

To recap, the objectives of the project include:

- I. Providers at AMC and FMC will report knowledge and usage of the current USPSTF guideline related to aspirin use for primary prevention of CVD and the cardiovascular risk calculator from the ACC/AHA by July of 2018.
- II. Providers at AMC and FMC will report a positive viewpoint related to implementation of the USPSTF guideline with plans to sustain usage in future practice by July of 2018.
- III. Data will be gathered from patients 40 years of age and older at AMC's health screening fair in April of 2018 to validate whether patients are taking aspirin per the USPSTF guideline.

A post-implementation survey was given to each provider who participated in the project to evaluate the results of implementing the 2016 USPSTF guideline at each clinic. All of the providers included in the project completed a survey. The post-implementation survey consisted

of a four-point Likert scale composed of six questions related to the project objectives. The health screening fair was evaluated with labs and vital signs from the fair and information from patient charts. Data were collected from 70 patients over the age of 40 and were collected on an Excel spread sheet to assist with analysis. The following sections include the project results presented in relation to the objectives they addressed.

Objective One

Objective one, to report knowledge and usage of the current USPSTF guideline and cardiovascular risk calculator from the ACC/AHA, was evaluated through use of the four-point Likert scale on the post-implementation survey. The statements provided on the survey to evaluate the first objective included:

- I. I am knowledgeable about the USPSTF's guideline related to aspirin use for primary prevention of CVD.
- II. I am knowledgeable about the cardiovascular risk calculator produced by the ACC/AHA.
- III. I applied the USPSTF guideline to all patients over the age of 40 during annual visits or hypertension, hyperlipidemia, and/or diabetes follow-up appointments.

Two (50%) of the providers stated they "agree" and two (50%) of the providers stated they "strongly agree" with "I am knowledgeable about the USPSTF's guideline related to aspirin use for primary prevention of CVD." Two (50%) of the providers stated they "agree" and two (50%) of the providers stated they "strongly agree" with "I am knowledgeable about the cardiovascular risk calculator produced by the ACC/AHA." Lastly, three (75%) of the providers stated they "disagree" and one (25%) of the providers stated they "agree" with "I applied the USPSTF guideline to all patients over the age of 40 during annual visits or hypertension,

hyperlipidemia, and/or diabetes follow-up appointments.” See table one for an illustration of these findings.

Objective Two

Objective two, to report a positive viewpoint related to implementation of the USPSTF guideline with plans to sustain usage in future practice, was evaluated through the use of the four-point Likert scale on the post-implementation survey. The statements provided on the survey to evaluate the second objective included:

- I. I feel that using the USPSTF guideline will benefit my practice and my patients.
- II. I plan to sustain use of the USPSTF guideline in my future practice.

Three (75%) of the providers stated they “agree” and one (25%) of the providers stated they “strongly agree” with the statement “I feel that using the USPSTF guideline will benefit my practice and my patients.” Two (50%) of the providers stated they “agree” and two (50%) of the providers stated they “strongly agree” with the statement “I plan to sustain use of the USPSTF guideline in my future practice.” See table one for an illustration of these findings.

Table 1

Post-Implementation Survey Results

Statement	Strongly Disagree	Disagree	Agree	Strongly Agree
I am knowledgeable about aspirin use for primary prevention of CVD	0	0	2 (50%)	2 (50%)
I am knowledgeable about the USPSTFs' guideline related to aspirin use for primary prevention of CVD.	0	0	2 (50%)	2 (50%)
I am knowledgeable about the cardiovascular risk calculator produced by the ACC/AHA	0	0	2 (50%)	2 (50%)
I applied the USPSTF guideline to all patients over the age of 40 during annual visits or hypertension, hyperlipidemia, and/or diabetes follow-up appointments.	0	3 (75%)	1 (25%)	0
I feel that using the USPSTF guideline will benefit my practice and my patients.	0	0	3 (75%)	1 (25%)
I plan to sustain use of the USPSTF guideline in my future practice.	0	0	2 (50%)	2 (50%)
Total Responses	0	3 (12.5%)	12 (50%)	9 (37.5%)

Objective Three

Objective three, to gather data from patients 40 years of age and older at the health screening fair to validate whether patients are taking aspirin per the USPSTF guideline, was evaluated by gathering labs and vital signs from the health screening fair and information from patient charts and applying them to the USPSTF guideline using the ACC/AHA calculator. Results indicated seven (10%) of the patients were on aspirin and qualified, 24 (34%) of the patients were not on aspirin and did qualify, five (7%) of the patients were on aspirin and did not qualify, and 34 (49%) of the patients were not on aspirin and did not qualify. Seventy random patients were used for the project from the health screening fair. Forty-seven of the patients were

female and 23 of the patients were male. The average age of the patients was 60. See Appendix H for an illustration of these findings.

A chi-square test of independence was performed by an expert statistician to help with analyzing the data from the health screening fair results. A chi-square test of independence determines whether categorical variables are independent or related (Kent State University, 2018). The test of was performed to check for an association between aspirin use and status (qualify or does not qualify). Conclusively, there was not enough evidence to suggest an association between aspirin use and status and there was no ability to identify the difference as statistically significant.

CHAPTER 6. DISCUSSION AND RECOMMENDATIONS

Interpretation of Results

The purpose of the project was successful adoption of the 2016 USPSTF guideline on aspirin use for primary prevention of CVD by providers at AMC and FMC. The project included a co-investigator led educational session to providers and staff at AMC and FMC clinics regarding the USPSTF guideline and ACC/AHA calculator. Guideline implementation occurred over the following three months. All of the project objectives were achieved. Results of the project indicated increased knowledge and usage of the guideline and a positive viewpoint related to implementation of the guideline with plans to sustain use in future practice by the providers in both rural communities. Data were also collected at a health screening fair at AMC to validate whether patients were taking aspirin per the USPSTF guideline. Data gathered from the fair concluded only 59% of patients (41 out of 70) were taking aspirin appropriately according to the USPSTF guideline. The results of each objective are interpreted and discussed below.

Objective One

Objective one was for the providers at AMC and FMC to report knowledge and usage of the current USPSTF guideline and cardiovascular risk calculator from the ACC/AHA. The objective was evaluated through use of the four-point Likert scale on the post-implementation survey. All (100%) of the providers stated they either “agree” or “strongly agree” with “I am knowledgeable about the USPSTF’s guideline related to aspirin use for primary prevention of CVD. All (100%) of the providers stated they either “agree” or “strongly agree” with “I am knowledgeable about the cardiovascular risk calculator produced by the ACC/AHA.” However, three (75%) of the providers stated they “disagree” and one (25%) of the providers stated they

“agree” with “I applied the USPSTF guideline to all patients over the age of 40 during annual visits or hypertension, hyperlipidemia, and/or diabetes follow-up appointments.” Although majority of the providers stated they disagreed with the third statement of the first objective, each of the providers that stated they “disagree” with the statement made a comment after returning the survey that the words “all patients” in the statement made them choose “disagree”, as they utilized the guideline on many patients, but not all. One provider wrote “not all” under the statement on the survey indicating her reason for choosing “disagree”. From the results on the post-implementation survey for objective one, a conclusion can be reasonably made that the providers at AMC and FMC reported knowledge and usage of the current USPSTF guideline related to aspirin use for primary prevention of CVD and the cardiovascular risk calculator from the ACC/AHA by July of 2018, and that objective one was met.

Objective Two

Objective two was for providers to report a positive viewpoint related to implementation of the USPSTF guideline with plans to sustain usage in future practice. The objective was evaluated through the use of the four-point Likert scale on the post-implementation survey. All (100%) of the providers stated they “agree” or “strongly agree” with the statement “I feel that using the USPSTF guideline will benefit my practice and my patients.” All (100%) of the providers stated they “agree” or “strongly agree” with the statement “I plan to sustain use of the USPSTF guideline in my future practice.” From the results on the post-implementation survey for objective two, a conclusion can be reasonably made that the providers at AMC and FMC reported a positive viewpoint related to implementation of the USPSTF guideline with plans to sustain usage in future practice by July of 2018, and that objective two was met.

Objective Three

Objective three was to gather data from patients 40 years of age and older at the health screening fair to validate whether patients are taking aspirin per the USPSTF guideline. The objective was evaluated by gathering labs and vital signs from the health screening fair and information from patient charts and applying them to the USPSTF guideline using the ACC/AHA calculator. Results from the health screening fair indicated only 59% of patients (41 out of 70) were taking aspirin appropriately according to the USPSTF guideline and 41% of patients (29 out of 70) were not taking aspirin appropriately according to the USPSTF guideline. From the data gathered from the health screening fair a conclusion can be reasonably made that object three was met. Data were gathered from patients 40 years of age and older at the health screening fair and the data validated whether patients were taking aspirin per the USPSTF guideline.

Project results from the health screening fair at AMC were consistent with literature reporting suboptimal aspirin use for primary prevention of cardiovascular disease despite the USPSTF's recommendations (Fiscella et al., 2014). A National Health and Nutrition Survey found that 59% of patients eligible for aspirin therapy for primary prevention were not instructed to start taking aspirin by their provider (AHRQ, 2016). Consistently, results from the health screening fair found that 34% of patients who attended the health screening fair at AMC may be eligible for aspirin therapy for primary prevention but are not currently taking aspirin. With continued use of the ACC/AHA calculator and USPSTF guideline by the providers at AMC, the co-investigator anticipates the number of eligible patients not taking aspirin for primary prevention to decrease.

Evaluation of Theoretical Framework

As discussed previously in chapter two, the Iowa Model of Evidence-Based Practice was used to help facilitate implementation of the 2016 USPSTF guideline regarding aspirin use for primary prevention of CVD at AMC and FMC. The problem-solving steps and feedback loops associated with the model helped to make clinical decisions within the project (Melnik & Fineout-Overholt, 2015). The only challenge encountered with use of the Iowa Model was associated with integrating and sustaining the practice change, as the project will not be monitored for key indicators through quality improvement before dissemination of the results. However, sustainability is probable due to the providers' plans to sustain use in future practice indicated on the post-implementation surveys.

Additionally, the Diffusion of Innovations theory was utilized to help with implementation of the 2016 USPSTF guideline regarding aspirin use for primary prevention of CVD at AMC and FMC. The Diffusion of Innovations theory was a beneficial reference with adoption of the USPSTF guideline at AMC and FMC. Specifically, the second objective for this project dealt with the adoption of a new idea and behavior, as the providers at AMC and FMC either "agreed" or "strongly agreed" with sustaining use of the USPSTF guideline in their future practice. A conclusion was also made that the innovation was successful due to the projects' innovation characteristics listed by Everett Rogers, the developer of the model. The five characteristics listed by Rogers included observability, relative advantage, compatibility, trialability, and complexity (Kaminski, 2011). The project was observable to the providers through the use of face to face communication by the co-investigator, showed relative advantage to current practice through literature review, was compatible with the values and needs of the

clinics included in the project, was easily explored by the providers before adopting the idea, and was simple for the providers to adopt into daily practice.

As discussed in chapter two, the Diffusion of Innovations theory includes five adopter categories regarding the rate of adoption of new innovations. The five categories include innovators, early adopters, early majority, late majority, and laggards (Pender et al., 2015). Following successful project outcomes, it was concluded that the providers at AMC and FMC can be considered early adopters of the 2016 USPSTF guideline regarding aspirin use for primary prevention of CVD. Early adopters hold the highest level of opinion and leadership within the system and are the adopters to confer with before making a change (Pender et al., 2015). The providers at AMC and FMC have a great deal of influence and leadership within each clinic and helped to facilitate the change. Additionally, the providers were the people I checked with before adopting the change at each clinic.

Lastly, the Logic Model (see figure 3), was useful in describing how interventions were used to meet the desired objectives. The logic model served as a schematic representation of the resources used to implement the project and bring about change. The inputs, outputs, and outcomes were accurate throughout the timeline of the project.

Limitations

There were a few limitations identified during the course of this project. The first limitation, and probably most significant, was not having the capabilities of embedding the ACC/AHA calculator and USPSTF guideline into the EHRs at each clinic. The providers had to open an Internet Explorer window and type the patient information into the ACC/AHA calculator to get the calculated CVD risk and then apply the risk score to the USPSTF guideline. There is a time and click burden for providers manually entering in data to complete the

calculation and determine the appropriate patient recommendation (Scheitel et al., 2017). One of the issues the providers noted was not being able to apply the guideline to all eligible patients due to time restraints and competing clinical demands. Having the calculator and guideline embedded into the EHRs would minimize the limitation of provider time restraints, as the computer would automatically calculate the patient's 10-year CVD risk for each patient and place the calculated result in the patient's chart. Having the CVD risk score automated would decrease the time needed to incorporate the guideline into daily practice, as the provider would only have to take the time to compare the CVD risk to the USPSTF guideline. A study completed by Scheitel et al. (2017) found that clinicians saved three minutes and 38 seconds of time and improved accuracy from 60.61% to 100% for the risk score calculation and guideline treatment recommendation with use of an informatics-based clinical decision support tool used to deliver automated cardiovascular risk scores and guideline-based treatment recommendations based on data in the EHR.

The second limitation of the project was that usage of the ACC/AHA calculator and USPSTF guideline was not tracked after the implementation period to determine the impact of the project with the providers at AMC and FMC. Chart audits were not performed due to the clinics differing EHRs and lack of capabilities. However, with the provider's increased awareness and knowledge of the USPSTF guideline with plans to sustain use in future practice, provider adherence to using the guideline can be anticipated. Furthermore, measuring usage of the ACC/AHA calculator and USPSTF guideline at each clinic site with the use of chart audits would not have contributed to meeting project outcomes, which made the information extraneous to the scope of this project.

The third limitation was use of the words “all patients” in the fourth statement on the post-implementation survey. The statement was “I applied the USPSTF guideline to all patients over the age of 40 during annual visits or hypertension, hyperlipidemia, and/or diabetes follow-up appointments.” The providers felt they needed to select “disagree” on the survey, as they were unable to practically apply the guideline to “all patients” over the age of 40 during annual visits, hypertension, hyperlipidemia, and/or diabetes follow-up appointments. To avoid this limitation, the wording should have been changed to “most patients” to make the statement more practical. However, objective one was still met, as the providers reported usage of the current USPSTF guideline related to aspirin use for primary prevention of CVD and the cardiovascular risk calculator.

The last limitation was from the health screening fair. The limitation stems from not having contact with each of the patients to specifically ask them about their use of aspirin and other patient history questions and having to manually enter patient data into the ACC/AHA calculator. A study completed by Scheitel et al. (2017) found that 40% of calculations that were manually entered and not automated were erroneous due to input of wrong patient data. To minimize this limitation, abundant time and care was taken to accurately enter data into the ACC/AHA calculator.

The information to make the decision about whether a patient was eligible for aspirin for primary prevention of CVD was taken from the health screening fair results and patient charts. Patients’ charts were used to check the patient’s history to see if the patients were smokers, diabetics, or taking aspirin for secondary prevention, to check current medications to see if they were already taking aspirin or were on blood pressure medications, and to check if they had an allergy preventing them from using aspirin or other bleeding risk factors. Although this

information was considered reliable, there could have been other reasons the patient was or was not taking aspirin that the chart did not disclose. Also, the patient could already have been taking aspirin without disclosure in the patient's chart due to aspirin being sold over-the-counter, as it has been found that 20% of patients taking a daily low-dose aspirin do so without a provider's recommendation (Howard, 2014). Even with the limitation of not having direct contact with each of the patients from the health screening fair, the information gathered was the most accurate and up-to-date information available, making the data dependable for the means of this project.

Recommendations

Use of the ACC/AHA calculator and USPSTF guideline related to aspirin use for primary prevention of cardiovascular disease is recommended to be continued at AMC and FMC based on positive project outcomes and supporting literature. To simplify clinical application and prevent the overuse and under use of aspirin, tools are recommended to be used by providers to help identify patients who are eligible to take aspirin for primary prevention of cardiovascular disease (Guirguis-Blake et al., 2016). The ACC/AHA calculator and USPSTF guideline serve as tools for providers to identify patients who are eligible for aspirin therapy for primary prevention and also provides recommendations based on the patients' results. With sustained use of the ACC/AHA calculator and USPSTF guideline, providers at AMC and FMC would improve their practice by properly guiding patients in their use of aspirin for primary prevention.

Each clinic is recommended to obtain EHRs capable of having the ACC/AHA calculator and USPSTF guideline embedded into patient charts or request an update of their current EHRs to include the calculator and guideline. Having the ACC/AHA calculator and USPSTF guideline embedded into patient charts with automatic population of data would not only improve accuracy in CVD risks scores but would save time and increase provider productivity (Scheitel et al.,

2017). Also, with the calculator and guideline embedded into the EHRs, the provider's risk judgement and usage when prescribing would improve (Fiscella et al., 2014).

The ACC/AHA calculator and USPSTF guideline could be applied to all clinics not actively using and applying the USPSTF guideline related to aspirin use for primary prevention. Of particular interest are rural clinics who often do not have access to EHRs with the calculators and guidelines embedded into patient charts. Applying the project in other rural clinics would allow for a greater amount of provider feedback and increased usage of the ACC/AHA calculator and USPSTF guideline among providers.

Implications for Practice

Results of the project support the need for increased use of the 2016 USPSTF guideline regarding aspirin use for primary prevention of CVD among healthcare providers in rural clinics. The project found that the providers at AMC and FMC were lacking use of the USPSTF guideline prior to implementation of the project and that a large percentage (41%) of patients who attended the health screening fair at AMC were not taking aspirin appropriately according to the USPSTF guideline. The literature review also supported the need for increased use of the USPSTF guideline proclaiming that despite the USPSTF's recommendations, many eligible patients do not receive a recommendation from their provider, and aspirin use remains suboptimal (Fiscella et al., 2014).

The two clinics involved in the project were a good representation of how increased knowledge of the USPSTF guideline can lead to a change in practice. All of the providers in both clinics stated they either "agree" or "strongly agree" that they plan to sustain use of the 2016 USPSTF guideline related to aspirin use for primary prevention of CVD in their future practice. To meet the health needs of the community, staying current with clinical practice guideline put in

place by entities such as the USPSTF is important. Guidelines bridge the gap between research and practice and are a valuable evidence-based tool used to guide clinical decision making in order to improve clinical outcomes and promote patient safety (Fischer, Lange, Klose, Greiner, & Kraemer, 2016). However, despite guideline development, guidelines are often not applied in practice and an estimated 30%-40% of patients receive treatment that is not evidence-based (Fischer et al., 2016). Fischer et al. (2016) concluded that provider knowledge and other barriers to guideline implementation need to be assessed by stakeholders before there can be a change in provider behavior. Irrefutably, healthcare providers in family practice will encounter patients questioning aspirin therapy for primary prevention, and the USPSTF guideline gives evidence-based recommendations that safely guide providers when recommending aspirin to patients.

New Findings

New 2018 studies regarding aspirin use for primary prevention have recently become available and are pertinent to the implications for practice within this project. The Aspirin in Reducing Events in the Elderly (ASPREE) trial investigated whether daily aspirin use in older adults prolonged a healthy life span (McNeil et al., 2018). The ASPREE trial found that daily use of a low-dose aspirin among older adults, predominately 70 years of age and older, did not prolong a disability-free survival (McNeil et al., 2018). Conclusions from the trial found a higher mortality rate among the aspirin users compared to those who received placebo (McNeil et al., 2018). The ASPREE trial also found that the older adults taking the daily low-dose aspirin had a significantly higher risk of having a major bleed without a significant lower risk of CVD compared to those who received the placebo (McNeil, et al., 2018). The ASPREE trial further supports the literature review for this project by evidencing that daily use of a low-dose aspirin in patients 70 years of age and older may not be appropriate for primary prevention of CVD.

The Aspirin to Reduce Risk of Initial Vascular Events (ARRIVE) study was created to examine the usefulness of a daily low-dose aspirin versus placebo in the primary prevention of a cardiovascular event in patients at moderate risk (10-20% 10-year CVD risk) (Gaziano et al., 2018). The study did not find that aspirin lowered the risk of having a major cardiovascular event in the enrolled patients (Gaziano et al., 2018). The study also stated that the decision about whether to initiate a low-dose aspirin for primary prevention of CVD should be made after considering the potential risks and benefits with the patient (Gaziano et al., 2018). The ARRIVE study further supports the literature review for this project by helping providers decide when aspirin use is necessary for primary prevention of CVD.

Dissemination

The last step within the feedback loops of the Iowa Model of Evidence-Based Practice is dissemination. Dissemination is important for advanced practice nurses to communicate knowledge and improve practice through evidence-based practice (Melnyk & Fineout-Overholt, 2015). The project plan was initially presented at the NDSU College of Health Professions Poster Presentation in April of 2018. In September of 2018 the project and results were presented via poster presentation at the annual North Dakota Nurse Practitioner Association (NDNPA) Pharmacology Conference. The project results will also be presented at the Spring 2019 NDSU College of Health Professions Poster Presentation. Further dissemination anticipated by the co-investigator will be submission of the project for publication to a suitable journal in the spring of 2019. Journals of interest include those that are focused on primary care and rural health.

Implications for Future Research

As discussed earlier, CVD and aspirin therapy are widely conversed topics in healthcare. Even though research is abundant within the topics of CVD and aspirin therapy, there are always

topics up for deliberation. The project, aspirin use for primary prevention, could be expanded in many ways. First off, an increase in the number of rural clinics included in the project would increase the amount of feedback received from providers and further validate the projects' outcomes. Of particular interest would be a comparison of rural clinics with EHR capabilities versus clinics without EHR capabilities similar to the clinics included in this project. Second, a retrospective chart audit on the providers included in the project could further measure the impact of the project on participating providers. However, limited EHR capabilities hinder the ability to do such audits on the providers in these two clinics. Although prohibitively time consuming, charts could be randomly reviewed manually if adherence to the guideline were to be improved.

Lastly, the inclusion of bleeding risk scores within the project could simplify clinical application for providers, as there is limited guidance available for providers estimating the benefit/risk of aspirin for primary prevention (Mora et al., 2016). Although a statement was already made that there have not been any clinically validated resources to determine a patient's bleeding risk, a mobile app called "Aspirin-Guide" and an algorithm flow chart have been created to help providers with the decision to place patients on aspirin for primary prevention (Mora et al., 2016). The app and algorithm combine the ACC/AHA CVD score and GI bleeding risk score based on published studies and the USPSTF evidence synthesis to provide guidance to whether a patient should be placed on aspirin (Mora et al., 2016). Furthering research on bleeding risk would be of great benefit to providers making the decision to start, stop, or continue patients on aspirin for primary prevention of CVD.

Application to Nurse Practitioner Role

NPs play a vital role in the primary care shortage, especially in rural areas. The AANP states that 89% of NPs are prepared to practice as primary care providers (PCP) and over 75% of NPs are currently working as PCPs (American Association of Nurse Practitioners [AANP], n.d.). In North Dakota there has been a 129% increase in licensed NPs since 2009 with 49% of licensed North Dakota NPs working in primary care (University of North Dakota College of Nursing & Professional Disciplines Department of Nursing, 2017). Also, NPs are more likely to practice in rural areas than any other primary care profession (AANP, n.d.). Primary care providers play an important role in CVD prevalence, as a large portion of the NP scope of practice deals with the management of acute and chronic conditions along with health promotion and disease prevention (AANP, n.d.). With the high prevalence of CVD and such a large number of NPs working as PCPs, there is no doubt that NPs will care for many patients questioning aspirin use for primary prevention of CVD.

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APPENDIX A. PERMISSION TO USE IOWA MODEL



Kimberly Jordan - University of Iowa Hospitals and Clinics <noreply@qualtrics-survey.com>



Fri 10/20, 2:11 PM
Schlepp, Sarah

Action Items



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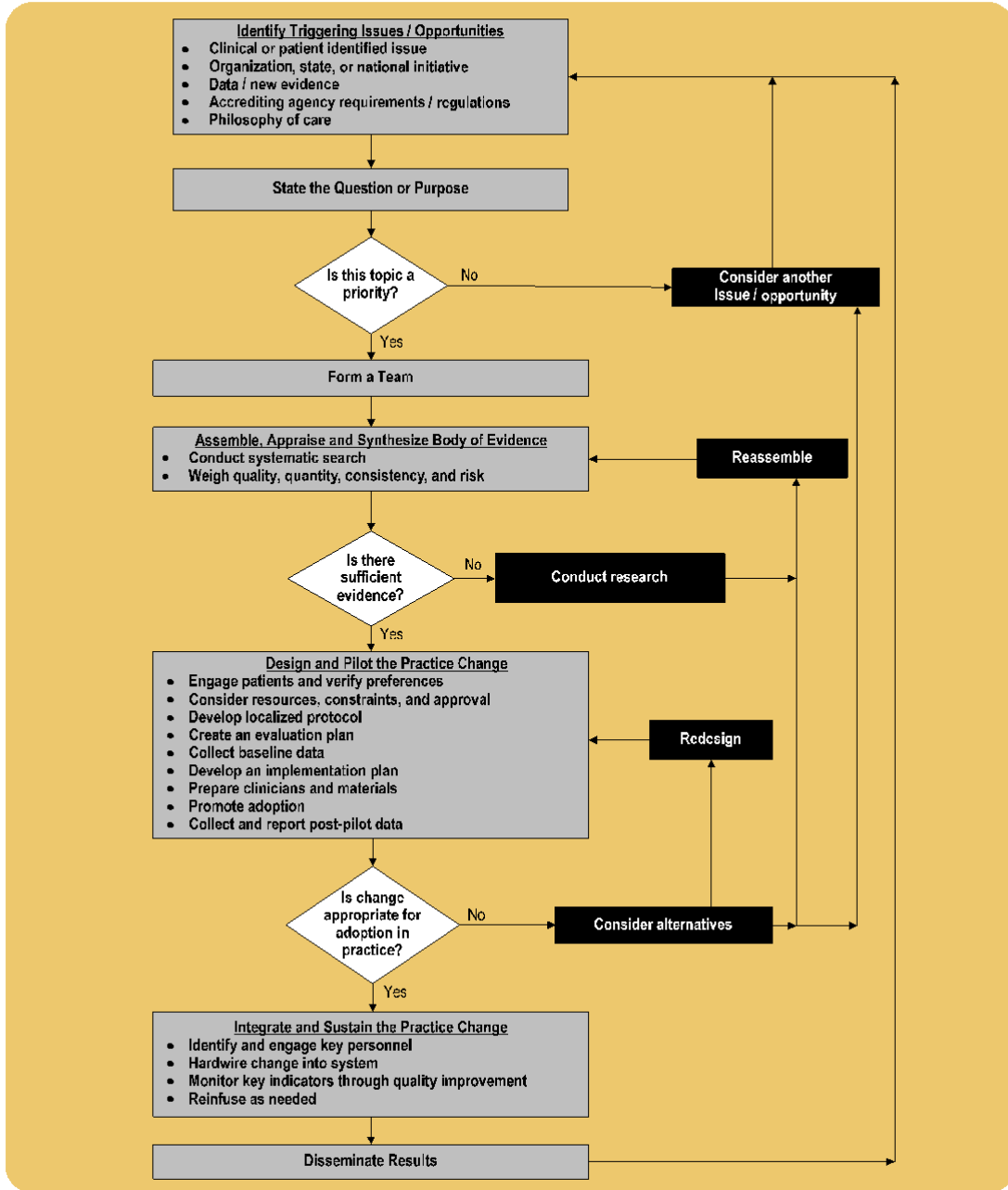
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APPENDIX B. IOWA MODEL

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



◆ = a decision point

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APPENDIX C. PROVIDER CONSENT FORM



School of Nursing
1919 University Drive North, D102
Fargo, ND 58108-6050
701.231.7395

Title of Study

This study is being conducted by:

Sarah Schlepp, DNP student. Phone: 701-535-0282. Email: sarah.e.schlepp@ndus.edu
Dean Gross, Assistant Professor of Practice. Phone: 701-231-8355. Email: dean.gross@ndus.edu

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.

- The United States Preventive Services Task Force (USPSTF) has a guideline in place regarding the use of low-dose aspirin for the primary prevention of cardiovascular disease (CVD).
- With the help of a CVD risk calculator created by the American Heart Association (AHA) and American College of Cardiology (ACC), a 10-year CVD risk can be calculated to help providers with the decision to start, stop, or continue aspirin for primary prevention.
- The goal of this project is to increase use of the USPSTF a guideline by providers in rural clinics who are not already implementing its recommendations.
- The objectives of the study include increased knowledge and usage of the USPSTF guideline and a positive viewpoint related to implementation of the guideline with plans to sustain usage in future practice.

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

- Despite the guideline in place by the USPSTF, many patients do not receive a recommendation from their provider and aspirin use remains suboptimal. Increased implementation of the USPSTF guideline is necessitated to properly guide providers when prescribing aspirin to patients for primary prevention.

What will I be asked to do?

- Each participant will be asked to apply the USPSTF guideline to each patient 40 years of age and older during annual visits or hypertension, hyperlipidemia, and/or diabetes follow-up appointments from April of 2018 to July of 2018.
- A post-implementation survey will be given to participants at the end of the study in July to evaluate the objectives of the project.

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

- The project will take place in the clinic setting. Total time commitment should only be a few extra minutes per patient eligible for application of the USPSTF guideline.



What are the risks and discomforts?

- Failing to implement the USPSTF guideline is a risk to the participants as the guideline properly guides providers when prescribing aspirin to patients for primary prevention.
- The risk will be minimized through proper education of the USPSTF guideline and relaying the importance of the recommendations to the participants.



What are the expected benefits of this research?

- **Individual Benefits:** Potential benefits of the project include successful adoption of the USPSTF recommendations by participants, appropriate primary CVD prophylaxis for patients eligible for aspirin therapy, and a reduced bleeding risk in patients who do not qualify for aspirin therapy.

Societal Benefits: The knowledge gained by participants will allow for sustained adoption of the USPSTF guideline with patients properly taking aspirin for primary prevention of CVD.

Do I have to take part in this study?

Your participation in this research is your choice. If you decide to participate in the study, you may change your mind and stop participating at any time.

What are the alternatives to being in this study?

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



Who will have access to my information?

No identifiable information will be collected during the course of the research.



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@ndus.edu, or Sarah Schlepp at 701-535-0282 or sarah.e.schlepp@ndus.edu.

What are my rights as a research participant?

You have rights as a research 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 research you may contact the IRB office at 701.231.8995, toll-free at 855-800-6717 or via email (ndsu.irb@ndsu.edu).

Documentation of Informed Consent:

You are freely making a decision whether to be in this research study. Signing this form means 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 study.

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

Your signature

Date

Your printed name

Date

Signature of researcher explaining study

Date

Printed name of researcher explaining study

APPENDIX D. LETTER OF INTENT TO IRB- AMC

Family Medical Clinic

612 Center Ave. N.
Ashley, ND 58413
Phone: 701-288-3448

April 5th, 2018

NDSU Institutional Review Board
NDSU Department 4000
PO BOX 6050
Fargo, ND 58108-6050

To whom it may concern,

This letter is to indicate the intent of the Ashley Medical Center to collaborate in Sarah Schlepp's practice improvement project, "Aspirin Use for Primary Prevention of Cardiovascular Disease." The project will start in April of 2018 and end in July of 2018. I am aware of Sarah's intent to help implement the USPSTF's guideline regarding aspirin use for primary prevention of cardiovascular disease with the providers at Ashley Medical Center. I understand the knowledge gained by providers will allow for sustained adoption of the USPSTF guideline with patients properly taking aspirin for primary prevention. Staff at Ashley Medical Center will be encouraged to participate, but participation is voluntary.

In this project, Ashley Medical Center personnel will take patient data from the health screening fair and apply it to the USPSTF guideline. A letter will be mailed to each patient with results and recommendations. Participating Ashley Medical Center personnel have been trained in the protection of human subjects, and the approved NDSU IRB protocol will be followed when conducting the project.

Thank you,

Jennifer Kaseman, LPN
Office Manager
Ashley Medical Center

APPENDIX E. LETTER OF INTENT TO IRB- FMC

Family Medical Clinic

10 9th Ave E.
Lisbon ND, 58054
Phone: 701-683-4711

March 29th, 2018

NDSU Institutional Review Board
NDSU Department 4000
PO BOX 6050
Fargo, ND 58108-6050

To whom it may concern,

This letter is to indicate the intent of Family Medical Clinic to collaborate in Sarah Schlepp's practice improvement project, "Aspirin Use for Primary Prevention of Cardiovascular Disease." The project will start in April of 2018 and end in July of 2018. I am aware of Sarah's intent to help implement the USPSTF's guideline regarding aspirin use for primary prevention of cardiovascular disease with the providers at Family Medical Clinic. I understand the knowledge gained by providers will allow for sustained adoption of the USPSTF guideline with patients properly taking aspirin for primary prevention. Staff at Family Medical Clinic will be encouraged to participate, but participation is voluntary.

Thank you,

Lyle Olson
Clinic Manager
Family Medical Clinic

APPENDIX F. IRB APPROVAL LETTER



March 27, 2018

Dr. Dean Gross
School of Nursing

IRB Approval of Protocol #PH18205, "Aspirin Use for Primary Prevention of Cardiovascular Disease"
Co-investigator(s) and research team: Sarah Schlepp

Protocol Reviewed: 3/27/2018 Protocol Expiration: 3/26/2019
Continuing Review Report Due: 2/1/2019

Research site(s): Ashley Medical Center and Family Medical Clinic Funding Agency: n/a
Review Type: Expedited category # 5, 7
IRB approval is based on the revised protocol submission (rec'd 3/26/2018). Please utilize the approved consents (version rec'd 3/6/2018).

Additional approval from the IRB is required:

- o Prior to implementation of any changes to the protocol (Protocol Amendment Request Form).
- o For continuation of the project beyond the approval period (Continuing Review Report Form). A reminder is typically sent approximately 4 weeks prior to the expiration date; timely submission of the report the responsibility of the PI. To avoid a lapse in approval, suspension of recruitment, and/or data collection, a report must be received, and the protocol reviewed and approved prior to the expiration date.

Other institutional approvals:

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

A report is required for:

- o Any research-related injuries, adverse events, or other unanticipated problems involving risks to participants or others within 72 hours of known occurrence (Report of Unanticipated Problem or Serious Adverse Event Form).
- o Any significant new findings that may affect risks to participants.
- o Closure of the project (Protocol Termination Report).

Research records are subject to random or directed audits at any time to verify compliance with human subjects protection regulations and NDSU policies.

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

Sincerely,

A handwritten signature in purple ink that reads "Kristy Shirley".

Kristy Shirley, CIP, Research Compliance Administrator

For more information regarding IRB Office submissions and guidelines, please consult www.ndsu.edu/irb. This Institution has an approved FederalWide Assurance with the Department of Health and Human Services: FWA00002439.

INSTITUTIONAL REVIEW BOARD

NDSU Dept 4000 | PO Box 6050 | Fargo ND 58108-6050 | 701.231.8995 | Fax 701.231.8098 | ndsu.edu/irb

Shipping address: Research 1, 1735 NDSU Research Park Drive, Fargo ND 58102

NDSU is an EO/AA university.

APPENDIX G. POST-IMPLEMENTATION SURVEY

Post-Implementation Survey

Healthcare providers: Please fill out the following survey to assist this investigator in identifying current strengths and needs with your experience with the USPSTF guideline related to aspirin use for primary prevention 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 the USPSTFs' guideline related to aspirin use for primary prevention of CVD.	-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 applied the USPSTF guideline to all patients over the age of 40 during annual visits or hypertension, hyperlipidemia, and/or diabetes follow-up appointments.	-1- Strongly disagree	-2- Disagree	-3- Agree	-4- Strongly agree
I feel that using the USPSTF guideline will benefit my practice and my patients.	-1- Strongly disagree	-2- Disagree	-3- Agree	-4- Strongly agree
I plan to sustain use of the USPSTF guideline in my future practice.	-1- Strongly disagree	-2- Disagree	-3- Agree	-4- Strongly agree

APPENDIX H. HEALTH SCREENING FAIR EXCEL SPREAD SHEET

ASPIRIN AND STATUS			# OF PATIENTS	% OF PATIENTS		
# of patients on aspirin and qualify			7	10%		
# of patients not on aspirin and qualify			24	34%		
# of patients on aspirin and do not qualify			5	7%		
# of patients not on aspirin and do not qualify			34	49%		
Total # of patients			70	100%		
Patient	Age	Gender	on & qualify	not on & qualify	on & do not qualify	not on & do not qualify
1	59	F		1		
2	58	F		1		
3	76	F			1	
4	46	F				1
5	63	F	1			
6	49	M				1
7	61	M		1		
8	70	M				1
9	58	M				1
10	74	M	1			
11	56	M				1
12	55	F		1		
13	59	F				1
14	45	M				1
15	54	F		1		
16	49	F			1	
17	40	F				1
18	66	M		1		
19	69	F		1		
20	60	M				1
21	64	M		1		
22	66	F	1			
23	58	M		1		
24	56	F		1		
25	69	M		1		
26	72	F				1
27	53	F		1		
28	71	F				1
29	64	M		1		
30	74	F				1
31	56	F		1		
32	55	F	1			
33	72	M				1
34	69	F		1		

Patient	Age	Gender	on & qualify	not on & qualify	on & do not qualify	not on & do not qualify
35	54	F		1		
36	47	M			1	
37	56	F		1		
38	76	F				1
39	76	M				1
40	66	F		1		
41	69	F				1
42	56	F				1
43	69	F		1		
44	57	M	1			
45	62	M				1
46	43	F				1
47	59	F		1		
48	76	F				1
49	69	F		1		
50	56	F			1	
51	43	M				1
52	50	M				1
53	63	F				1
54	52	F				1
55	49	F			1	
56	63	F		1		
57	68	F	1			
58	44	M				1
59	64	F				1
60	58	M				1
61	57	F				1
62	60	F				1
63	67	F				1
64	50	F				1
65	71	F				1
66	68	F		1		
67	68	F				1
68	62	F	1			
69	61	F				1
70	56	M		1		
Average age=	60.44	F=47, M=23	Total=7	Total=24	Total=5	Total=34

APPENDIX I. EXECUTIVE SUMMARY

Executive Summary

Aspirin Use for Primary Prevention of Cardiovascular Disease



USPSTF Recommendations

- A daily low-dose aspirin should be initiated for primary prevention of CVD in patient's 50 to 59 years of age who have a 10% or higher 10-year CVD risk and do not have a high bleeding risk. (B recommendation)
- The decision should be individualized on whether to start patients 60 to 69 years of age with a 10% or higher 10-year CVD risk, on a low-dose aspirin for primary prevention of CVD. (C recommendation)
- There is currently not enough evidence to determine the benefit versus harms of starting aspirin for primary prevention of CVD in patient's older than 70 years of age and younger than 50 years of age. (I recommendation)

Introduction

Cardiovascular disease (CVD) is a major cause of morbidity and mortality in the United States and aspirin is a well-known medication strongly associated with CVD prevention. Aspirin has undeniable benefits in the role of secondary prevention of CVD, however, the benefits are ambiguous when associated with primary prevention. The decision to start aspirin for primary prevention becomes complicated due to aspirin's effect on coagulation and the risk of gastric ulceration.

The United States Preventive Services Task Force (USPSTF) has level B recommendations in place regarding the use of low-dose aspirin (81 mg) for primary prevention of CVD. 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 guideline and CVD calculator offer healthcare providers an easy-to-navigate tool to determine proper patient use of aspirin. However, despite the USPSTF guideline, appropriate aspirin use remains suboptimal.

Project Design

The purpose of the project is successful adoption of the 2016 USPSTF guideline on aspirin use for primary prevention of CVD by providers at AMC (Ashley Medical Center) and FMC (Family Medical Clinic).

The project began with education to providers and staff at AMC and FMC regarding the USPSTF guideline and the ACC/AHA calculator. Following the educational session, implementation of the USPSTF guideline occurred for three months. There were two nurse practitioners (NP) from AMC and one NP and one physician assistant from FMC included in the project. Evaluation was performed through the use of a post-implementation survey.

Application to the Nurse Practitioner Role

- NPs play a vital role in the primary care shortage, especially in rural areas.
- NPs are more likely to practice in rural areas than any other primary care profession.
- 89% of NPs are prepared to practice as primary care providers (PCP) and over 75% of NPs are currently working as PCPs.
- A large portion of the NP scope of practice deals with the management of acute and chronic conditions along with health promotion and disease prevention.
- With the high prevalence of CVD and such a large number of NPs working as PCPs, there is no doubt that NPs will care for many patients questioning aspirin use for primary prevention of CVD.

Data were also collected from a health screening fair at AMC to validate whether patients were taking aspirin per the USPSTF guideline and to denote the significance of the proposed project in the rural communities. The USPSTF guideline was applied to 70 random patients over the age of 40.

Project Results

Results of the project demonstrated increased knowledge and usage of the guideline and a positive viewpoint related to implementation of the guideline with the providers in both of the communities having plans to sustain use in future practice.

Data gathered from the health screening fair concluded only 59% of patients (41 out of 70) were taking aspirin appropriately according to the USPSTF guideline and 41% of patients (29 out of 70) were not taking aspirin appropriately according to the USPSTF guideline.

Recommendations

Use of the ACC/AHA calculator and USPSTF guideline related to aspirin use for primary prevention of cardiovascular disease is recommended to be continued at AMC and FMC based on positive project outcomes and supporting literature. With sustained use of the ACC/AHA calculator and USPSTF guideline, providers at AMC and FMC would improve their practice by properly guiding patients in their use of aspirin for primary prevention.

The ACC/AHA calculator and USPSTF guideline could be applied to all clinics not actively using and applying the USPSTF guideline related to aspirin use for primary prevention. Applying the project in other rural clinics would allow for a greater amount of provider feedback and increased usage of the ACC/AHA calculator and USPSTF guideline among providers.

Conclusion

Results of the project support the need for increased use of the 2016 USPSTF guideline regarding aspirin use for primary prevention of CVD among healthcare providers in rural clinics. Healthcare providers in family practice will encounter patients questioning aspirin therapy for primary prevention, and the USPSTF guideline gives evidence-based recommendations that safely guide providers when recommending aspirin to patients. The two clinics involved in the project were a good representation of how increased knowledge of the USPSTF guideline can lead to a change in practice.