

**Implementing the 2018 ACC/AHA Cholesterol Management Guidelines in Primary Care:
Exploring the Provider and Patient Experience**

Sara E. Jurado & Leydi M. Espinosa

Rutgers University School of Nursing

DNP Chair: Dr. Ann Marie Mauro

DNP Team Member: Dr. Kathyann Duncan

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Abstract

Utilization of evidence-based practice guidelines is an essential part of a provider's role in the management of chronic diseases. However, a gap has been identified in provider knowledge and application of the 2018 American College of Cardiology (ACC) and American Heart Association (AHA) Cholesterol Management Guidelines for the primary prevention of cardiovascular disease. The project purpose was to promote provider: 1) adherence to the 2018 ACC/AHA Cholesterol Management Guidelines with the use of the 10-year ASCVD risk score, and 2) utilization of the risk score to facilitate patient-provider risk communications following training in a primary care practice in an urban community in Northern New Jersey. Results from the project identified application of guidelines and utilization of the 10- year risk score in 35.8% of eligible patients, while those who engaged in a risk discussion rated the patient-provider interaction with high levels of confidence and satisfaction. Findings from the project identify a continued need for organizational support to sustain the application of clinical guidelines including the utilization of the 10-year risk score needed to guide-patient provider discussions.

Keywords: cholesterol management, ASCVD risk calculator, patient-provider risk discussion, shared decision-making.

Introduction

Cardiovascular disease (CVD) is prevalent in many developed countries, and the leading cause of death in the United States (Benjamin et al., 2019). Not only does CVD account for the significant decrease in quality of life of those affected, but it also places a tremendous economic burden on the U.S. healthcare system (Benjamin et al., 2019; Heller et al., 2017). One of the significant factors contributing to the development of CVD is hyperlipidemia, and thus appropriate cholesterol management has become a cornerstone to preventing cardiovascular events (Benjamin et al., 2019; Grundy et al., 2018).

As a response to this pervasive and costly problem, major national and local campaigns such as the Million Hearts Initiative, Healthy People 2020, and Healthy New Jersey, have endorsed the importance of appropriate cholesterol management as outlined by the 2018 American College of Cardiology (ACC) and American Heart Association (AHA) Cholesterol Management Guidelines (Egan et al., 2016; U.S. Department of Health and Human Services, 2017; New Jersey Department of Health, 2013). The current guidelines stress the need for calculating a patient's 10-year atherosclerotic cardiovascular disease (ASCVD) risk score, engaging the patient in risk discussions, followed by shared decision-making, and ultimately the use of appropriately dosed statin medications (Grundy et al., 2018).

Despite the mounting evidence pointing to the efficacy of ASCVD risk assessment tools and statin therapy, providers are not consistently implementing the ACC/AHA guidelines in their practice (Lowenstern et al., 2018; Wong et al., 2016). Therefore, it is essential to understand the barriers encountered by primary care providers regarding the implementation and utilization of the ACC/AHA guidelines. It is also valuable to gain insight into how these implementation measures impact shared decision-making between the patient and the provider. Due to the

overwhelming need for CVD prevention and better guideline adherence among primary care providers, this project sought to 1) promote provider adherence to the 2018 ACC/AHA Cholesterol Management Guidelines, and 2) facilitate ASCVD risk communications through patient-provider shared decision-making with the use of a 10-year ASCVD risk assessment calculator for the primary prevention of CVD in adults.

Background and Significance

Cardiovascular disease is described by Benjamin et al. (2019) as an umbrella term for the presence of various diseases of the circulatory system. These include atherosclerotic heart disease, myocardial infarction (MI), angina, stroke, heart failure, arrhythmias, and valvular structure disorders. For the epidemiological data provided, hypertensive diseases and peripheral circulatory diseases are also included within the definition of CVD. For this project, ASCVD referred to the following conditions outlined by the 2018 ACC/AHA Cholesterol Management Guidelines: MI, angina, coronary or other arterial revascularization, stroke, transient ischemic attack, or peripheral artery disease including aortic aneurysm (Grundy et al., 2018).

Prevalence and Mortality

Cardiovascular disease is vastly prevalent, with high rates of mortality across various populations. It is more prevalent among men, accounting for 428,434 deaths versus 412,244 deaths in women (see Appendix A) (AHA, 2017; Benjamin et al., 2019). The risk of developing CVD also increases with age. According to the AHA (2017), the likelihood of individuals developing CVD more than doubles from age range 24 to 45 (see Appendix B). Overall, CVD is also much more prevalent in racial and ethnic minority populations, particularly among non-Hispanic blacks (AHA, 2017). Current data shows us that 57.1% of non-Hispanic black females and 60.1% of non-Hispanic black males have some form of CVD (Benjamin et al.,

2019). The World Health Organization (WHO, 2019) also places those in low to middle-class groups at higher risk for developing CVD.

Financial Burden

In addition to the high prevalence and mortality, CVD represents a high economic burden on the U.S. healthcare system. Between the year 2014 and 2015, the U.S spent \$351.2 billion in the management of CVD (Benjamin et al., 2019). The WHO (2019) reports that 85% of cardiovascular deaths are due to MI and stroke. Not surprisingly, MI and atherosclerotic heart disease are among the most expensive conditions to treat in U.S. hospitals (Benjamin et al., 2019). In New Jersey, CVD was responsible for 200,000 total hospital admissions in 2009, representing a systemic and financial strain to the state (NJ Department of Health, 2013).

Out in the community, individuals face the physical and financial sequelae of CVD in the form of decreased quality of life and loss of employment. A study by Song et al. (2018) determined that in the first months after individuals experience cardiovascular events or have a related procedure, they can lose anywhere between 31 to 61 hours of work, amounting to a \$998-\$1842 lost per month. The figures mentioned above are indicative of serious health and financial problems for the lives of individuals, their families, and the country. If current trends persist, by the year 2035, the indirect and direct costs of CVD in America will exceed \$1 trillion (AHA, 2017).

Global, National & Local Initiatives

Various initiatives such as the Global Hearts, Million Hearts, and Healthy People 2020 have developed campaigns to address the problem of CVD. The WHO (2019), Global Hearts Initiative works to support various nations around the world to prevent and control CVD. This global initiative recognizes the need to reduce CVD risk through lifestyle modifications with a

three-step approach: MPOWER for tobacco control, SHAKE for salt reduction and HEARTS for strengthening CVD management in primary health care (WHO, 2019). The Global Hearts initiative highlights the importance of primary prevention by providing primary care practices with six evidence-based teaching modules to aid providers in addressing CVD risk (WHO, 2019).

Healthy People 2020 is an evidence-based agenda developed to guide health and disease prevention in the U.S through various goals, objectives and tracking measures of national health indicators (Office of Disease Prevention and Health Promotion, 2019). One of the goals of Healthy People 2020 is to improve the overall cardiovascular health in the U.S. population (Office of Disease Prevention and Health Promotion, 2019). However, due to the complex and multifaceted nature of CVD, this goal can be achieved by simultaneously employing different interventions that reduce the risk of cardiovascular events. Some of these interventions proposed by Healthy People 2020 include promoting lifestyle changes, hypertension management, cholesterol reduction, appropriate aspirin use, and increased awareness of heart attack and stroke in the community (Office of Disease Prevention and Health Promotion, 2019).

Another collaborative initiative, the Million Hearts Campaign developed by various U.S. government agencies, is committed to preventing 1 million CVD events by 2022 (U.S. Department of Health and Human Services, n.d.). Like the proposed interventions of Healthy People 2020 and Global Hearts, the Million Hearts Campaign also highlights the importance of cholesterol management in the “ABCs” of CVD prevention: aspirin, blood pressure control, cholesterol management, and smoking cessation (U.S. Department of Health and Human Services, 2017).

In response to the high CVD mortality rate in New Jersey, local initiatives have been developed by the NJ Department of Health. Partnering for a Healthy New Jersey (PHNJ) is a disease prevention and health promotion plan aimed at identifying health risks impacting NJ residents while implementing evidence-based strategies to improve the overall health of the state (NJ Department of Health, 2013). This plan also aims at increasing blood cholesterol screening from 78.8% to 86.7% (NJ Department of Health, 2013).

Prevention of Cardiovascular Disease

A common theme found in the initiatives mentioned above is that cholesterol management is one of the most important factors in the prevention of CVD. Therefore, the ACC and AHA developed detailed guidelines to support providers in the appropriate management and prevention of ASCVD. A vast amount of evidence tells us that the correct use of these guidelines is effective in preventing cardiovascular events in individuals with a history of CVD (secondary prevention) and in individuals with no prior history (primary prevention) (Heller et al., 2017; Mortensen et al., 2015; Pencina et al., 2014). More importantly, the use of the ACC/AHA guidelines can bring providers 78% closer to achieving the Healthy People 2020 goal of reducing CVD (Egan et al., 2016).

The first step in primary prevention is identifying patients at risk. According to the 2018 ACC/AHA Cholesterol Management Guidelines, it is highly recommended that providers determine a patient's 10-year ASCVD risk score to guide clinical decision-making, identify the need for statin therapy, and create an individualized treatment plan (Grundy et al., 2018). Not only does the use of ASCVD risk estimates aid providers in formulating evidence-based clinical decisions, but it also allows the patient and provider to make shared decisions and track potential benefits from lifestyle modifications and medications (Lloyd-Jones et al., 2018).

The second step in primary prevention is utilizing the ASCVD risk score to guide therapy selection. The use of statin therapy to reduce ASCVD by lowering low-density lipoproteins (LDL) is endorsed by the 2018 ACC/AHA Cholesterol Management Guidelines (Grundy et al., 2018). Data shows that when the ACC/AHA guidelines are used to prevent CVD with the use of statins, 243,589 cardiovascular events are prevented annually and quality of life is significantly improved (Egan et al., 2016; Heller et al., 2017). In addition to decreasing the risk of cardiovascular events, the appropriate and consistent use of 10-year ASCVD risk score to optimize the use of statin therapy has been shown to reduce medical expenditure, providing a total savings of more than \$120 million (Dudl et al., 2014).

Current Guideline Adherence

Despite the existence of established guidelines and supportive data, providers are not consistently utilizing ASCVD risk scores and statin therapy for primary prevention of CVD. A study published by Bakhai et al. (2018) determined that in primary care, the rate of ASCVD risk score calculation can be less than 1%. Not surprisingly, statin use for primary prevention of CVD is also low, as only 50% of eligible patients are currently prescribed statins (Mercado et al., 2015; Pencina et al., 2014). Additionally, of those patients that are on statins, only half are appropriately dosed and reach their LDL goals (Navar et al., 2017; Wong, 2016). Some possible explanations for this trend are the provider's hesitancy to treat LDLs more aggressively and low uptake of current clinical guidelines (Navar et al., 2017).

On the other side of CVD prevention lies the patient. Those without a history of CVD often perceive their risk for developing CVD differently than what their actual risk score shows and are less likely to adhere to their cardioprotective medications (Navar et al., 2016; Turin et al., 2015). In addition to inaccurate perceptions of their disease, a lack of involvement in developing

their plan of care has also been cited as a barrier to adherence to statins, which in turn, lead to higher LDL levels, and increased risk factors for developing CVD (Turin et al., 2015).

To address these patient-related barriers, the ACC/AHA guidelines highlighted the importance of the patient-provider discussion and shared decision-making (Grundy et al., 2018). It presents a special challenge for providers, as they often fail to utilize 10-year ASCVD risk scores to communicate actual risk, and seldom invite the patient to participate in the clinical decision-making process actively (Bakhai et al., 2018). It is evident that there is room for improvement, but little is known about what barriers exist in the utilization of the ACC/AHA guidelines for cholesterol management in primary care. The evidence tells us that this is an opportunity to implement life-saving primary prevention methods and explore the provider and patient perspectives.

Needs Assessment

Cardiovascular disease is a global problem, affecting many developed countries like the U.S. In 2016, CVD claimed 17.9 million lives, accounting for more than one-third of all deaths around the world (WHO, 2019). Even more alarming is that global data trends indicate that the problem of CVD continues to grow. It is projected that by the year 2030, CVD will cause more than 23.6 million deaths per year, globally (Benjamin et al., 2019).

In the U.S., nearly half of the adult population over the age of 20 has CVD (Benjamin et al., 2019). According to Benjamin et al. (2018), this equates to one death every 38 seconds, which amounts to approximately 2,300 American deaths daily. Cardiovascular disease kills more people every year than cancer and chronic lower respiratory disease, combined (Benjamin et al., 2019).

The Centers for Disease Control and Prevention (CDC, 2016), identify heart disease as the leading cause of mortality for NJ residents, accounting for 3,401 total deaths in 2016. The PHNJ initiative identified heart disease, cancer, stroke, and diabetes as major players in increasing the disability and death rates of its residents (NJ Department of Health, 2013). With a high burden of disease, NJ residents continue to be placed at an increased risk for CVD due to lack of disease prevention. As of 2015, the state continues to fail in achieving the goal for cholesterol screenings, with only 82% of all adults having blood cholesterol screening (NJ Department of Health, 2019). Thus, more initiatives aimed at improving cholesterol management for NJ adults are needed.

The site chosen for this project was a private practice serving residents of Maplewood, NJ and other surrounding cities in Essex County. According to the U.S. Census Bureau (2017), Maplewood has an estimated total population of 24,706 residents, of which 50% are of age 40 or older and predominantly Black. These factors place the patient population of Maplewood at a disproportionately higher risk for developing CVD. Therefore, primary care providers face a real challenge in the prevention and management of CVD in this community.

The project directors identified a gap in knowledge and application of current cholesterol management guidelines in fall 2018 through clinical practice and personal communications with the primary physician. During these communications and direct patient observation, it was noted that approximately one-third of established patients at the practice, the majority of whom were middle-aged and Black, were at high risk for CVD with elevated cholesterol levels (Practice owner/physician, personal communication, October 28, 2018). Prior to the project, practice patients 20 to 65 years old were screened via non-fasting lipid panel, and many were treated for hyperlipidemia. However, no one was screened with an ASCVD 10-year risk assessment tool

(Primary physician, personal communication, October 28, 2018). The treatment plan was decided based upon results from the patient's lipid profile, other comorbidities, and family medical history. Prior to training, the primary physician reported unfamiliarity with the 10-year ASCVD risk assessment tools to guide clinical decisions and the initiation of statin therapy at the appropriate intensity level (primary physician, personal communication, October 28, 2018). Although the primary physician encouraged shared decision-making, there was no standard method in place to communicate ASCVD risk to patients (primary physician, personal communication, October 28, 2018). The high-risk population and lack of provider knowledge of 2018 ACC/AHA Cholesterol Management Guidelines for primary prevention of CVD made it apparent that there was a need for a practice change.

Clinical Question

Although initiatives have been implemented at the local, state, and national levels to reduce the risk for CVD, uptake of guidelines remains low and problematic. Most significantly, the underutilization of guidelines, lack of risk assessments, and ineffective risk communications are consistently related to negative patient outcomes. Therefore, better interventions are needed in the primary care setting to improve provider application of the 2018 ACC/AHA Cholesterol Management Guidelines. The following clinical question is intended to address the need for CVD prevention initiatives: "Following training, do providers in a primary care setting adhere to cholesterol management guidelines and utilize the risk score to discuss primary prevention of cardiovascular disease in adult patients ages 40-75 during a two-month period?"

The project explored two aspects of implementation: the provider experience and patient perspective. The target audiences were: 1) medical assistants/personnel responsible for patient intake and healthcare providers in the practice, including student physicians completing fourth

year clerk ship in family practice and nurse practitioner students completing their clinical rotations in family practice; and 2) practice patients ages 40 to 75 with no previous history of CVD. The proposed interventions included implementation of the 2018 ACC/AHA Cholesterol Management Guidelines and use of the 10-year ASCVD risk score to guide the patient-provider risk discussion and initiation of statin therapy at an appropriate intensity following training.

Aims and Objectives

The proposed project intended to achieve two specific goals identified by measurable and time-focused objectives. The first aim focused on promoting provider adherence to the 2018 ACC/AHA Cholesterol Management Guidelines with the following corresponding objectives. Providers would:

- 1.1. Use the 10-year ASCVD risk score to guide patient-provider discussions regarding CVD risk and treatment plan options.
- 1.2. Initiate statin therapy at an appropriate intensity level, guided by the patient's 10-year risk score and 2018 ACC/AHA Cholesterol Management Guidelines.
- 1.3. Assess their experiences with implementation of the 2018 ACC/AHA Cholesterol Management Guidelines in clinical practice.

The second aim focused on facilitating ASCVD risk communications through patient-provider shared decision-making with the use of the 10-year ASCVD risk assessment calculator with the following objectives:

- 2.1. Providers would utilize the 10-year ASCVD risk calculator to facilitate ASCVD risk discussions, as recommended by the 2018 ACC/AHA Cholesterol Management Guidelines.

2.2. Patients would express satisfaction with communication of their ASCVD risk from their provider.

2.3. Patients would express confidence in their ASCVD risk plan of care made in consultation with their provider.

Review of Literature

A literature review was conducted to explore elements of the clinical question addressing the: 1) implementation of clinical practice guidelines (CPGs), 2) underutilization of the 2018 ACC/AHA Cholesterol Management Guidelines, 3) barriers and facilitators in implementation of cholesterol management guidelines, and 4) the use of decision aids in ASCVD risk communications to facilitate shared decision-making.

Databases accessed for the literature review with assistance from the Rutgers Smith Library health sciences librarian included Medline, CINAHL, Joanna Briggs Library, PubMed, Scopus, and the Rutgers Smith Library website. Separate literature searches were performed to fully address the two aspects of this project: 1) the implementation and utilization of guidelines, and 2) patient-provider risk communications. The search strategies utilized involved key terms used in the literature inquiry regarding:

1. Guideline implementation, including physicians/primary care, clinical practice guidelines, evidence-based practice, and quality assurance.
2. Patient outcomes, including physician-patient relations, patient/treatment outcomes, patient education, patient-reported outcome measures, cardiovascular disease, cardiovascular disease prevention, cholesterol/HDL/LDL/VLDL, patient compliance, along with patient self-management including self-care, risk discussion, assessment, perception, and decision aids.

Search limits included dates of publications within the year 2010 to 2019, articles in the English language, those about human subjects, and searches that included abstracts and full-text articles. One hundred and seven potential research articles were identified and accessed electronically for possible inclusion. Further analysis of the articles warranted exclusion based on the quality of evidence, applicability to the PICOT question, and validity. Articles were classified according to The Johns Hopkins Nursing Evidence Levels (Newhouse et al., 2005). Articles of strength levels I-V, of high or good quality were included. A description of the articles included in this review of literature can be found in the Table of Evidence (see Appendix C). In addition to databases, reference lists from relevant articles were utilized for a more comprehensive review.

Use of Clinical Practice Guidelines

Guideline adoption continues to be a hurdle in general practice. Currently, CPGs serve as evidence-based practice frameworks to improve the quality of care and patient outcomes (Melnyk, 2015). Guidelines aim to decrease the gap between provider knowledge and treatment options by providing cost-effective treatments endorsed by scientific evidence (Fischer et al., 2016). However, research has consistently recognized a disconnect between established clinical guidelines and implementation by healthcare providers.

Studies on the use of CPGs have identified that the “development” of these guidelines does not necessarily translate to their timely “implementation” or “utilization” in clinical practice (Melnyk, 2015). Evidence-based guidelines are recognized as representing only 30 to 40% of all implemented treatments, creating inconsistency and variability in care (Fischer et al., 2016). Non-compliance with evidence-based guidelines is associated with overtreatment, misdiagnosis, and unnecessary ordering of diagnostic testing (Fischer et al., 2016). It is evident that this is an

area of concern, as misutilization or underutilization of guidelines serves as a potential risk to patients while signifying increasing costs to the healthcare system.

Non-adherence of cholesterol management guidelines. This concept of underutilization also applies to cholesterol management guidelines. Despite mounting evidence urging the need to reduce CVD through appropriate cholesterol management, the literature illustrates underutilization of the Pooled Cohort Equation to identify ASCVD risk, and appropriate initiation of statin medication (Bakhai et al., 2018). A study by Ng et al. (2016), recognized that 55% of patients with secondary risk for a cardiovascular event were prescribed statin therapy at lower levels than those recommended by the ACC/AHA cholesterol management guidelines. It is crucial to address this issue because ASCVD risk calculation score, especially in the primary prevention of cardiovascular disease, has been associated with the increased diagnosis of unknown hyperlipidemia and increased initiation of appropriate statin therapy (Bakhai et al., 2018).

Interestingly, the utilization of cholesterol management guidelines differs across health care settings. In primary care, 38% of clinicians reported applying ACC/AHA guidelines to “very few patients” (Jame et al., 2015). Primary care providers are also less likely to adhere to ACC/AHA cholesterol management guidelines and implement the use of ASCVD calculation to guide statin initiation in comparison to specialists, such as cardiologists (Lowenstern et al., 2018). Additionally, as little as 1% of eligible patients have received their 10-year ASCVD risk score in the internal medicine setting (Bakhai et al., 2018).

Challenges to guideline adherence in primary care. Higher levels of non-adherence to cholesterol management guidelines have been identified in smaller urban practices such as the one that serves as the site for this project. Shelley et al. (2018) points out that only 49% of

patients with ASCVD risk in smaller practices are meeting the expected outcomes of the implementation of the Million Hearts ABCs initiative. It is due to the special implementation challenges experienced by smaller practices that often lack the organizational support needed to institute quality improvement (QI) interventions (Shelley et al., 2018). To facilitate the process of guideline implementation, the Institute of Medicine (2011) report, *Clinical Practice Guidelines We Can Trust*, calls for effective collaboration between guideline developers and implementers to promote synchronization and improve guideline adoption.

An example of such support is the EvidenceNOW Initiative backed by the Agency for Healthcare Research and Quality (AHRQ), aimed at addressing the suboptimal utilization of the Million Hearts ABCs to reduce the risk for heart attacks (Shelley et al., 2018). The EvidenceNOW Initiative provides external support to small primary care practices to facilitate QI using expert consultation, on-site coaching, data management and feedback, and collaborative learning (AHRQ, 2018). This initiative was successful in increasing the use of QI interventions by small primary care practices from 66% to 77% and optimizing CVD health in more than 8 million patients through improvements in statin prescribing, hypertension management and smoking cessation (AHRQ, 2018). Therefore, with appropriate support and a systematic approach, small primary care practices can adopt QI interventions to improve guideline adherence and patient care.

Quality Improvement for The Provider

As mentioned previously, QI strategies can successfully improve guideline adherence by addressing some of the barriers at the organization level. However, provider-related issues, the focus of this project, are of equal importance when addressing inconsistent CPG implementation. To address the problem of CPG implementation at the provider level, Fischer et al. (2016),

recognized the need for a “structured” plan to address barriers to adherence through: 1) guideline “dissemination” that focuses on bridging gaps in knowledge through educational support and training, 2) “social interaction” that aims to reduce conceptual barriers through multidisciplinary engagement and collaborative learning, and 3) “decision support systems” and “standing orders” that integrate work-flow alerts and increase clarity by prompting providers to utilize guidelines to make clinical decisions (Fischer et al., 2016). Bakhai et al. (2018) successfully structured implementation of cholesterol management guidelines using the Plan Do Study Act (PDSA) QI model by reducing provider barriers to guideline use.

Barriers and solutions. Barriers identified by providers in implementing ACC/AHA cholesterol management guidelines include lack of provider knowledge about current guidelines, inexperience using the risk assessment tool, and practice time constraints (Bakhai et al., 2018; Egerton et al., 2017).

Jame et al. (2015) identified that as many as 41% of primary care clinicians lacked enough knowledge of cholesterol management guidelines needed to implement them correctly in practice. Therefore, the first step in addressing provider adherence is to increase knowledge of the guidelines by instituting QI interventions (Lowenstern et al., 2018). Bakhai et al. (2018) suggests holding training sessions to educate providers on the most current guidelines. Resources that summarize the guidelines placed in clinical areas readily available for provider use at the point-of-care have also been found effective (Bakhai et al., 2018). Quick reference guides may be useful for providers with time constraints that prevent them from reading the guidelines in detail at the point-of-care (Jame et al., 2015).

The use of the ASCVD risk assessment calculator has also proved to be a challenge for providers. Jame et al. (2015) found that 23% of providers identified these barriers with the 10-

year ASCVD risk calculation based on pooled cohort equations: lack of validity, fear of overtreatment, and inability to apply the calculator to all populations based on race. These clinicians reported that ASCVD risk calculations did not provide universal applicability, especially to minority populations. Those who found the calculator useful in guiding patient discussions also identified its limited usefulness in non-English speaking patients and those with low literacy levels, many of whom may be ethnic minorities (Jame et al., 2015). Additionally, these providers admitted that criticism of the validity of the guidelines by others contributed to their mistrust and fear of overtreatment. Grundy et al. (2018) recommended further research to develop more broadly applicable tools for risk assessment in patients from diverse racial/ethnic groups.

Although pooled cohort equations may have limitations, it is important for providers to know that these 10-year ASCVD risk calculators have the best validity as compared to other risk calculators and are well-calibrated to predict risk near thresholds, minimizing the risk for overtreatment (Grundy et al., 2018). Therefore, QI efforts are needed to facilitate calculator usage. Bakhai et al. (2018) suggests this may be accomplished by emphasizing its importance during provider training and instituting EMR chart reminders to calculate patient risk. These QI efforts increased ASCVD calculator utilization by up to 14.2% among physicians and residents rotating in an internal medicine clinic with sustainable utilization of 33% after one year (Bakhai et al., 2018).

Primary care providers have also identified time constraints as a persistent barrier to calculating ASCVD risk (Bakhai et al., 2018). It can be time-consuming for providers in a busy clinical practice to manually enter patient statistics into the calculator. Unfortunately, this translates to missed opportunities to appropriately assess patient risk leading to decreased

guideline adherence. Bakhai et al. (2018) suggest that greater adherence can be achieved by integrating the ASCVD calculator into the EMR as it automates risk calculation, and streamlines clinical processes, saving providers time. Therefore, it is possible to achieve improved guideline adherence by addressing provider lack of familiarity with current guidelines, reinforcing the importance of evidence-based practices, and efficiently incorporating guidelines into provider workflow through the EMR.

Quality Healthcare and The Patient-Provider Relationship

Improving quality care is at the heart of healthcare innovation and the development of CPGs. The Institute of Medicine (2001) report, *Crossing the Quality Chasm: A New Health System for the 21st Century*, calls for care delivery that is evidence-based and patient-centered through healthcare interventions that are respectful of patient preferences and create an opportunity for involvement in the plan of care development. Therefore, it is essential to consider how the implementation of the patient-provider risk discussion framed by the cholesterol management guidelines affects the patient's satisfaction with risk communications and shared decision-making.

The quality of the patient-provider relationship is highly dependent on the effectiveness of communication between the parties. According to Lambert-Kerzner et al. (2015) effective patient-provider communication occurs when the communication involves: 1) conversations that are bidirectional, 2) patients who are comfortable asking questions and communicating disagreement to their provider, and 3) patients actively participating in their treatment. Conversely, ineffective patient-provider communication and missed opportunities for collaboration have the potential to negatively affect patient outcomes by increasing systolic

blood pressure, LDL and Hemoglobin A1c levels (Parchman, et al., 2010; Van Der Laan et al., 2017).

Despite the evidence supporting the importance of effective patient-provider communication, providers continue to use a “biomedical problem-solving” approach rather than collaborative decision-making, which leaves patients feeling “reduced to their disease” (Brundisini et al., 2015). Without open communication, it is difficult for providers to get a well-rounded view of their patients past their diagnosis. This does not allow the patient to fully comprehend their diagnosis and become engaged in their plan of care (Lambert-Kerzner et al., 2015).

Risk Communication

A vital component of the 2018 ACC/AHA Cholesterol Management Guidelines are patient-provider risk discussions which serve to: 1) inform the patient about their calculated ASCVD risk score, 2) explore the patient’s risk-enhancing conditions, and 3) engage patients in shared-decision making to plan healthy lifestyle modifications and statin drug therapy (Grundy et al., 2018). The literature supports the need to effectively communicate calculated risk to improve statin adherence. It is especially relevant in the primary prevention of CVD, an often symptom-less condition in comparison to established CVD (Lansberg et al., 2018). Effective communication of increased risk may help patients decide if statins are appropriate for them. According to Harmsen et al. (2014), patients who were aware of their actual risk for developing ASCVD were more likely to adhere to their statin medication regimen when providers explained how their medications could reduce their absolute risk.

Use of decision aids to communication risk. Decision aids such as the ACC ASCVD Risk Estimator Plus, are evidence-based tools that help providers and patients make informed,

collaborative health decisions and facilitate patient-provider risk discussions (International Patient Decision Aid Standards Collaboration, 2017). A systematic review by Stacey et al. (2017) encourages the use of decision aids, as they are likely to be successful in engaging the patient in the clinical discussion, increase the patient's knowledge of their disease, and improve their perception of their plan of care. Sheridan et al. (2014), made similar conclusions based on their study which found that the use of decision aids significantly increased patient knowledge of CVD prevention strategies by 21% ($p < 0.0001$), accuracy of risk perception by 33% ($p < 0.0001$), and intentions to follow care plan to reduce CVD risk by 21% (95% *CI*).

While the literature shows the importance of providers incorporating an ASCVD risk assessment calculator in their practice and increasing adherence to ACC/AHA cholesterol management guidelines, the question becomes, can quality improvement strategies targeted at provider guideline adherence also translate to effective ASCVD risk communications and shared decision-making? The literature yields promising results. Cooper et al. (2011) found that physician communication skills training improved the patient-provider relationship and significantly increased rates of shared decision-making ($p = 0.03$). Harmsen et al., (2014) found positive results evident by an increase of 32% (95% *CI*) in patient adherence to statin medications after providers implemented the use of 10-year risk assessments along with individualized educational sheets to guide their consultations with patients. Interestingly, Harmsen et al. (2014) also found that as a result of the patient-provider discussion, patients were on average more confident in their treatment decisions and more satisfied with their risk communications (95% *CI*, 4.05 and, 4.23, respectively).

To summarize, this literature review asserts that a gap in provider knowledge may lead to the decreased application of clinical guidelines in practice. Research has shown that QI that

focuses on enhancing provider knowledge through education, training, and streamlining workflow, have the potential to optimize the calculation of ASCVD risk scores. However, investigations targeting provider implementation of ACC/AHA cholesterol management guidelines are lacking.

Although there is evidence to support the importance of patient-provider communications, few studies specifically address the effect of utilizing specific risk assessment tools such as the ACC ASCVD Risk Estimator Plus, on patient outcomes (Stacey et al., 2017). The literature also suggests that there is a strong need for evidence that evaluates the “quality” of the patient-provider discussion with the use of the ACC Risk Estimator. This information can reveal how the communication of CVD risk affects the patient perception of risk communication and satisfaction with shared decision-making.

Theoretical Models

This project was formulated based on the PDSA (Institute for Healthcare Improvement, 2019), and Theory of Planned Behavior (Ajzen, 1991) frameworks.

Plan-Do-Study-Act

The PDSA framework (see Appendix D) was designed to test change within a quality assurance project (Institute for Healthcare Improvement, 2019). Originally developed by Associates in Process Improvement, the PDSA cycle is the second part of the Model for Improvement that specifically focuses on the change processes (Institute for Healthcare Improvement, 2019). The PDSA cycle is frequently used by small and large healthcare organizations, to integrate the latest evidence into current practices (Massoud et al., 2006). The Institute for Healthcare Improvement (2019) explains the four steps of the PDSA cycle as follows:

1. Plan: This step outlines the project objectives, specific steps needed to enact change, data collection process, target audience while identifying important stakeholders.
2. Do: The project is carried out according to a plan with systematic documentation of observed outcomes.
3. Study: Data analysis is performed that includes a comparison of actual data to predicted outcomes.
4. Act: Concepts learned from data analysis and project implementation are compiled to determine the successes of the project, highlight areas of improvement, and plan for sustainability.

The PDSA cycle was used to guide implementation of the 2018 ACC/AHA Cholesterol Management Guidelines in a primary care practice to include: 1) training providers on the use of the 2018 Cholesterol Management Guidelines; 2) integration of the ACC ASCVD Risk Estimator Plus into the electronic medical record (EMR); and 3) streamlining provider and staff work-flow. This project analyzed provider's experiences with implementation of the 2018 ACC/AHA Cholesterol Management Guidelines. Lessons learned from the project were utilized to modify provider's future practice and provide a plan for sustainable improvement.

The Theory of Planned Behavior

The Theory of Planned Behavior, previously known as the Theory of Reasoned Action, was introduced in the 1980s to understand an individual's intent to behave in a certain manner in situations under their control (Boston University School of Public Health, 2018). This model (See Appendix E) proposed that health-related behavior is driven by two main tenets: 1) the individual's level of "motivation" (intent), highly dependent on the perceived likelihood that a behavior will lead to the desired outcomes, and 2) the individual's "perception of control" of the

outcomes (Ajzen, 1991). The Theory of Planned Behavior encompasses various dimensions of health-related behaviors that pertain to internal and external patient factors. This project primarily focused on four: “attitudes” toward the behavior, the strength of motivational factors (*behavioral intention*), the extent to which an influential party, such as a provider, approves of the behavior (*social norms*), and the individual’s “perception of power” over the behavior (Boston University School of Public Health, 2018).

The risk discussion potentially allows providers a unique opportunity to influence the patient’s perception of their risk, which suggests that risk-reduction behaviors are successful in preventing CVD. Using shared decision-making, the provider can place some of the focus of control on the patient, to empower them to engage in risk-reducing behaviors.

Methodology

This project implemented the 2018 ACC/AHA Cholesterol Management Guidelines, with a focus on primary prevention of CVD. A training session was conducted with the office staff and providers on the use of the ACC ASCVD Risk Estimator Plus and shared decision-making during patient-provider discussions. A retrospective chart review was conducted to determine the rate of ASCVD risk score completion and statin medication initiation by providers at the site. The chart review evaluated two months of retrospective outcomes from the initiated date of implementation. The COMRADE Survey, developed by Edwards et al., (2003) was used to study risk communication and shared-decision making, it was distributed to patients after the patient-provider discussions. Perceived experiences with implementation were assessed via the Swedish Improvement Measurement Questionnaire (SIMQ) developed by Andersson et al. (2013). A debriefing session was conducted with providers and staff after data analysis to present project findings.

Setting

The setting for the project was a privately-owned primary care practice in an urban community in Northern New Jersey. A site agreement was signed by the practice provider which allowed the project directors to conduct the project at the site (see Appendix F).

At the time of implementation, the practice employed two primary care physicians and 4 students, including two third-year medical students completing primary care clinical clerkship and two advanced practice nursing (APN) students completing a family practice rotation. The APN students rotated approximately every 6 months, and the medical students rotate every five weeks. The practice also employed six front desk personnel, two of whom functioned as medical assistants responsible for patient intake.

The patient population at the practice included predominately non-white patients, who were largely Caribbean and African American. The practice had approximately 3,000 patients with an average of 800 patients seen per month. About thirty percent of the total patient population was identified as having an increased risk for experiencing a CVD event (primary physician, personal communication, October 28, 2018).

Target Audience

The target audiences were primary care providers, staff, and patients in the private practice. Due to their high level of involvement in direct patient care, students were also considered providers. For guideline implementation, participants consisted of 2 primary physicians, and three student providers (2 medical and 1 APN) completing clinical rotations at the practice who were responsible for patient care. Along with six front desk staff/medical assistants responsible for patient intake or registration. Targeted patient participants included English-speaking patients age 40-75 years old, with bloodwork showing LDL levels of 70 or

greater. Patients with a prior history of CVD and LDL levels of 190 or greater were excluded per the 2018 ACC/AHA Cholesterol Management Guidelines for 10-year ASCVD risk assessment and patient-provider risk discussion.

Ethics and Human Subjects Protection

Project approval was obtained from the Rutgers Biomedical and Health Sciences Institutional Review Board. Project participation posed minimal risk to all participants and survey responses were anonymous. Staff were assured their decision regarding participation would not affect their employment, and they were not be asked to disclose personal identifying information, except for their job role. Aggregate responses were used to report findings to the entire staff to develop a sustainability plan. Patient personal health information to assess project outcomes was collected and de-identified by assigning a code number. Only the co-investigator/project directors had access to the list linking the patient's name and code number. Possible benefits to providers and staff include improving workflow, patient care, and adherence to evidence-based guidelines. Potential benefits to patients include improved patient outcomes and reduced the risk for cardiovascular events.

Participant recruitment and consent. An announcement was made by the co-investigators/project directors approximately four weeks prior to the start of the project informing providers, medical assistants/front desk staff of the mandatory professional development training regarding the guidelines and use of the ACC ASCVD Risk Estimator Plus. Additionally, a flyer was posted in the office break room where it was visible to all staff and providers (see Appendix G). Providers and staff provided informed consent (see Appendix H) to participate in evaluating implementation. Participants were screened for eligibility and consented in person by the co-investigators/project directors on the last day of the 2-month

implementation period. Participants were counseled that participation in the project was voluntary, would not interrupt their usual operations, and they would receive a \$10 gift card upon survey completion. A waiver of consent (see Appendix I) was obtained to conduct a retrospective chart review to identify all patients who should have had an ASCVD risk score calculated and/or the associated ACC/AHA guidelines implemented during the 2-month project implementation period.

Recruitment and consent for the patient clinical evaluation and risk discussion was not required as this was part of the usual care. Patients meeting the inclusion criteria that were involved in a risk discussion with their provider were recruited and consented to participate in the assessment of their perception of shared decision-making. Patient recruitment by the co-investigators/project directors took place in the exam room immediately after patient intake using an oral scripted recruitment message (see Appendix J). Informed consent was obtained in the exam room immediately before or after the patient consultation with the provider (Appendix K). Participants were informed that their participation was voluntary, and they received a \$10 gift card as compensation. Participation did not alter their usual care. Patients were invited to ask questions about the project and received a copy of the consent form.

Outcome Measures

Outcome measures for the implementation portion of the project were assessed utilizing a retrospective patient medical record review that was tracked electronically using a chart review tracking form (see Appendix L) to determine if:

1. Eligible patients had a documented risk score in their EMR.
2. Providers prescribed statins at an appropriate intensity level based on the patient's ASCVD risk score and 2018 ACC/AHA Cholesterol Management Guidelines.

3. Providers adjusted statin therapy levels based on the patient's current risk score.
4. Providers engaged in an ASCVD risk discussion with their patients.

The chart review tracking form was also used to compile demographic data including age, gender, and race. Additionally, co-investigators/project directors kept a log (see Appendix M) of de-identified, qualitative, anecdotal comments about guideline implementation voiced by providers, staff, and patients. During the project period to gain further insight into barriers or challenges experienced.

After a two-month implementation period, a 25-item modified version of the Swedish Improvement Questionnaire (SIMQ) was given to providers and staff members to assess their perspective on project implementation (see Appendix N). The SIMQ consists of two dimensions: 1) improvement effectiveness and 2) internal improvement process. The first 3 items of the questionnaire describe the overall improvement effectiveness. The next 22 items evaluate various processes of internal improvement in 8 subdimensions: resource scarcity, standardization, of procedures, expectations of rewards and sanctions, improvement group leadership, freedom to express doubts, and learning encouragement. The questions are rated on a five-point scale with responses such as "Not at all" rated at zero increasing to "A lot," rated at a 4 (Andersson et al., 2013). Improvement effectiveness dimension scores can range from 0-12, while internal improvement scores range from 0-88. Therefore, the total score for the SIMQ can range from 0 to 100. An overall Cronbach's alpha coefficient of 0.72 has been reported, suggesting high internal consistency reliability (Andersson et al., 2013). The SIMQ did not establish question validation utilizing psychometric properties. Content validity was established with the use of focus groups and help from an expert in the field of quality management

(Andersson et al., 2013). A modified version of the SIMQ was used with written permission from its author.

Immediately after the patient-provider discussion and obtaining consent, the patient completed the COMRADE paper survey (see Appendix O) developed by Edwards et al. (2003) to evaluate risk communication and shared decision-making. The 20-item COMRADE scale includes statements encompassing two dimensions of the patient-provider discussion. The first ten statements address risk communication, which enables process evaluation from the patient's perspective, while the other ten relates to confidence in the decision (Edwards et al., 2003). The statements are scored using a five-point Likert-scale, with five indicating the patient strongly agrees with the statement and 1 indicating strong disagreement with the statement. Therefore, the total score for each survey can range from 0 to 100 points. Questionnaire consumers and general practitioners were interviewed to identify important domains and assess for validity. Edwards et al. (2003) reported high validity, as confidence in decision was correlated with enablement ($p < 0.001$), adherence to treatment ($p < 0.01$) and reduced anxiety/concern ($p < 0.001$). When used to evaluate shared decision-making in patients with schizophrenia, the COMRADE scale showed strong reliability (Cronbach's alpha coefficient: .93; Bartlett's test of specificity: $p < 0.001$) (Pérez-Revuelta et al., 2018). Although the COMRADE scale has not yet been used specifically in cholesterol management, it has been successfully adapted to assess 10-year CVD risk communication and shared decision-making in type 2 diabetes (Welschen et al., 2012). The original version of the COMRADE scale was used in its entirety, with written permission from its author.

For data collection, patient participants were asked to fill out a demographic sheet (see Appendix P) attached to the COMRADE survey. Demographic sheets and surveys were

numbered (e.g., 001-100) before distribution and tracked using an Excel document (Appendix Q). Participants were asked to refrain from writing any identifiable information on the survey and demographic sheet to preserve confidentiality.

Procedures

Modification of electronic medical record (EMR). Before providing the professional development training, the practice EMR staff super-user was contacted to request access to the practice EMR. Links to the ACC ASCVD Risk Estimator Plus and the National Lipid Association Clinician's Lifestyle Modification Toolbox websites were integrated into the EMR to facilitate its access to providers and staff. The EMR provider company was also contacted to modify the EMR interface with capability of inputting patient risk score, and patient care plan regarding risk communications.

Training sessions. A brief training session (see Appendix R) and workflow trial, lasting approximately 20 minutes was conducted for all medical assistants and front desk personnel in the practice on which patients need ASCVD risk score calculation, what information is needed to calculate risk, how to access the calculator, other informational tools, and where to document the risk score in the EMR. A workflow diagram (see Appendix S) was presented, and the staff was given the opportunity to practice the workflow during the session. Another training session (see Appendix T) and mock case lasting approximately 60 minutes was conducted for all practice providers covering topics on the 2018 ACC/AHA Cholesterol Management Guidelines, the ACC ASCVD Risk Estimator Plus, how to calculate a patient's risk score, how to utilize it to guide clinical decision-making and document risk discussions. The providers were given the opportunity to use the calculator through the EMR and conduct a simulated patient encounters to practice the patient-provider risk discussion and workflow. Additional educational training

sessions were conducted for providers and staff as needed on an individual or group basis during the two-month implementation period as needed.

Risk communications. Communication of patient risk and shared decision-making took place in the examination room before the end of the consultation. The entire discussion was not scripted, as one of the goals was to individualize treatment based on the provider's judgment and specific needs of each patient. However, the providers followed a checklist (see Appendix U) adapted from Martin et al. (2015) to guide the discussion. To facilitate the explanation of risk and increase patient understanding, a script (see Appendix U) was developed using the format suggested by the Mayo Clinic (n.d.). Providers had access to this document inside the CVD Prevention Toolkit available in each exam room (see Appendix V). In addition to the script, the CVD Prevention Toolkit contained paper copies of the guidelines, workflow charts, and patient education handouts addressing lifestyle modifications such as diet, exercise and smoking cessation, along with information about cardioprotective medications, and coronary artery calcium testing. These documents were placed in easily accessible folders in each exam room to facilitate access of resources for providers at the point of care.

Once the provider communicated the risk to the patient, the provider proceeded to follow the ACC ASCVD Risk Estimator Plus to evaluate the patient's treatment options, including risks and benefits of statins, lifestyle modifications and gave each patient educational handouts relevant to the patient's plan of care. The provider and staff had access to these documents for immediate printing by following the link in the EMR to the National Lipid Association Clinician's Lifestyle Modification Toolbox website.

Patient survey. Patients meeting the inclusion criteria that received a risk assessment and consented to participate were given a demographic sheet and COMRADE survey enclosed

inside a sealed envelope immediately after signing the consent. The participants were asked to fill out the survey in the waiting room and place the survey back in the envelope before returning it to the co-investigators/ project directors. Upon completion of the survey, participants received a \$10 gift card before leaving the office.

Provider/staff survey. Providers and staff meeting the inclusions criteria and who consented to participate were asked to complete the paper SIMQ to measure the effects of implementation. The providers and staff completed the survey once at the end of the 2-month implementation period in the office. Upon completion of the survey, participants received a \$10 gift card from the co-investigators/project directors. Following the completion of data collection and analysis, a debriefing session was presented to staff and providing findings from the project.

Data Analysis

Cronbach's alpha coefficients were calculated for the SIMQ and COMRADE total and subscale scores. Data collected from the retrospective patient medical record chart reviews, provider/staff SIMQ scores, and patient COMRADE scores were analyzed using descriptive statistics, including frequencies, means, modes and ranges. All quantitative data were analyzed utilizing SPSS, Version 25 developed by IBM Corp. (2017). Qualitative thematic analysis was conducted for anecdotal notes taken during implementation to better understand provider, staff, and patient experiences with guideline implementation, risk calculator utilization, and address project barriers as they arose.

Data maintenance and security. Patient health data was stored in a password-protected cloud environment that was only accessible by the project directors, using Office 365 for Rutgers student accounts and the Microsoft Teams App as a means for collaboration. Patient health data collected from the chart review was de-identified and assigned an identification number by the

project directors. The lists generated to link the patient data to the identification number was stored electronically in a password-protected document only accessible by the project directors. All printed data including signed consents, demographic data collection tracking sheets and paper surveys was stored in a locked cabinet by the project directors.

After final project presentation and report approval, IRB closure will be completed. Data will be retained for a minimum of three years per regulatory guidelines. Paper documents were destroyed in accordance with Rutgers IRB guidelines using the Rutgers University Shredding Services and electronic files on Microsoft One Drive were permanently deleted with assistance from the Rutgers Office of Information Technology.

Budget and Resources Needed

The budget for this project was a total of \$1691, which included the entire cost of printed materials (flyers, surveys, and patient education handouts), folders, envelopes, refreshments served during in-services, participant incentives, additional materials/services needed for project dissemination, and provider, staff, and patient participant gift cards (see Appendix W). Training and debriefing were provided during normal office hours, thus no additional costs from wages were incurred. Printing of patient education materials and point-of-care references was done with the project site resources. All costs incurred through use of paper and toner to print educational material were included in the site overhead budget, approved by the office coordinator. The co-investigators/project directors were solely responsible for covering the cost of printing the paper surveys, flyers, and patient education handouts for the duration of the project.

Project Timeline

The project spanned a total of 18 months, including the time needed for proposal development, IRB submission, implementation, and formal presentation of the project results (see Appendix X). Project implementation and data collection began on October 15, 2019 and ended on December 10, 2019.

Results

Demographics

A total of 226 patient medical records met the retrospective chart review age inclusion criteria for provider guidelines adherence. Of these, 207 patient records met inclusion criteria based on CVD history. Since there were only a few non-English-speaking patients, these records were not excluded based on language. Therefore, the only exclusion criterion was a documented CVD history. Of the 207 patients included in the chart review, the average age was 53 years ($SD = 9.07$) and most were between ages 40 to 50 ($n = 98, 47.3\%$) while the next largest group was ages 51 to 60 ($n = 57, 27.5\%$) (Table 1). As depicted in Table 2, a large majority of patients were Black/African American ($n = 123, 59.4\%$) and female ($n = 168, 81.2\%$).

All seven eligible participants completed the SIMQ including two physicians, three student providers (2 medical students, 1 APN), and two medical assistants. Of the 34 eligible patients recruited, 24 completed the COMRADE survey, for an overall response rate of 71%. Reasons cited for not participating included lack of time and concerns that the results would not make any positive changes to their care, regardless of the outcome. The mean age of patients who completed the COMRADE was 55 years ($SD = 9.48$), and all were between 40 to 71 years old, with the majority between the ages of 40 to 70 (Table 3). As depicted in Table 4, most COMRADE participants were female ($n = 23, 95.8\%$), Non-Hispanic ($n = 23, 95.8\%$) and

African American/Black ($n = 20$, 83.3%). A total of 39 qualitative notes were collected from providers, staff, and patients.

Reliability of Outcome Measures

The Cronbach's alpha reliability coefficients for the SIMQ were the following: total scale .90, improvement effectiveness subscale .48, and internal improvement processes subscale .91. The total SIMQ and internal improvement subscale scores indicated a high level of internal consistency reliability. Further analysis showed that by deleting one item about improving work, the Cronbach's alpha coefficient for the improvement effectiveness subscale improved significantly to .84. Since several of the internal improvement subdimension scores had poor reliabilities (.34 to .63), only those with reliabilities of .70 or greater were included in the analysis: resource scarcity (.75), group leadership (.92), and decision influence (.90). The Cronbach's alpha reliability coefficients for the COMRADE demonstrated high internal consistency reliability for the total scale (.99), satisfaction subscale (.98), and confidence subscale (.99).

Provider Adherence to Guidelines and Risk Score Utilization: The results of the EMR review showed that of the 207 patients eligible to receive a risk score, only 35.8% ($n = 74$) had one calculated (Table 5). While statin initiation was not applicable in 43.5% ($n = 90$) of cases, statins were initiated in only 9 cases (1.45%) when 51.7% ($n = 107$) of patients were eligible for initiation (Table 6). Likewise, most patients ($n = 112$, 54.1%) were eligible for statin modification but statins were modified in only a few cases ($n = 3$, 1.45%). Providers documented using the risk score to guide risk discussions only 11.6% of the time. In 43% ($n = 89$) of records, the risk discussion was not applicable and in approximately one third of records, it was unclear from the EMR whether the discussion took place.

Provider/Staff Satisfaction with Guidelines Implementation

Table 7 outlines the SIMQ psychometric properties and scores. Analysis revealed a high rate of satisfaction with the ASCVD risk calculator implementation with a mean score of 9.57 ($SD = 1.4$). Overall improvement was rated as “quite a bit” effective 52.4% of the time, while 33.3% rated it “a lot” effective and only 14.3% rated the implementation as having “some” effectiveness. The internal improvement dimension also showed positive results with a mean score of 62.43 ($SD = 15$, $\alpha = .91$) out of 88. Under the resource scarcity subdimension participants reported that implementation of the ASCVD risk calculator did not interfere with other office resources, which resulted in a mean score of 14.43 ($SD = 3.31$, $\alpha = .745$). Group leadership also resulted in high mean score of 15.43 ($SD = 5.8$, $\alpha = .92$), indicating high levels of satisfaction with project directors’ leadership throughout implementation. However, participants reported having only “some” influence in the decision-making process 42.9% of the time, yielding a low mean score of 8.29 ($SD = 5.88$, $\alpha = .898$) for the decision influence subdimension.

Patient Satisfaction with ASCVD Risk/Plan Communication

After their patient-provider risk discussions, most ($n = 21$, 87.5%) patients rated their interactions highly with a total COMRADE score ranging from 76 to 100 ($M = 88.25$, $SD = 18.7$, $\alpha = .99$). COMRADE subscale scores were also high for satisfaction ($M = 43.5$, $SD = 9.8$, $\alpha = .98$) and confidence ($M = 44.75$, $SD = 9.3$, $\alpha = .99$) out of a possible score of 50 for each. These results indicate that patients had a high level of overall confidence and satisfaction with their risk discussions and plans of care.

Qualitative Analysis

Qualitative notes were analyzed based on two overall themes: facilitators and barriers to guideline implementation (Table 9). Benefits to patient care and practice improvement were

voiced by providers and patients including facilitation of statin prescribing by providers, benefits in early risk detection for patients, and financial benefits to the practice. Implementation of the risk calculator enabled the practice to bill for ASCVD risk score calculation under cardiovascular disease screening and for risk reduction counseling.

Time constraints and organizational factors were among the most commonly occurring barriers. Although few patients reported inability to participate in the COMRADE survey due to lack of time, most of the data shows time had a bigger impact on bigger impact staff and providers. High patient volume and understaffing along with other organizational barriers prevented staff from calculating risk scores and providers from following clinical guidelines. One of the most important barriers was described by a medical assistant and provider: inability to access current labs from EMR due to backlog of scanning lab results into the system. Knowledge deficit was associated with a lack of health literacy regarding cardiovascular disease, lack of familiarity with use of the tool, which patients qualified for ASCVD risk score calculation implying lack of familiarity with the guidelines. Problems such as down times with the EMR system and risk calculator also arose during implementation. Co-investigators/ project directors addressed these barriers through fast quality improvement cycles, which included provider/staff training, implementing EMR reminders alerting staff and providers to ask patients regarding having cardiovascular disease and to facilitate risk score documentation.

Discussion

Patient Population

The demographic results of the retrospective medical records chart review and COMRADE survey are a fair representation of the project site patient population that is predominantly middle-aged, African American/Black and Black Caribbean. A total of 34

patients were recruited for participation in the COMRADE survey, which is approximately 30 percent of the intended target of 100 patients. Various factors accounted for the limited number of recruited patients. The schedules of the co-investigators/project directors did not allow their daily presence at the project site for consenting and distributing surveys. Additionally, organizational barriers such as understaffing did not allow for consistent score calculation and risk discussion on all days, thus making patients ineligible for survey completion.

It is worth mentioning that one of the reasons for conducting this project at this site was the numerous data pointing to evidence that Blacks are twice as likely to die from preventable heart disease (Centers for Disease Control, 2013). Due to its patient population, CVD prevention is of the utmost importance for this primary care practice. Additionally, the results of the participant ages are encouraging, as the overarching purpose of interventions like these are to engage patients in risk discussions as early as possible in their lifetime. This is important to highlight because 6 out of 10 people under the age of 65 will have a preventable CVD event or death from stroke (Centers for Disease Control, 2013). Although various factors could have contributed to the low number of male participants, the literature suggests that a major factor is the difference in healthcare-seeking behavior between men and women. A study by Thompson et al. (2016) found that women are significantly more likely than men to seek a primary care provider when they have a health concern.

Guidelines Implementation

Findings from the chart review, qualitative anecdotal themes, and the SIMQ survey facilitated co-investigators/ project directors understanding of the provider experience related to adherence to the 2018 American College of Cardiology and American Heart Association Cholesterol Management Guidelines with the application of ASCVD risk calculator. Provider

and staff training offered quality improvement support to further enable adherence to the guidelines. Project findings identify the importance of streamlining workflow and integrating participation from medical staff to facilitate risk score calculation. While the EMR was modified to enable risk score documentation, the slowdown of uploading laboratory documents into the EMR made it challenging for staff and providers to access values needed to determine the ASCVD risk score. Additionally, time constraints and inconsistent provider application of evidence-based guidelines continue to pose as barriers to score calculation, statin prescribing and patient-provider risk discussions.

Training the providers and staff in the use of the calculator and guidelines was an important factor in adherence, as the literature identifies a lack of training and knowledge as limitations in the utilization of the CVD risk assessment tool (Bakhai et al., 2018). Providers and staff actively participated and were receptive to the educational training. After this intervention, findings from the chart review identified that approximately one third of patients received a risk score. A higher rate of score calculation was not achieved, perhaps due to time constraints, demands from a high patient load, and most significantly, limited medical assistants available to facilitate risk score calculation. Interestingly, various other factors found in the EMR may have presented as barriers to score calculation, statin initiation/modification, and risk discussions. Among the most prominent is an absence of current labs in the EMR, which prevents risk score calculation, as LDL and HDL values must be known to determine risk score. Records of patients that did not have current laboratory values documented in the EMR were due to clerical delays or because patients were new to the practice.

Providers' ability to adequately utilize risk score calculation in statin management supports the literature, which identifies risk calculation as an effective method in primary

prevention of CVD through early detection and treatment of hyperlipidemia using statins (Bakhai et al., 2018). Here, the EMR revealed that in 10 cases, statins were not initiated or modified because the patient was already on the appropriate statin. Although a low number of patients were initiated on statins, 43.5% of patients did not meet criteria for statin management and 54% did not have their statin modified despite qualifying for modification. Part of shared decision-making implies that the patient and provider may chose not to start or modify their statin medications, which may have occurred in many of these cases. This is consistent with Lansberg et al. (2018) who describes that lack of statin modification is attributed to patient resistance. However, these findings also highlight the importance of patient-provider risk discussion to develop individualized treatment plans for patients that may chose other methods of CVD prevention recommended by the guidelines, such as lifestyle modifications prior to starting statins. Thus, the risk discussion is considered a fluid process that should be revisited as the patient progresses through their individual plan of care.

Risk discussion documentation was challenging for providers. However, it is worth noting that more risk discussions may have taken place than indicated by the EMR. Analysis revealed that 104 of the 207 records reviewed were incomplete (e.g., providers did not document plan of care), thus making it difficult to determine whether the risk discussion took place and whether the risk score influenced the discussion. It should be noted that only 10 of records reviewed corresponded to new patients.

The SIMQ revealed positive feedback from staff and providers. The improvement uncertainty subdimension assessed implementation in relation to problems arising with development and how easy was it to know the steps necessary to utilize the ASCVD risk calculator, which was rated as “very easy” 43% of the time. Perhaps most notably, 43% of the

staff and provider responses indicated that the ASCVD risk calculator and project support their practice. Providers and staff shared positive responses about the risk calculator tool's effectiveness as well as the support and the freedom for autonomy they received from project directors and practice leadership. Although these participants reported positive organizational support, time constraints continued to represent a considerable barrier that was attributed to a lack of staff support needed to facilitate risk calculation and an overload of patients. These findings are consistent with the literature, which recognizes limited organizational support and time constraints as factors in the underutilization of quality improvement measures (Bakhai et al., 2018; Shelley et al., 2018). Although previous research identified that small practices often lack organizational support needed to institute quality improvement measures, this site supported a culture of continued learning for its staff and providers, which can work to offset other potential barriers.

Among the most persistent barriers identified in the anecdote log were time constraints and organizational factors such as staffing, clerical backlog, and delayed EMR documentation by the providers. Changes in the practice organizational structure, including the leave of medical assistants, magnified time constraints. These organizational changes resulted in less medical assistants available to meet patient and provider demands. Medical assistants found it difficult to facilitate risk scores on days where there was a high census of patients and a limited number of medical assistants for patient intake. Literature identifies practice time constraints as a mounting barrier in providers usage of the risk assessment tool and application of cholesterol management guidelines (Bakhai et al., 2018). Identifying ways to address barriers through organizational support can further enhance the application of the ASCVD risk calculator in small practices. On the other hand, project results identified financial benefits to the practice as a result of cholesterol

guideline implementation. Calculation of patient risk score and engaging in risk discussions enables the practice to bill for these CVD prevention procedures, which was not being done before implementation. While this may serve as a financial incentive for more providers to integrate cholesterol management guidelines into their practice, patients can also experience potential financial benefits by reducing the financial strain associated with the treatment of cardiovascular events.

Shared Decision-Making

The results of the COMRADE survey showed that patients were able to learn about their actual risk from their providers who explained the meaning of the score in a way that was easy for the patient to understand. Moreover, they were active participants in the discussion, were given the opportunity to ask questions about their choices, and the chance to understand the treatment modalities. These are important factors in shared decision-making, as the end goal of primary prevention interventions is to empower the patient and to attain positive outcomes. The literature proposes that positive outcomes can be facilitated if the patient feels empowered to make those changes, with support from their provider (Harmsen et al., 2014). In this case, patients were not only satisfied with their risk discussion, but felt that their decision was tailored specifically to their needs and reflects the values important to them.

The ACC Risk Estimator Plus

In addition to the 2018 AHA/ACC Cholesterol Management Guidelines, the 10-year ASCVD risk calculator was also implemented to facilitate the patient-provider discussion, which ultimately resulted in high patient confidence and satisfaction. The use of decision aids, like the ASCVD risk calculator, to successfully engage the patient in risk discussions and improve their knowledge of their disease, its management and prevention has been supported (Sheridan et al.,

2014; Stacey et al., 2017). Although the retrospective chart review revealed a relatively low rate of calculator utilization to guide risk discussions, this decision aid was well-received by patients when used to inform them about their risk and treatment options. Patients reported high levels of satisfaction with the information they were provided and perhaps more importantly, left their encounter feeling that they made an informed choice.

Implications

The implementation of the 2018 ACC/AHA Cholesterol Management Guidelines served as the groundwork for quality improvement in the primary care practice by positively influencing patients, providers, and staff. The following implications as they pertain to organizational and patient outcomes are discussed: clinical practice, healthcare policy, quality and safety, education, economic and organizational.

Clinical Practice

Prior to implementation, the standard of practice in this office mirrored data found by Bakhai et al. (2018) indicating that the rate of ASCVD risk calculations in primary care was less than 1%. After implementation, 54% of eligible patients did not have their statins modified and providers utilized risk scores to guide risk discussion 12% of the time. Although these results reveal an improvement to previous practice, it is evident that more work is needed. The literature supports the use of EMR reminders to increase the utilization of risk assessment tools (Bakhai et al., 2018). The EMR system can direct providers and staff to the risk calculator but also alert providers to complete their risk-discussion as part of their plan of care. This can increase utilization and streamline documentation, which was a challenge for providers in this practice.

The low rate of statin utilization by providers can be attributed to fear of overtreatment and negative outcomes as identified by Jame et al. (2015). To overcome this concern greater emphasis must be placed in promotion of research highlighting the benefits in application of cholesterol management guidelines in cardiovascular risk reduction. The practice is encouraged to continue incorporating training on the use of evidence-based guidelines as part of provider onboarding with emphasis on the benefits of statin use for primary prevention of CVD. As mentioned previously, patient resistance is a high contributor to underutilization of statins. While patient satisfaction was rated highly during risk discussions, this does not imply that patients are more likely to choose statins as the first treatment option. However, patients found the risk discussions to be a valuable influence in their health choices. Thus, a greater emphasis on follow-up will need to be placed during training sessions to encourage providers to re-visit the patient's plan of care and reconsider statin use.

An underutilization of ASCVD risk score to guide patient-provider risk discussion was also identified, with only 12%, of providers utilizing the score. Literature indicates that providers who have implemented the use of the risk calculator identify low literacy levels as a barrier in application (Jame et al., 2015). Providers at the practice are encouraged in the future to avoid the use of medical terms and use lay terms to overcome this hurdle. Time constraints continue to be a barrier identified in researched and echoed by providers at the practice as a hurdle in the application of the risk tool. To overcome this barrier the practice recognizes the possible need for future onboarding of medical assistants to facilitate risk calculation and reduce time constraints.

Education

This project made an effort to emphasize that continuous education and training is necessary for all healthcare providers to be able to incorporate the latest evidence into their clinical practice. Through the course of the project, providers were trained on the 2018 ACC/AHA Cholesterol Management Guidelines and the use of the calculator. They were also provided with suggestions on how to conduct risk discussions with checklists that served as reminders of what information should be discussed with patients. Overcoming the “knowledge explosion” proves to be a big challenge for many providers, as enormous amounts of clinical information is made available daily, it is impossible to access it all and efficiently translate it to quality care (Institute of Medicine, 2012). Educational systems need to be at the forefront of overcoming these barriers by encouraging providers to attend periodic workshops to stay current on clinical guidelines. The Institute of Medicine (2012) also recommends that professional societies, such as the American Nurses Association, develop educational programs to facilitate lifelong learning.

Patient education also plays a big part in achieving good outcomes. In addition to educational handouts, the ASCVD risk calculator was used to educate patients about their risk and care plan. The calculator features graphic displays of risk results and interactive decision-making aids that can be used for the patient to visualize how each intervention (e.g., statin use) can decrease their risk. Evidence-based recommendations are also incorporated into the calculator to guide the plan of care. Although this project did not investigate what aspects of the calculator was most useful for the patients or providers, its use in general was positively received. In a systematic review, Stacey et al. (2017) found similar success in using decision aids to increase patient knowledge. The results of this project support the literature findings as patients had high satisfaction and confidence levels in their risk discussion with their provider

and use of the ASCVD risk calculator. Decision aids are useful tools for patient education that can be easily accessed and used at the point of care.

Health Policy

The results of this project call for all primary care providers to strive to improve the 1% rate of risk calculations by incorporating a risk assessment tool to prevent CVD and engaging in shared decision-making with their patients. This type of quality improvement is easier said than done, especially for small independent primary care practices. A study by Balasubramanian et al. (2018) found that only 40% of small-medium sized practices use quality improvement methods to change practice, and 57% track quality of CVD prevention methods for purposes of goal setting or comparison with local or national benchmarks. Smaller practices struggle to meet national goals of CVD prevention. According to Shelley et al. (2018), less than half of small urban practices meet the Million Hearts goal for cholesterol management.

External support in the form of a primary care coalition may be able to provide small practices the tools to implement quality improvement projects. An example of such initiative is explained by Chou et al. (2018) through Healthy Hearts for Oklahoma (H2O). The H2O program seeks to build a “quality improvement infrastructure” comprised of small primary care practices of Oklahoma that would collaborate to disseminate and implement evidence-based practices through “bundled” quality improvement projects (Chou et al., 2018). Like the H2O program, small practices in NJ could benefit greatly by collaborating to develop their own quality improvement center staffed with informatics experts, clinical coordinators, practice facilitators, all working to increase evidence translation and preventing CVD (Chou et al., 2018).

Quality and safety

Various state and national initiatives have placed CVD prevention at the top of their list. The Million Hearts Initiative and Healthy People 2020 have set goals to reduce the incidence of CVD events and deaths (Office of Disease Prevention and Health Promotion, 2019; U.S. Department of Health and Human Services, 2017). However, it should be emphasized that preventing CVD goes beyond meeting national benchmarks. The most important goal of cardiovascular disease prevention is saving millions of lives each year (WHO, 2019). This project fills the gap in support that is needed by a small primary care practice to translate clinical guidelines into practice, leading to patient-centered care.

Without and quality improvement initiatives, providers can miss opportunities to identify patients at risk for CVD which can potentially hinder the safety and quality of life of the patient. Therefore, it is necessary to increase implementation of projects to facilitate the use of clinical guidelines and to highlight the value of shared decision-making to improve delivery of patient-centered care. The patient-provider risk discussion places the patient at the forefront of their care and allows them to develop confidence that they are actively working towards CVD prevention with the help of their provider. As a result, patients are not simply following a prescription; they are part of the solution.

Shared decision-making is not a novel idea. The Institute of Medicine (2001) for instance, has emphasized its importance since the publication of their report: *Crossing the Quality Chasm: A New Health System for the 21st Century*. Since then, healthcare quality shifted its focus towards a patient-centered approach. Despite its slow uptake, primary care practices are now seeing the value of shared decision-making and exploring ways to incorporate it into practice. Turin et al. (2015) explains that statin non-adherence can be improved through effective patient-provider partnerships and patient-centered risk discussions. Shared decision-

making has also been used to increase antipsychotic medication adherence and improve the patient-provider therapeutic alliance (Pérez-Revuelta et al., 2018). The results of this project support the current body of literature to endorse the positive influence of shared decision-making. This project has brought to light that it is possible to enhance risk discussions in a way that is beneficial for both sides of the stakeholder coin: the patient and provider.

Economic

The project poses economic benefits to the healthcare system, the practice, and its patients. The most significant benefits are associated with reducing atherosclerotic disease risk, which is one of the most expensive conditions to treat (Benjamin et al., 2019). A study by Heller et al. (2017) estimated that when providers follow the 2018 ACC/AHA Cholesterol Management Guidelines, the cost of screening for CVD along with the cost of treatment, medications, and provider visits can amount to approximately \$28 billion. Additionally, lost wages and possible permanent disability also place negative lasting implications on low-income populations with a higher risk of experiencing socioeconomic disparities. However, when we look at instituting primary prevention strategies, our healthcare system can save more than \$36 billion every year (Heller et al., 2017).

The economic implications to clinical practices and other healthcare systems are evident by the ability to acquire and sustain implementation of the ASCVD risk calculator screening tool and teaching materials without any additional economic expenses. As indicated in the final budget, the practice did not incur any costs throughout implementation. The practice was equipped with computer capabilities and infrastructure to incorporate the ASCVD risk calculator and integrate its use into the EMR. The calculator and patient education handouts were accessed through a free public website. No additional salary compensation was owed to the staff or

providers, as all implementation and training was done during office hours. Handouts were printed and made available by the project directors. Future printing of patient education handouts will be done by the practice as needed, which is predicted to be minimal as electronic copies are also made available to patients through the EMR. Aside from printing costs, it is not anticipated that the practice would incur any other expenses as a result of continuing this practice. Providing the screening as billable service represents an economic benefit to this practice and other healthcare practices that offer ASCVD risk screening. In a time of excessive healthcare expenditure with small return on investment, interventions that increase quality of care while decreasing healthcare costs should be endorsed.

Organizational

On an organizational level, this project worked to supplement this practice by providing quality improvement steps, knowledge translation, and office workflow modifications. However, due to significant clerical barriers and lack of internal resources, it is unlikely that implementation of the Cholesterol Management Guidelines and use of the ASCVD Risk Calculator would have occurred without this project. This is not surprising due to the barriers small practices face with guideline implementation, such as the lack of knowledge regarding quality improvement measures, lack of time, and lack of support specialized for small primary care practices (Balasubramanian et al., 2018). This project sought to fill the gaps in knowledge and process development to overcome some of these barriers.

To ensure sustainable quality improvement in this practice, one provider and one staff member were invited to take on the role of quality improvement champions, responsible for training all incoming members of the organization. The 2018 ACC/AHA Cholesterol Management Guidelines and ASCVD Risk Calculator training and patient education materials

developed for this project were made available to these individuals for future use. Through this project the practice came to realize that even small steps taken toward quality improvement in a small primary care practice are valuable.

Sustainability

The results of the project were presented to the providers and staff of the project site, with the plan for sustainability and further improvement. Project sustainability focused on equipping the practice and its providers with the tools and the training needed to continue integrating ASCVD 10-year risk assessment into daily practice. To achieve this, staff and provider workflow have been modified to support the utilization of the tool into daily patient screening. The ASVD risk calculator has been integrated into the EMR to sustain and facilitate the utilization of the risk tool. Patient face sheets have been modified to support the utilization of the tool and alert providers to the patient's score at the point of care. Finally, each clinical room was equipped with learning material for any new providers to access, learn and put into practice.

As the project progressed, it was noted that the project site serves as a teaching hub for medical students and nurse practitioner students constantly engaged in scholarly quality improvement. The next steps for this project are to: 1) involve other students in the practice and educate them on the current state of the project, 2) expand patient outcomes to include cholesterol levels and medication adherence, and 3) perform periodic audits and compare to national benchmarks for CVD prevention. With permission of Rutgers faculty, announcements will also be made to current DNP students attending DNP Project Bootcamp sessions about the details of this project and ideas for its expansion (e.g., investigate patient outcomes). These students are typically in the planning stages of their DNP project looking for ideas for their

project. Thus, this is a good opportunity to not only further disseminate the results of the project, but also to give other interested students the opportunity to expand on this quality improvement initiative.

Future Scholarship and Research

Due to time constraints and the methodology, this project was somewhat limited in the patient outcomes it assessed. Most notably, this project did not measure long-term medication adherence. The primary physician at the practice was interested to see the changes in those patient outcomes. Ongoing evaluation of implementation of the 2018 ACC/AHA Cholesterol Management Guidelines is needed to determine possible long-term benefits to patient outcomes and small practice benefits including evaluation of pre and post cholesterol levels to determine benefits of statin initiation and modification. Continued evaluation can help determine the long-term benefits of patient-provider risk discussion on reducing patients' long-term risk for a cardiovascular event.

The project highlights the need for more research to investigate what aspects of the risk discussion (e.g., teaching style, language, visual aids, health literacy, motivational interviewing) are most effective in producing positive patient outcomes. Additionally, the project sample was small and results largely reflect the African American/Black female perspective of risk communications; therefore, the findings are not generalizable beyond the current setting. Furthermore, Black men are at highest risk for developing CVD (Centers for Disease Control, 2013). Thus, more efforts are needed to recruit more African American/Black men for future investigations and more importantly, increasing the number of African American/Black male patients seeking preventative care with a focus on CVD prevention. Implementing the 2018 ACC/AHA Cholesterol Management Guidelines in larger primary care practices with a diverse

patient population and more providers may shed light on additional barriers to shared decision-making.

Professional Reporting

The results of this project will be presented to Rutgers faculty and students during poster day in spring 2020 semester. A completed manuscript will also be made available in the Rutgers School of Nursing repository that can serve as reference for future DNP students. A manuscript is planned for publication to *The Journal for Nurse Practitioners*, to build awareness regarding barriers and facilitators identified by providers in the implementation of the risk tool. Lastly, an abstract of the project will be developed for submission to New Jersey League of Nursing annual conference. Ultimately, it is hoped that the project can be implemented by other DNP students in small primary care practices that lack the organizational support to implement quality improvement projects focusing on the application of ACC/AHA Cholesterol Management Guidelines.

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Table 1

Age Group of Patients Meeting Inclusion Criteria for Retrospective Chart Review

Age group	Frequency	Percent
40-50	98	47.3%
51-60	57	27.5%
61-70	48	23.2%
71-75	4	1.9%
Total	207	100%

Note. Mean patient age was 53 ($SD = 9.07$).

Table 2

Race and Gender of Patients Meeting Inclusion Criteria for Retrospective Chart Review (N = 207)

Demographic	Frequency	Percent
Gender		
Male	39	18.8%
Female	168	81.2%
Race		
White	9	4.3%
Black/African American	123	59.4%
Hispanic/Latino	3	1.4%
Asian/Pacific Islander	4	1.9%
Unable to Determine	68	32.9%

Table 3

Age Group of Patients Who Completed COMRADE Survey (N = 24)

Age group	Frequency	Percent
40-50	9	37.5%
51-60	9	37.5%
61-70	5	20.8%
71-75	1	4.2%
Total	24	100%

Note. Mean patient age was 55 ($SD = 9.48$).

Table 4

Demographics of Patients Who Completed COMRADE Surveys (N = 24)

Demographic	Frequency	Percent
Gender		
Male	1	4.2%
Female	23	95.8%
Ethnicity		
Hispanic/Latino	1	4.2%
Non-Hispanic/Latino	23	95.8%
Race		
White	2	8.3%
Black/African American	20	83.3%
Asian/Pacific Islander	1	4.2%
Other/Not Listed	1	4.2

Table 5

ASCVD Risk Score Calculation Rate and Utilization Among Eligible Patients Included in Retrospective Chart Review (N = 207)

Score Utilization	Frequency	Percent
Risk score calculated		
Yes	74	35.8%
No	132	63.8%
Not Applicable	1	0.48%
Score used to guide risk discussion		
Yes	24	11.6%
No	22	10.6%
Not Applicable	89	43%
Unable to Determine from EMR	72	34.8%

Table 6

Statin Utilization Based on ASCVD Risk Score Among Eligible Patients Included in Retrospective Chart Review (N = 207)

Statin Utilization	Frequency	Percent
Newly Prescribed Statin		
Yes	9	4.3%
No	107	51.7%
Not Applicable	90	43.5%
Unable to Determine from EMR	1	0.48%
Statin Modified		
Yes	3	1.45%
No	112	54.1%
Not Applicable	91	44%
Unable to Determine from EMR	1	0.48%

Table 7

*Swedish Improvement Measurement Questionnaire Total and
Subscale Scores*

Dimension	Mean	SD	Possible Scores
SIMQ Total Score	72.00	15.26	0-100
Improvement Effectiveness	9.57	1.40	0-12
Internal Improvement Processes	62.43	14.99	0-88
Resource Scarcity	14.43	3.31	0-20
Group Leadership	15.43	5.8	0-20
Decision Influence	8.29	5.88	0-20

Note. Subdimensions of internal improvement processes subscales with Cronbach's alpha reliability coefficients < .70 excluded.

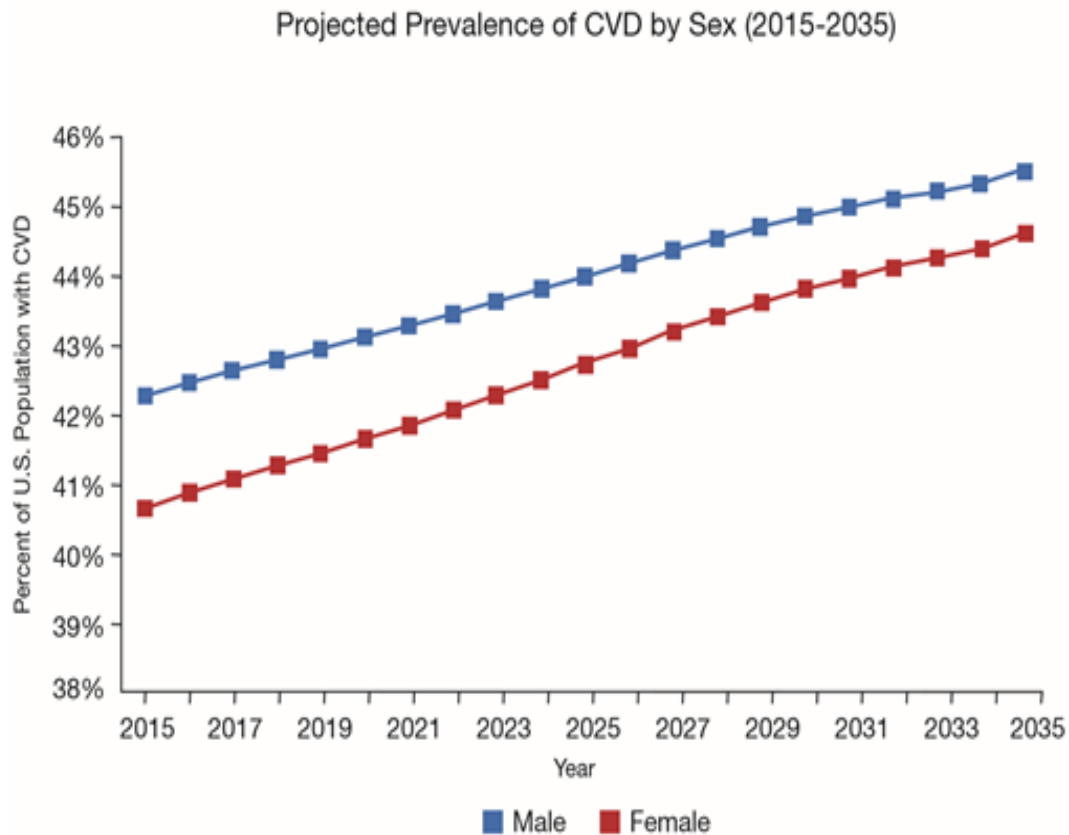
Table 8

Implementation Anecdotal Themes

Theme	Description
Facilitators	Provider familiarity with CVD risk assessments and guidelines prior to implementation. Provider observation of positive patient outcomes with the use of the risk calculator, guidelines, and patient education tools. Patients receptive to knowing their risk. Positive financial effects for organization: CVD risk assessment billable procedure/consult.
Barriers	Time constraints affecting the organization, staff, providers and patients. Need for reminders regarding tool usage, guidelines, EMR documentation. Hesitation to adopt new tool into practice. Patient concerns about potential negative effects of guideline utilization to their own health or usual care. ASCVD Risk Estimator Plus website malfunction, need to use alternate calculator website. Organizational factors: Staff shortage, clerical backlog, provider documentation behind schedule. Lack of knowledge about clinical guidelines, risk assessment tool and health literacy.

Appendix A

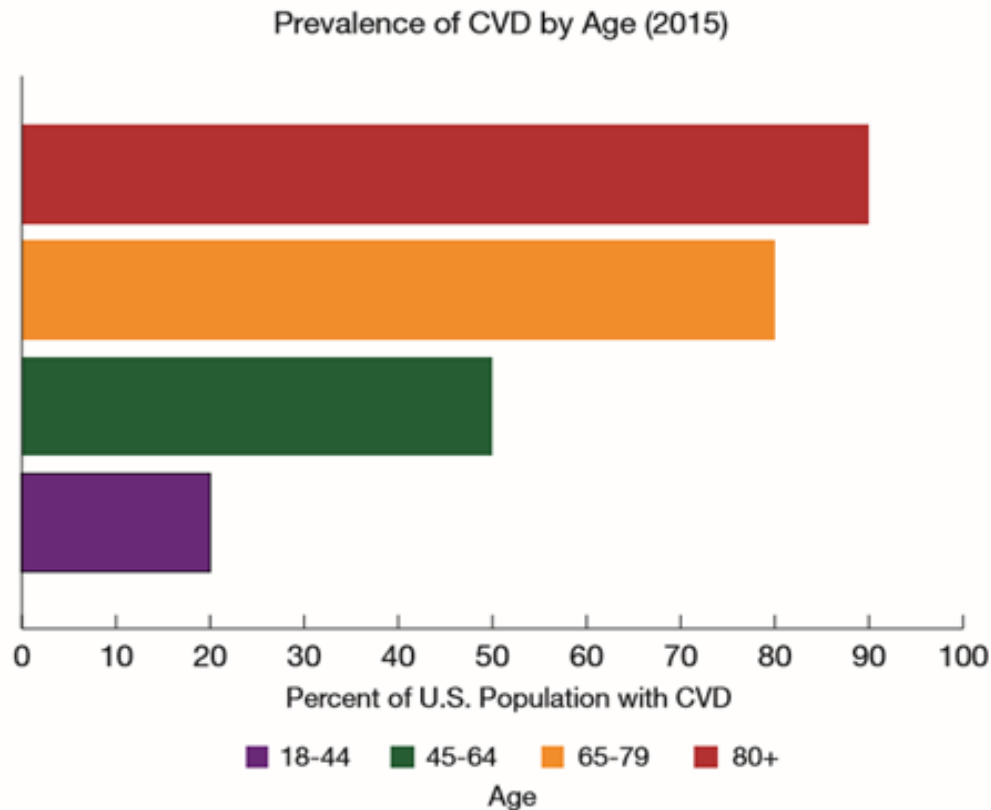
Prevalence of CVD in Males and Females in the United States



Note. Cardiovascular disease is projected to increase steadily for men and women in the U.S., with a higher prevalence in men. Adapted from *Cardiovascular Disease: A costly Burden for America. Projections Through 2035*, by The American Heart Association, 2017 (<https://www.heart.org/-/media/files/get-involved/advocacy/burden-report-consumer-report.pdf?la=en&hash=0A2A75E9FE82F7BEAE6A6A0FDB64E3FCE2BD8669>). Copyright 2017 by The American Heart Association Office of Federal Advocacy.

Appendix B

Prevalence of CVD in the United States in Different Age Groups



Note. In 2015, the highest prevalence of cardiovascular disease was among individuals over 65 years of age. Adapted from *Cardiovascular Disease: A costly Burden for America. Projections Through 2035*, by The American Heart Association, 2017 (<https://www.heart.org/-/media/files/get-involved/advocacy/burden-report-consumer-report.pdf?la=en&hash=0A2A75E9FE82F7BEAE6A6A0FDB64E3FCE2BD8669>). Copyright 2017 by The American Heart Association Office of Federal Advocacy.

Appendix C

Table of Evidence

Article #	Author & Date	Evidence Type	Sample, Sample Size, Setting	Study Findings that answer the EBP Question	Limitations	Evidence Level & Quality
1	(Agency for Healthcare Research and Quality, 2018)	Opinion of respected authority based on scientific evidence.	N/A	External support through QI improvement in small primary clinics has: - Identified higher statin and aspirin prescriptions. - Increase in tobacco cessation counseling 12% to 70%.	Non-research-based evidence and therefore considered lower quality evidence.	Level: V; Quality A: High
2	(Bakhai et al., 2018)	Quality Improvement	- (n=313 patient visits) - (n=40 internal medicine residents) - Academic Internal Medicine Clinic treating primary care patients in an urban setting.	- An increase in utilization of 10yr ASCVD tool from 1% to 12% in 12-months period. - Increase in patient-centered care based on ASCVD score. - Increase in ASCVD risk evaluation in primary prevention from 4% to 18% post-intervention. - A 33% ASCVD risk score compliance 12 months post-intervention. - Increase of 359 patients initiated on statin therapy	- Patient-based barriers to compliance not examined. - Lack of generalizability based on setting limitations. - Statin intensity changes not examined.	Level V; Quality B: Good
3	(Brundisini et al., 2015)	Systematic review of qualitative studies, with meta-analysis.	86 empirical qualitative studies included, published between 2002-2013.	- based on utilization of guidelines. - There are significant differences in the perceived barriers to medication adherence between patients and providers. - The patient's perspective should be considered when developing quality improvement interventions.	- Only English-language articles included. - Does not include qualitative data published before 2002. - Does not include large number of qualitative research specifically on the provider's perspective.	Level III; Quality A: High
4	(Cooper et al., 2011)	Randomized controlled trial	- (n=41) primary care physicians - (n=279) hypertension patients. - Approximately 60 to 100% of the patients African American, and 35% to 55% earned below 200% of the federally defined poverty guidelines. - Recruitment from 14 urban, community-based practices in Baltimore, Maryland.	- Physician communication skills training resulted in positive communication change scores from baseline (-0.52 vs. -0.82, p=0.04). - Training resulted in significantly greater improvements in patients report of physicians' PDM (β=+6.20 vs. -5.24, p=0.03) - Training resulted in positive information exchange (β=+0.32 vs. -0.32, p=0.03) - Systolic blood pressure reduction occurred (non-	- Low follow-up among physicians limited the number of patients recruited. - Reduced statistical power to detect differences in primary outcomes due to patient recruitment under target. - Data collection on processes of care challenged by varied practices. - Inability to ascertain patient adherence to appointments.	Level I; Quality B: Good

				significant) in patients with uncontrolled hypertension at baseline.	- Inability to gather data on prescription refill rates. - Competing clinical demands across intervention groups may have affected communication. - Inability to determine if patients belonging to subgroup received greater benefit from interventions.	
5	(Egerton et al., 2017)	Systematic review of qualitative studies, with meta-analysis.	- 8 studies met inclusion criteria, including peer reviewed and published studies. - Studies identified results from 83 health practitioners.	Themes associated with non-compliance with guidelines included: - Limited perceived risk and need for guidelines. - Lack of knowledge and preparation in instituting guidelines in practice. - Personal beliefs and attitudes. - Patients lack agreement with provider recommendations.	- Small sample size. - Limited supportive quotations. - No documentation of barriers encountered by allied health personnel.	Level III; Quality B: Good
6	(Fischer et al., 2016)	Systematic review of observational studies with meta-analysis	- 69 articles met inclusion criteria.	- Provider barriers in implementation include lack of agreement, lack of self-efficacy, and lack of skills. Lack of plausibility.	- Limited search sources/need for a broader search. - No disease specific outcomes	Level III; Quality B: Good

				- Organizational barriers include difficulty in creating a culture of educational support. - External provider barriers are organizational restraints, workload, financial, and no external facilitation.		
7	(Harmsen et al., 2014)	Cluster RCT	- (n=34) primary care practitioners - 23 practices located in Southern Denmark. - (n=240) patients responded to questionnaires. - Patients were aged 40 to 69 years with a total-cholesterol level above 4 mmol/l (155 mg/dl), corresponding to the lower limit in Danish cardiovascular prevention guidelines.	- Prolongation of Life format for risk communication resulted in 5.4% of patients filling a statin prescription. - Absolute Risk Reduction format resulted in 25.0% of patients filling a statin prescription.	- Selection bias from the providers, as they were responsible for patient recruitment. - Consultations were not recorded, no data collected on the performance of consultations. - Attrition bias from the providers due to a high dropout rate. - Selection bias from the providers- those providers choosing to participate may have had existing interest/knowledge of risk communication. - Not much information provided about specific primary care practices.	Level I; Quality B: Good

8	(Institute of Medicine, 2011)	Opinion of respected authorities and/or nationally recognized expert committees/consensus panels based on scientific evidence.	N/A	- Recognizes the need for CPG adoption and evaluation. - Standard 8 identified the need for ongoing evaluation of the effectiveness of CPG and updating them based on changes in evidence. - Standard 3 promotes organizational support to clinicians through collaboration between guideline developers and providers.	- Lack of transparency of guidelines. - Harmonization among interdisciplinary providers and between developer and implementer. -Lack of multi-stakeholder agreement.	Level IV; Quality A: High
9	(Institute of Medicine, 2001)	Opinion of respected authorities and/or nationally recognized expert committees/consensus panels based on scientific evidence.	- Review of data and recommendations compiled by the Committee on Quality of Healthcare in America. - This review of literature is an update to the original review developed by the RAND corporation in 1998. - Systematic review of articles from 1987 to 1997. - Approximately 200 articles met the inclusion criteria.	- The quality of care varies between practice setting and geographic location. - Quality of care rarely meets professional standards. - Six aims for improvement. Health care should be: Safe, effective, patient-centered, timely, efficient, and equitable.	- Only included sources found in leading peer-reviewed journals. - No focus on specific clinical areas. - Not a big focus on reports of patient experience or satisfaction. - Did not include the impact of quality improvement activities. - Did not conduct a quality appraisal of the studies included.	Level IV; Quality A: High

10	(Jame et al., 2015)	Cross-sectional observational	- (n=183) primary care clinicians. - Primary care settings North Carolina, San Francisco Bay Area	- 35% compliance in guidelines and ASCVD use in younger providers in comparison to only 23% in older providers. - 47% of providers had yet to decide if they would implement the guidelines in practice. Only 25% of providers identify utilizing the guidelines in many of their patients. - 41% of providers identified a lack of knowledge of ACC/AHA guidelines. - 23% reported they did not use the calculator because it was difficult. - 47% did not agree with the guidelines.	- Self-reported. - Targeted to Northern California limited generalizability. - Non-respondent demographics was not identified.	Level III; Quality B: Good
11	(Lambert-Kerzner et al., 2015)	Qualitative study within an RCT	- The original RCT was the "Multi-Faceted Intervention to Improve Cardiac Medication Adherence and Secondary Prevention Measures – The Medication Study."	- Two-third of the patients identified bidirectional communication as important. - Medication adherence was improved by patient-provider collaboration, which included discussions about their treatment plan	- Since the participants were recruited from an RCT, this study could be subject to attribution bias. - Most of the participants are male. - Since patients recruited from a previously conducted	Level III; Quality B: Good

			- Original RCT (n=253) patients. - This qualitative study collected data on (n=64) of those participants. - Most participants white males with a mean age of 66.5 years. - Four Veterans Health Administration medical centers (Denver, Little Rock, Durham, and Seattle)	- with themselves and their families.	- study, no direct observations of the intervention were made.	
12	(Lansberg et al., 2018)	Literature review, quality improvement strategies.	N/A	- Approximately half of patients the prescribed statin medications are non-adherent. - Medication non-adherence stems from systemic, provider-related and patient-related factors. - Patient-related factors are multifaceted.	This literature review was non-research based and therefore considered lower quality evidence.	Level V; Quality B: Good
13	(Lowenstern et al., 2018)	Cross-sectional observational	- (n=774 clinicians) - 51 primary care practices - 82 cardiology clinics - 8 endocrinology clinics	- Physicians and advanced practice clinicians complied with guidelines at a lower level than cardiologists. - Providers who adopted guidelines were more	- ASCVD risk calculation was based on patients currently on statins. No preliminary data was available. - No provider rationale for clinical decisions.	Level III; Quality A: High

				likely to employ the 10-year ASCVD risk tool.	- Lack of concordance with hypothetical and observed statin prescribing.	
14	(Melnik, 2015)	Literature review, non-research	N/A	Utilization of guidelines: - Promotes good patient outcomes - Reduce variations in care. Development of guidelines does not equate to utilization.	N/A	Level V; Quality B: Good
15	(Ng et al., 2016)	Retrospective observational study	- (n=193) patients in an urban clinic. - Adults > 21 and older on statin therapy during last 12 months.	- 68% of patients were adequately initiated on statin therapy based on guideline criteria. - Patients with secondary risk were prescribed statins in non-concordant with guidelines. - 46.9% of patient with ASCVD risk showed non-adherence. - Only 31.6% of patients received follow up assessment of lipids. - Only 29% achieved treatment goals with only statin initiation.	- Small sample size. - Only one-year monitoring.	Level III; Quality B: Good

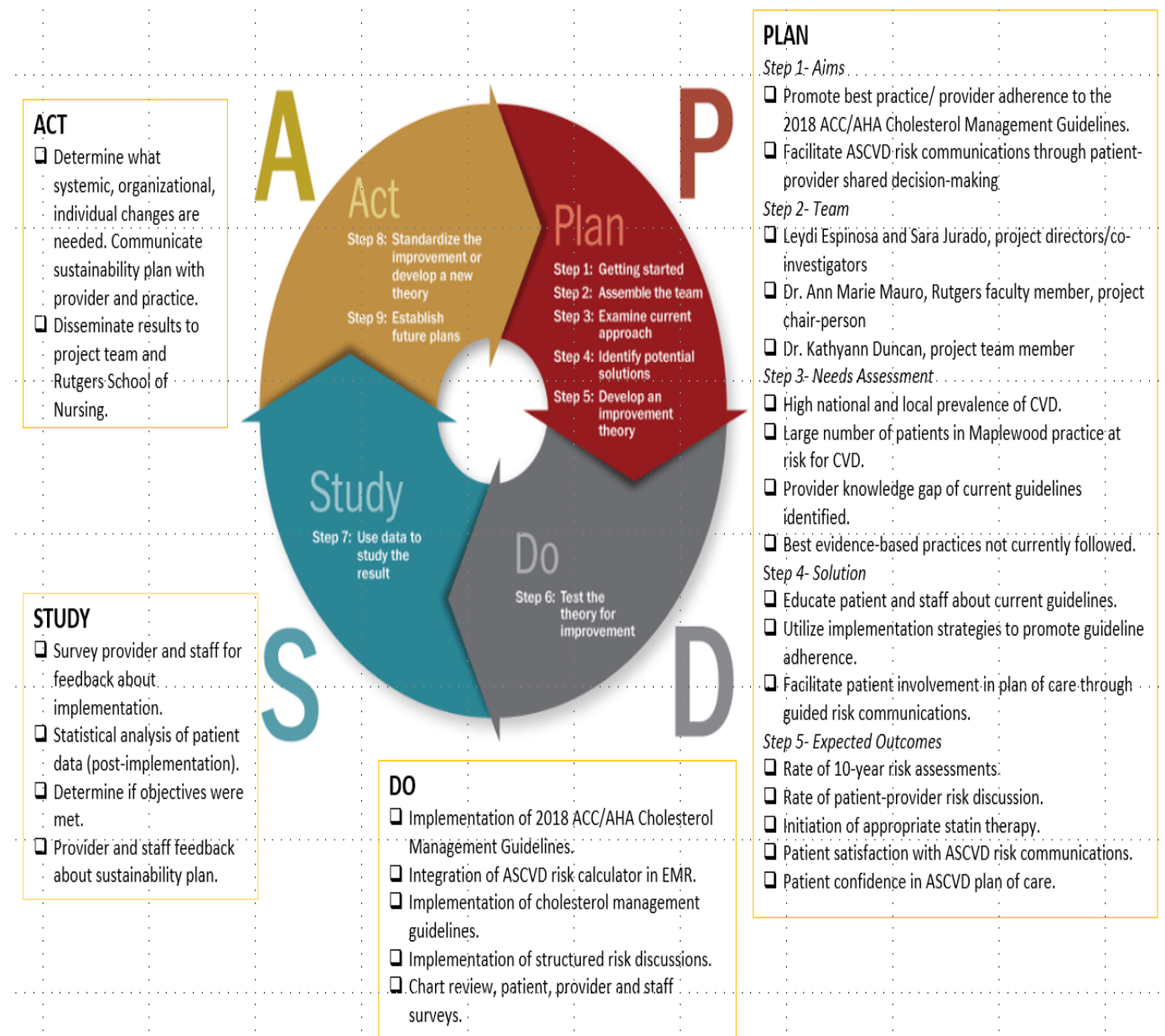
16	(Parchman et al., 2010)	Observational prospective study	- 166 participants responded to original questionnaires, and 141 returned follow-up questionnaires. - The mean age of the participants was 57.7 years (SD = 10.7); 61% were female, and 51% Hispanic. - Participants recruited from 5 independent primary care practices in the South Texas Ambulatory Research Network.	- Patient participation/activation and medication adherence improved between the baseline and follow-up surveys: - Significant average decrease of 0.03% in hemoglobin A1c. - Significant decrease in systolic blood pressure of 0.3-mm Hg. - LDL average rate of decrease at 2.89 mg/dL	- Small sample of primary care practices. - No randomization - Recruitment/ sample bias towards participants who are healthier and more actively involved in their care, or higher level of activation.	Level III; Quality B: Good
17	(Shelley et al., 2018)	Cluster RCT	- (n=134) primary care clinics - Conducted in New York City.	- Only 49% of secondary risk patients were meeting Million Hearts targets. - 41% of clinics were meeting cholesterol management goals in comparison to larger clinics. - A gap in the management of composite measures for ASCVD event.	- Small sample size non-exclusive of 123 practices. - Lack of randomization	Level I; Quality A: High
18	(Sheridan et al., 2014)	Secondary analysis of RCT	- (n=160) patients from one university internal medicine clinic in North Carolina.	Implementation of decision aid: - increased knowledge of CVD risk by 33% (p<0.0001)	- Determination of sample size was limited by ability of authors to calculate CVD risk differences in participants.	Level I; Quality A: High

			- 40-79 years old, male and female - No prior CVD	- increased knowledge of CVD reduction strategies by 21% (p<0.0001) - decreased decisional conflict (-0.63; p<0.0001) - increased rate of patient-discussion by 31% (p<0.0001) increased patient intention to engage in risk-reduction behaviors by 21% (95% CI)	- Not enough heterogeneity in sample population (mostly white, high education level, high self-efficacy). - Lack of control for between group education-levels. - Inability to measure the specific coaching methods that yield success. - Small subgroups did not allow for independent study of specific decision aid components.	
19	(Stacey et al., 2017)	Systematic review of RCTs with meta-analysis	- 105 RCT studies met inclusion criteria for meta-analysis. - RCTs, involving 31,043 participants. - Studies from 10 countries: Australia, Canada, China, Finland, Germany, Netherlands, Spain, Sweden, UK, USA, Australia, Canada.	Decision aids improve: - Knowledge of options - Understanding of important values in decision-making - Expectations of benefits and harms of treatment - Participatory decision-making	Inadequate power to detect between-subgroup differences in: - Effectiveness - Variability in the decision contexts - The elements within the patient decision aids	Level I; Quality A: High

					- The type of comparison delivered - The targeted outcomes - The evaluation procedures	
20	(Van Der Laan et al., 2017)	Systematic review of observational studies	- 44 studies met the final inclusion criteria. - The search included articles from January 1990 to July 2016.	- Antihypertensive medication non-adherence associated with: - Higher co-payments - Experience of side-effects - Poor patient-provider relationship	- High heterogeneity of studies did not allow for meta-analysis. - Significance of other factors (covariates) affecting medication adherence not reported in all studies. - Only studies with strong methodology included. - Only studies conducted in the U.S. included.	Level III; Quality B: Good

Appendix D

Plan-Do-Study-Act (PDSA) Implementation Model

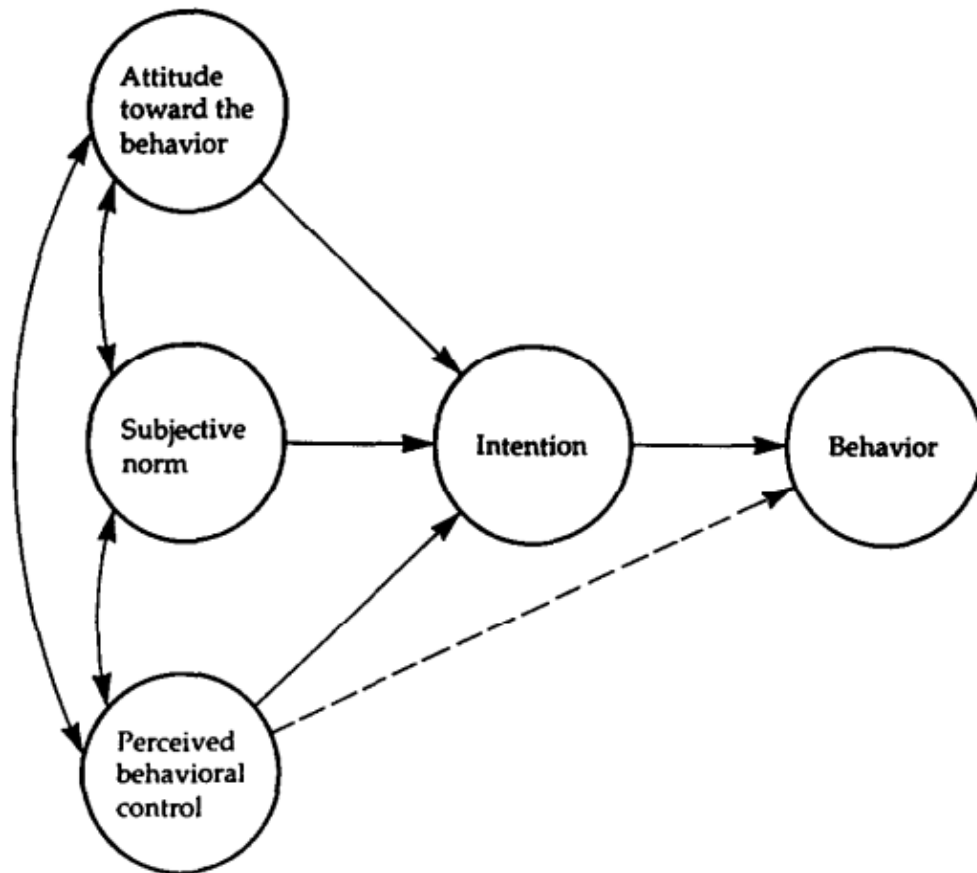


From *Plan-Do-Study-Act*, by Tribal Evaluation Institute, 2016

(<http://www.tribaleval.org/cqi/plan-do-study-act-pdsa/#step7>). In the public domain.

Appendix E

Theoretical Model: The Theory of Planned Behavior

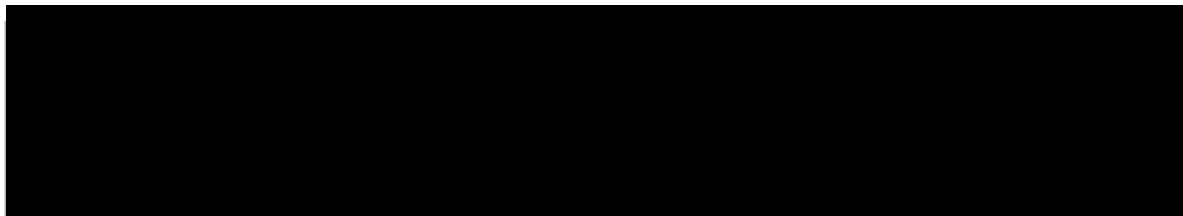
**FIG. 1. Theory of planned behavior.**

From “The Theory of Planned Behavior,” by I. Ajzen, 1991, *Organizational Behavior and Human Decision Processes*, 50(2), p. 182 ([https://doi.org/10.1016/0749-5978\(91\)90020-T](https://doi.org/10.1016/0749-5978(91)90020-T)).

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Appendix F

Site Agreement



Date: [08/01/2019]

Re: Letter of Cooperation For [REDACTED]

Dear Dr. Ann Marie Mauro,

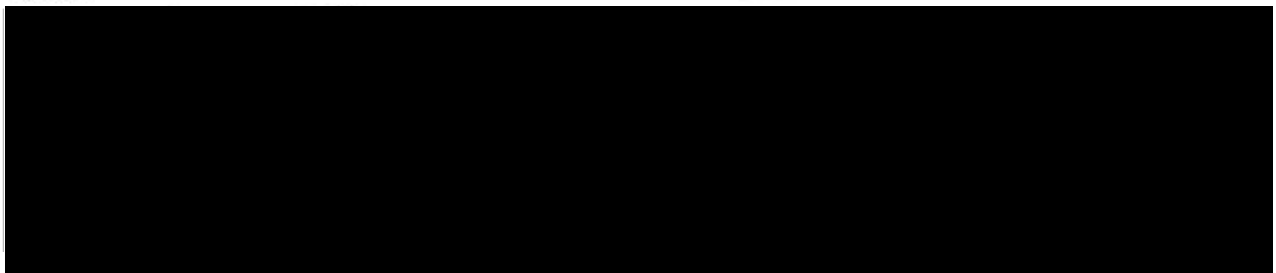
This letter confirms that I, as an authorized representative of [REDACTED] allow you, the Principal Investigator and Co-investigators/Project Directors *Sara Jurado and Leydi Espinosa* access to conduct study-related activities at the listed site, as discussed with you and the project team and briefly outlined below, and which may commence when you provide evidence of IRB approval for the proposed study.

- **Project Site(s):** [REDACTED]
- **Project Purpose:** *This research study aims to increase provider adherence of the 2018 ACC/AHA Cholesterol Management Guidelines and improve patient-provider risk communications for the primary prevention of cardiovascular disease.*
- **Project Activities:**
 - ◊ *Provide mandatory professional development training to providers and office staff related to 2018 ACC/AHA Cholesterol Management Guidelines and implementation.*
 - ◊ *Access to EMR database for patient data collection of laboratory values, medical history and medications prescribed.*
 - ◊ *Surveys will be distributed to patients to determine perception of risk and participation in shared decision-making.*
 - ◊ *Surveys will be distributed to site employees and providers to determine implementation barriers.*
- **Participant Enrollment:** *Participant inclusion criteria includes providers, medical assistants responsible for patient intake and clerical personnel responsible for patient registration, male and female patients ages 40-75 without history of atherosclerotic cardiovascular disease (primary prevention). Study enrollment will occur over approximately a 2-month period. Total target sample size is 111.*
- **Site Support:** [REDACTED] *agrees to provide space to conduct research study activities, authorize site employees to identify persons who might qualify for surveys, and retrieve patient data from EMR and patient files.*
- **Data Management:** *The patient and employee data collected will be de-identified to protect the identity and privacy of the project participants. Data accessed via EMR is password protected as per the organization's policy. The de-identified data collected will be accessed only by the Co-investigators/Project Directors and protected with password locked devices.*
 - ◊ *Patient data collected includes age, race, ethnicity, gender identity, previous medical history, current ASCVD risk score, cholesterol levels, and treatment plan. Patient's perspectives will also be collected via survey.*
 - ◊ *Employee data collected includes role in the organization and perspectives of implementation collected via survey.*
- **Anticipated End Date :** 12/31/2020.

We understand that this site's participation will only take place during the study's active IRB approval period. All study-related activities must cease if IRB approval expires or is suspended. I understand that any activities involving Personal Private Information or Protected Health Information may require compliance with HIPAA Laws and Rutgers Policy.

Our organization agrees to the terms and conditions stated above. If we have any concerns related to this study, we will contact the Principal Investigator. For concerns regarding IRB policy or human subject welfare, we may also contact the Rutgers IRB (see orra.rutgers.edu/hssp).

Regards,



Appendix G

Staff Training Announcement

Announcement

Sara Jurado and Leydi Espinosa, graduate Rutgers nursing students will be providing a mandatory professional development training session regarding the use of a 10-year Atherosclerotic Risk Assessment Calculator and the use of 2018 American College of Cardiology and American Heart Association Cholesterol Management Guidelines.

Who: This is required for physicians, medical/nurse practitioner students completing clinicals in the Fall 2019, and patient care staff.

What: A professional development training session on the 2018 ACC/AHA Cholesterol Management Guidelines and the use of the ACC Risk Estimator Plus.

When: Training will begin at 12 p.m. Tuesday (Date). Provider training will take approximately 60 minutes and staff training approximately 15 minutes.

Where: In the office. Lunch will be served after the sessions.

Questions?: Please contact principal investigator Dr. Ann Marie Mauro at [REDACTED] or co-investigators/project directors Sara Jurado at [REDACTED] and Leydi Espinosa at [REDACTED]

Appendix H

Provider/Staff Consent Form

CONSENT TO TAKE PART IN ANONYMOUS RESEARCH STUDY

TITLE OF PROJECT: Implementation of the 2018 ACC/AHA Cholesterol Management Guidelines: Exploring the Patient and Provider Experience

Principal Investigator: Ann Marie P. Mauro, PhD, RN, CNL, CNE, FAAN

Co-Investigators/Project Directors: Sara E. Jurado BSN, RN and Leydi M. Espinosa BSN, RN

This consent form is part of an informed consent process for a research study. It will provide information that will help you decide whether you want to take part in this study. It is your choice to take part or not. Your alternative is not to take part in this study. You will be given a copy of this form to keep for your records.

Who is conducting the study and what is it about?

You are being asked to take part in a research study being conducted by Principal Investigator Dr. Ann Marie Mauro, Rutgers School of Nursing Associate Dean and Professor, and her Co-Investigators/Project Directors Sara Jurado and Leydi Espinosa, doctor of nursing practice students in the Rutgers School of Nursing. The purpose of this study is to enhance provider knowledge of 2018 ACC/AHA Cholesterol Management Guidelines, increase the use of the ACC ASCVD Risk Estimator Plus, improve statin therapy prescribing, and explore provider experiences with implementation.

The Principal Investigator Dr. Ann Marie Mauro, Rutgers School of Nursing Associate Dean and Professor, may be reached at [REDACTED] or [REDACTED] and Co-Investigators/Project Directors Sara Jurado at [REDACTED] and Leydi Espinosa at [REDACTED]

What will I be asked to do if I take part in the study?

You will be asked to complete the Swedish Improvement Measurement Questionnaire (SIMQ), which is used to assess your perspective of the implementation of the 2018 ACC/AHA Cholesterol Management Guidelines and ACC ASCVD Risk Estimator Plus, once at the end of the guidelines implementation period. The SIMQ will take about 15-20 minutes to complete. We anticipate approximately 111 participants will take part in the study, including 5 providers, 6 staff, and 100 patients.

Who may take part in this study and who may not?

Medical assistants (18-89 years old) responsible for patient intake, clerical personnel (18-89 years old) responsible for patient registration, and physicians and medical/nurse practitioner students (18-89 years old) responsible for direct patient care may take part in this study. Staff or medical assistants not responsible for patient intake or registration and providers not responsible for patient care and those who will not be at the practice during the guidelines implementation period, may not participate in this study.

What are the risks of harm or discomforts I might experience if I take part in the study?

It is not expected for the participants to experience any discomfort during the project, which poses minimal risk. Your name or personal health information will NOT be collected in the survey. The answers to the survey will remain anonymous. A data security plan is in place to protect your anonymity. If any questions may make you feel uncomfortable, you can skip those questions or withdraw from the project altogether. If you decide to withdraw at any time before you have finished the survey, your answers will not be recorded.

Are there any benefits to me if I choose to take part in this study?

There are no direct benefits to you for taking part in this project. You will be contributing to knowledge about enhancing cholesterol management guidelines and the use of the 10-year ASCVD risk assessment tool.

Will I be paid to take part in this study?

Each participant will be given a \$10 gift card after completion of the SIMQ.

How will information about me be kept private or confidential?

The survey is anonymous. No information will be collected that can identify who you are. Completed surveys will be stored in a locked cabinet controlled by the co-investigators/project directors. Responses may be converted to digital format and stored on a password-protected computer that can only be accessed by the study team. Paper copies will then be destroyed. The data will be retained for a minimum of three years per regulatory guidelines.

No information that can identify you will appear in any professional presentation or publication.

What will happen to information I provide in the project after the study is over?

The information collected about you for this project will not be used by or distributed to investigators for other research.

The study team and the Institutional Review Board at Rutgers University are the only parties that may see the data, except as may be required by law. If the findings of this research are professionally presented or published, only group results will be stated.

What will happen if I do not wish to take part in the study or I later decide not to stay in the project?

It is your choice whether you take part in the study. You may choose to take part, not to take part, or you may change your mind and withdraw from the study at any time. In addition, you can choose to skip questions that you are not comfortable answering. If you do not want to enter the study or decide to stop taking part, your relationship with the project staff will not change, and you may do so without penalty and without loss of benefits to which you are otherwise entitled. Please note, however, that once you have submitted your responses, you may no longer withdraw them as we will not know which ones are yours.

Who can I call if I have questions?

If you have questions about taking part in this study, you can contact Principal Investigator Dr. Ann Marie Mauro at [REDACTED] or [REDACTED]. You can also contact the Co-Investigators/Project Directors Sara Jurado at [REDACTED] and Leydi Espinosa at [REDACTED].

If you have questions about your rights as a project participant, you can call the IRB Director at Newark Health Science (973)-972-3608.

We will provide you a copy of this consent form for your records.

By beginning this survey, I acknowledge that I am 18 years of age or older and have read and understand the information. I agree to take part in the project, with the knowledge that I am free to withdraw my participation in the survey without penalty.

Appendix J

Recruitment Scripts

Patient Recruitment Script

Co-Investigators/Project Directors: "Would you be interested in participating in a brief survey about your visit today in exchange for a \$10 gift card?"

Provider/Staff Recruitment Script

Co-Investigators/Project Directors: "We would like your feedback about your experience implementing the 2018 ACC/AHA Cholesterol Management Guidelines. Would you be interested in participating in a brief survey about your experience at the end of the guidelines implementation period in exchange for a \$10 gift card?"

Appendix K

Patient Consent Form

CONSENT TO TAKE PART IN A RESEARCH STUDY

TITLE OF STUDY: Implementation of the 2018 ACC/AHA Cholesterol Management Guidelines: Exploring the Patient and Provider Experience

Principal Investigator: Ann Marie P. Mauro, PhD, RN, CNL, CNE, FAAN

Co-Investigators/Project Directors: Sara E. Jurado BSN, RN and Leydi M. Espinosa BSN, RN

STUDY SUMMARY: This consent form is part of an informed consent process for a research study and it will provide information that will help you decide whether you want to take part in this study. It is your choice to take part or not.

The **purpose of the research** is to promote provider implementation of the 2018 ACC/AHA Cholesterol Management Guidelines and their use in the patient-provider cardiovascular risk discussion. If you take part in the research, you will be asked to fill out a demographic questionnaire and complete the COMRADE paper survey. It will take approximately 10-15 minutes for you to complete the demographic questionnaire and survey.

Possible harms or burdens of taking part in the study are minimal and a data security plan is in place to protect your confidentiality. Possible benefits of taking part are minimal and include contribution to knowledge about heart disease risk communications.

An alternative to taking part in the research study: Your alternative to taking part in the research study is not to take part in it.

The information in this consent form will provide more details about the research study and what will be asked of you if you choose to take part in it. If you have any questions now or during the study, if you choose to take part, you should feel free to ask them and should expect to be given answers you completely understand. After your questions have been answered and you wish to take part in the research study, you will be asked to sign this consent form. You are not giving up any of your legal rights by agreeing to take part in this research or by signing this consent form.

Who is conducting this study?

Dr. Ann Marie Mauro, Rutgers School of Nursing Associate Dean and Professor is the Principal Investigator of this research study. The Principal Investigator Dr. Ann Marie Mauro, Rutgers School of Nursing Associate Dean and Professor, may be reached at [REDACTED] or [REDACTED]

A Principal Investigator has the overall responsibility for the conduct of the research. However, there are often other individuals who are part of the research team. Co-Investigators/Project Directors Sara Jurado at [REDACTED] and Leydi Espinosa at [REDACTED]

The Principal investigator or another member of the study team will also be asked to sign this informed consent. You will be given a copy of the signed consent form to keep.

Why is this study being done?

This study is being done to promote the implementation of clinical guidelines in a primary care practice. With the use of the COMRADE survey, we will explore the patient-provider discussions and how well the patient's risk for developing heart disease is communicated.

Who may take part in this study and who may not?

Adult male and female individuals that are 40-75 years old with LDL cholesterol levels of 70 or greater may participate in this study. Those who are not English-speaking, have a prior history of cardiovascular disease and/or have LDL cholesterol levels of 190 or greater, may not participate in this study.

Why have I been asked to take part in this study?

You are being asked to partake in this study to assist the study team in evaluating the implementation of clinical guidelines in your primary care practice and the quality of the discussion you had with your provider.

How long will the study take and how many subjects will take part?

The COMRADE survey and demographic information sheet will take about 10-15 minutes to complete. We anticipate the study to last approximately 2-months and 111 participants to take part in the study overall, including 5 providers, 6 staff, and 100 patients.

What will I be asked to do if I take part in this study?

If you agree to participate, you will be asked to complete the 20-item COMRADE survey and a brief demographic information sheet asking for your age, gender identity, ethnicity and race. The COMRADE survey questions will ask about your satisfaction with the discussion about heart disease risk you had with your provider and satisfaction with your treatment plan. The questions do not ask specific information about your diagnosis, plan of care or other health information. There are no direct links between the survey, your name, or your electronic medical record.

What are the risks of harm or discomforts I might experience if I take part in this study?

It is not expected for the participants to experience any discomfort during the study, which poses minimal risk. Your name or personal health information will NOT be collected in the survey. The answers to the survey will remain anonymous.

A data security plan is in place to protect your confidentiality. If any questions may make you feel uncomfortable, you can skip those questions or withdraw from the study altogether. If you decide to quit at any time before you have finished the survey, your answers will not be recorded.

Are There Any Benefits To Me If I Choose To Take Part In This Study?

There are no direct benefits to you for taking part in this study. You will be contributing to knowledge about the manner in which providers should communicate risk of heart disease with their patients. Ultimately, the knowledge gained from this study will allow development of practices that are centered around providing the best care for patients to reduce heart disease.

What Are My Alternatives If I Do Not Want To Take Part In This Study?

Your alternative is not to take part in this study.

How Will I Know If New Information Is Learned That May Affect Whether I Am Willing To Stay In The Study?

During the study, you will be updated about any new information that may affect whether you are willing to continue taking part in the study. If new information is learned that may affect you after the study or your follow-up is completed, you will be contacted.

Will There Be Any Cost To Me To Take Part In This Study?

Participation in this study will not cost you anything.

Will I Be Paid To Take Part In This Study?

At the completion of the COMRADE survey and demographic information sheet, you will receive a \$10 gift card.

How Will Information About Me Be Kept Private Or Confidential?

The survey is anonymous. No information will be collected that can identify who you are. Completed surveys will be stored in a locked cabinet controlled by the Co-Investigators/Project Directors. Responses may be converted to digital format and stored on a password-protected computer that can only be accessed by the Co-Investigators/Project Directors. Completed surveys will be retained for a minimum of three years, then destroyed per regulatory guidelines.

No information that can identify you will appear in any professional presentation or publication. After the study is over the information collected for this study will not be used or distributed to investigators for other research.

The study team and the Institutional Review Board at Rutgers University are the only parties that may see the data, except as may be required by law. If the findings of this research are professionally presented or published, only group results will be stated.

What Will Happen If I Do Not Wish To Take Part In The Study Or If I Later Decide Not To Stay In The Study?

It is your choice whether to take part in the research. You may choose to take part, not to take part, or you may change your mind and withdraw from the study at any time.

If you do not want to enter the study or decide to stop taking part, your relationship with the study staff will not change, and you may do so without penalty and without loss of benefits to which you are otherwise entitled. Please note, however, that once you have submitted your responses, you may no longer withdraw them as we will not know which ones are yours.

Who Can I Contact If I Have Questions?

If you have questions about taking part in this, you can contact the Principal Investigator Dr. Ann Marie Mauro, Rutgers School of Nursing Associate Dean and Professor, at [REDACTED] or

[REDACTED] You may also contact the Co-Investigators/Project Directors Sara Jurado, Rutgers School of Nursing, at [REDACTED] or Leydi Espinosa, Rutgers School of Nursing, at [REDACTED]

If you have questions about your rights as a research subject, you can contact the Rutgers IRB Director at Newark Health Science (973)-972-3608.

PERMISSION (AUTHORIZATION) TO USE OR SHARE HEALTH INFORMATION THAT IDENTIFIES YOU FOR A RESEARCH STUDY

The next few paragraphs tell you about how investigators want to use and share identifiable health information from your medical record in this research. Your information will only be used as described here or as allowed or required by law. If you sign this consent form, you agree to let the investigators use your identifiable health information in the research and share it with others as described below. Ask questions if there is something you do not understand.

What Is The Purpose Of The Research And How Will My Information Be Used?

You are being invited to take part in this research study which is described at the beginning of this form. The purpose of collecting and using your health information for this study is to help investigators answer the questions that are being asked in the research.

What Information About Me Will Be Used?

- Medical history or treatment
- Medications
- Consultations
- Laboratory/diagnostic tests or imaging

Who May Use, Share or Receive My Information?

The research team may use or share your information collected or created for this study with the following people and institutions:

- Rutgers University Investigators Involved in the Study
- The Rutgers University Institutional Review Board and Compliance Boards
- The Office for Human Research Protections in the U.S. Dept. of Health and Human Services

Those persons or organizations that receive your information may not be required by Federal privacy laws to protect it and may share your information with others without your permission, if permitted by the laws governing them.

Will I Be Able To Review My Research Record While The Research Is Ongoing?

No. We are not able to share information in the research records with you until the study is over. To ask for this information, please contact the Principal Investigator, the person in charge of this research study.

Do I Have To Give My Permission?

No. You do not have to permit use of your information. But, if you do not give permission, you cannot take part in this study. (Saying no does not stop you from getting medical care or other benefits you are eligible for outside of this study.)

If I Say Yes Now, Can I Change My Mind And Take Away My Permission Later?

Yes. You may change your mind and not allow the continued use of your information (and to stop taking part in the study) any time before you submit the COMRADE survey. If you take away permission, your

information will no longer be used or shared in the study. Please note that once you submit your responses to the survey, there is no way to withdraw from the study as we will not know which survey is yours. If you say yes now but change your mind before submitting the completed survey, you may verbally inform the co-principal investigators/project directors who are obtaining your consent of your decision.

How Long Will My Permission Last?

Your permission for the use and sharing of your health information will last until end of the research study.

AGREEMENT TO PARTICIPATE**Subject Consent:**

I have read this entire consent form, or it has been read to me, and I believe that I understand what has been discussed. All of my questions about this form and this project have been answered. I agree to take part in this study.

Subject Name (Print): _____

Subject Signature: _____ Date: _____

Signature of Investigator/Individual Obtaining Consent:

To the best of my ability, I have explained and discussed all the important details about the study including all of the information contained in this consent form.

Investigator/Person Obtaining Consent Name (Print): _____

Signature: _____ Date: _____

Chart Review Tracking Form

[illegible]

Appendix M

Anecdotal Comments Log

Anecdotal Notes

Date/Note/Project Director Initial

Appendix N

Swedish Improvement Measurement Questionnaire (SIMQ)

Date:

Role:

Swedish Improvement Measurement Questionnaire (SIMQ)

Instructions for participants:

The purpose of this questionnaire is to evaluate your experience with the use of the American College of Cardiology ASCVD Risk Estimator Plus or 10-Year ASCVD Risk Estimator. On top of the questionnaire form, please write your role or title at the practice and the date. Answer all the questions by marking the box which best corresponds to your answer. When the questionnaire refers to “Quality improvement tool” or “Improvement idea,” they are referring to the use of 10-year Risk Estimator Tool. When the questionnaire refers to “Participant,” they are referring to yourself. When referring to “Project Directors,” the survey is referring to Sara Jurado and Leydi Espinosa.

Improvement effectiveness outcome					
	Not at all (0)	A little (1)	Some (2)	Quite a bit (3)	A lot (4)
1. Overall, how satisfied are you with the progress that has been made in the work to develop ASCVD Risk Calculator during the past month?					
2. How much does the improvement idea ASCVD Risk Calculator contribute to improving the work at your unit?					
	Far below (0)	Somewhat below (1)	As expected (2)	Somewhat above (3)	Far above (4)
3. To what extent is your progress with the improvement idea ASCVD Risk Calculator below or above your original expectations?					
Internal Improvement Processes (8 sub dimensions)					
<i>Improvement Uncertainty</i>	Very easy (0)	Quite easy (1)	Moderate (2)	Quite difficult (3)	Very difficult (4)
4. How easy is it for you to know ahead of time what steps are necessary to develop the ASCVD Risk Calculator?					

	Not at all (0)	Once (1)	Every other week (2)	Every week (3)	Every day (4)
5. How often in the past month did problems arise during development of the ASCVD Risk Calculator?					
Resource scarcity					
6. How much must your ASCVD Risk Calculator compete with other activities within your unit, when it comes to:	Not at all (0)	Little (1)	Some (2)	Quite a bit (3)	A lot (4)
7.. Economic resources?					
8. Material, space, and equipment?					
9.Attention from the executive level?					
10. Personnel?					
11.Time to work with the improvement idea?					
Standardization of procedures	Very little (0)	Little (1)	Moderate (2)	Much (3)	Very much (4)
12. To what extent is your work on the ASCVD Risk Calculator supported by the methods used in the improvement program?					
Expectations of Rewards and Sanctions					
13. How likely is it that the following will occur if the goals of the ASCVD Risk Calculator have been achieved:	Not likely (0)	Hardly likely (1)	Likely (2)	Very likely (3)	Totally likely (4)
14.. Everyone involved, as a group, will be rewarded or recognized for their collective efforts					

15. Only some participants will be reprimanded or told to "shape up" to improve their efforts						
Improvement Group Leadership	Absolutely do not	Mostly do not	Neutral (2)	Mostly agree	Absolutely agree (4)	Mean (SD)

	agree (0)	agree (1)		(3)		
16. The project directors of the improvement idea encourages the participants to take initiative						
17. The participants involved in the ASCVD Risk Calculator idea are aware of their individual responsibilities						
18. The project directors for the improvement idea places great emphasis on getting the work done.						
19. The project directors have great confidence in the participants involved in the improvement idea						
	Not at all (0)	Little (1)	Some (2)	Quite a bit (3)	A lot (4)	Mean (SD)
20. Do those involved in working with the improvement idea receive feedback from "improvement support"/their supervisor on how they can improve their work?						
<i>Freedom to Express Doubts</i>	Absolutely do not agree (0)	Mostly do not agree (1)	Neutral (2)	Mostly agree (3)	Absolutely agree (4)	Mean (SD)
21. To avoid causing disharmony I often feel I cannot say what I think about the work on the improvement idea.						
<i>Learning Encouragement</i>	Absolutely does not apply (0)	Mostly does not apply (1)	Neutral (2)	Mostly apply (3)	Absolutely applies (4)	Mean (SD)
22. If a colleague tries something new and fails, this is viewed as something that could harm her/his future career in the practice.						
23. The practice prioritizes experimenting with new ideas.						
<i>Decision Influence</i>						

24. How much influence have you had on each of the following decisions that might have been made during the past month?	No decision made * (0)	None (1)	Little (2)	Some (3)	Quite a bit (4)	A lot (5)
25.Preparing goals and measures for the improvement idea?						
26.Deciding which activities should be carried out within the improvement idea?						
6c. Deciding on economic funds and resources for the improvement idea?						
27.Recruiting colleagues to work with the improvement idea?						

Appendix O

COMRADE Survey

B.1. Satisfaction with Communication**1. The doctor made me aware of the different treatments available.**

☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
Strongly Disagree	Disagree	Neutral	Agree	Strongly Agree

2. The doctor gave me the chance to express my opinions about the different treatments available.

☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
Strongly Disagree	Disagree	Neutral	Agree	Strongly Agree

3. The doctor gave me the chance to ask for as much information as I needed about the different treatment choices.

☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
Strongly Disagree	Disagree	Neutral	Agree	Strongly Agree

4. The doctor gave me enough information about the treatment choices available.

☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
Strongly Disagree	Disagree	Neutral	Agree	Strongly Agree

5. The doctor gave enough explanation of the information about treatment choices.

☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
Strongly Disagree	Disagree	Neutral	Agree	Strongly Agree

6. The information given to me was easy to understand.

☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
Strongly Disagree	Disagree	Neutral	Agree	Strongly Agree

7. I know the advantages of treatment or not having treatment.

☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
Strongly Disagree	Disagree	Neutral	Agree	Strongly Agree

8. I know the disadvantages of treatment or not having treatment.

☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
Strongly Disagree	Disagree	Neutral	Agree	Strongly Agree

9. The doctor gave me a chance to decide which treatment I thought was best for me.

☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
Strongly Disagree	Disagree	Neutral	Agree	Strongly Agree

10. The doctor gave me a chance to be involved in the decisions during the consultation

☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
Strongly Disagree	Disagree	Neutral	Agree	Strongly Agree

B2. Confidence in Decision

1. Overall, I am satisfied with the information I was given.

☐ 1 Strongly Disagree ☐ 2 Disagree ☐ 3 Neutral ☐ 4 Agree ☐ 5 Strongly Agree

2. My doctor and I agreed about which treatment (or no treatment) was best for me.

☐ 1 Strongly Disagree ☐ 2 Disagree ☐ 3 Neutral ☐ 4 Agree ☐ 5 Strongly Agree

3. I can easily discuss my condition again with my doctor.

☐ 1 Strongly Disagree ☐ 2 Disagree ☐ 3 Neutral ☐ 4 Agree ☐ 5 Strongly Agree

4. I am satisfied with the way in which the decision was made in the consultation.

☐ 1 Strongly Disagree ☐ 2 Disagree ☐ 3 Neutral ☐ 4 Agree ☐ 5 Strongly Agree

5. I am sure that the decision made was the right one for me personally.

☐ 1 Strongly Disagree ☐ 2 Disagree ☐ 3 Neutral ☐ 4 Agree ☐ 5 Strongly Agree

6. I am satisfied that I am adequately informed about the issues important to the decision.

☐ 1 Strongly Disagree ☐ 2 Disagree ☐ 3 Neutral ☐ 4 Agree ☐ 5 Strongly Agree

7. It is clear which choice is best for me.

☐ 1 Strongly Disagree ☐ 2 Disagree ☐ 3 Neutral ☐ 4 Agree ☐ 5 Strongly Agree

8. I am aware of the treatment choices I have.

☐ 1 Strongly Disagree ☐ 2 Disagree ☐ 3 Neutral ☐ 4 Agree ☐ 5 Strongly Agree

9. I feel an informed choice has been made.

☐ 1 Strongly Disagree ☐ 2 Disagree ☐ 3 Neutral ☐ 4 Agree ☐ 5 Strongly Agree

10. The decision shows what is most important to me.

☐ 1 Strongly Disagree ☐ 2 Disagree ☐ 3 Neutral ☐ 4 Agree ☐ 5 Strongly Agree

Appendix P

COMRADE Demographics

Patient Demographic Collection Sheet

1. What is your age? _____

2. What is your gender identity?

Male _____ Female _____ Transgender Male _____ Transgender Female _____

Gender Non-Conforming _____ Not Listed (please specify) _____

3. What is your ethnicity?

Non-Hispanic _____ Hispanic/Latino _____

4. What is your race? (Select all that apply)

White _____ Black or African American _____ Asian/Pacific Islander _____

American Indian/Alaska Native _____ Not listed (please specify): _____

5. Did you talk to your provider about your risk for heart disease? Yes _____ No _____

Survey Tracking Sheet

[illegible]

Appendix R

Staff Training Module

Staff Training and Workflow Overview

*3 Minutes***1. Which patients need a risk score calculated using 10-year Risk Estimator Plus.**

1.1 Inclusion Criteria

1.2 Exclusion Criteria

*2 Minutes***2. What information is needed to calculate the patient's risk score.**

1.1 Biographical data

1.2 Lab data

*5 Minutes***3. Where can I access the risk score calculator.**

1.1 Accessing the tool

1.2 Using the staff workflow diagram

*2 Minutes***4. Where should patients risk score be documented.**

1.1 patient face sheet

1.2 electronic -medical record

*8 Minutes***5. Mock Run and Questions**

1.1 Using the staff workflow diagram

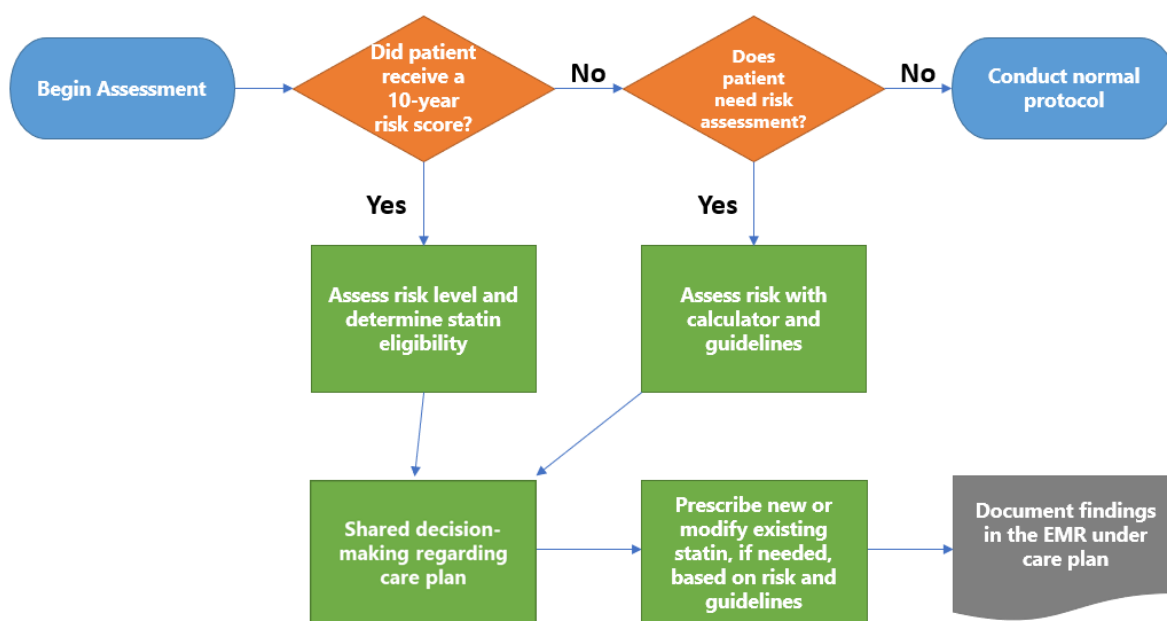
1.2 Meet Mr. Jones mock case

Estimated Duration (15 to 20 Minutes)

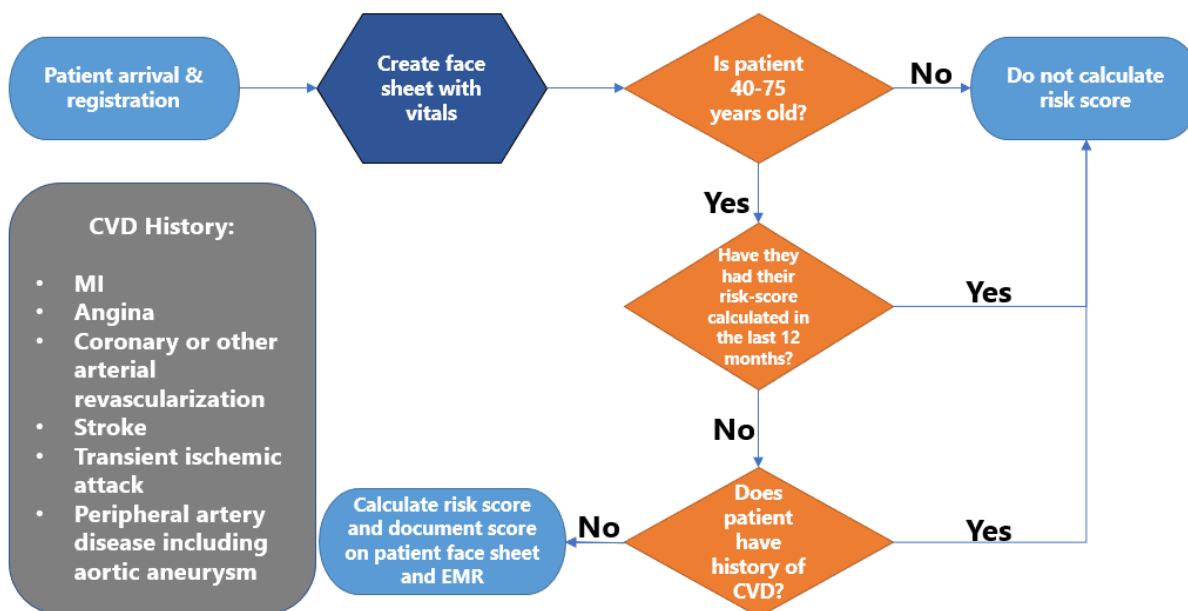
Appendix S

Workflow Pocket Card

Provider Workflow Diagram



ASCVD Staff Workflow



Appendix T

Provider Training Module

2018 ACC/AHA Cholesterol Management: Providers Use of the 10 ASCVD
Risk Assessment Tool

Teaching Outline Topics

Time Frame:*(10 Minutes)***Topic 1: 2018 American Association of Cardiology/ American Heart Association Cholesterol Management Guidelines**

- 1.1 Overview of secondary prevention with focus on primary prevention
- 1.2. Risk enhancing factors

*(5 Minutes)***Topic 2: What the Atherosclerotic Risk Assessment Calculator and why it's important.**

- 2.1 Risk levels based on 10-year ASCVD risk score.

*(5 Minutes)***Topic 3: What patient's quality to have their 10-year ASCVD risk estimated.**

- 3.1 Inclusion criteria
- 3.2 Exclusion criteria

*(5 Minutes)***Topic 4: Use of the tools 10-year ASCVD risk score for statin prescribing and modification***(30 Minutes)***Topic 5: Let's use the tool and Question and Answer Session**

- 5.1 Shared decision making
- 5.2 Using the provider workflow diagram
- 5.3 Mock case "Meet Mr. Jones".

(50-60 Minutes Total)

Appendix U

Provider Discussion Checklist/Script

CVD Prevention Checklist

Follow this checklist to guide the clinical discussion with your patients. This list includes all the topics recommended for discussion by the 2018 ACC/AHA Cholesterol Management Guidelines. "What is ASCVD Risk?" script is also provided to facilitate explanation of the risk assessment tool and meaning of risk score.

Provider-Patient Risk Discussion Checklist

Did you...	
Review risk factors and the 10-year risk estimate? (see script to the right)	☐
Address treatable nonlipid factors (e.g. hypertension, diabetes, smoking)	☐
Review diet and physical activity habits	☐
Endorse healthy lifestyle and provide relevant advice/materials/referrals	☐
Discuss potential risk reduction from lipid-lowering therapy and recommend statins as first-line therapy	☐
Discuss the potential for adverse effects/drug interactions	☐
Assess confidence in risk-based treatment decisions; if uncertain, offer further options to refine risk estimate (e.g. CAC score)	☐
Invite patient to ask questions and express values/preferences	☐

What is ASCVD RISK? (Explain to your patient...)

- This tool is used to calculate your risk of having a heart attack or stroke in the next 10 years.
- Based on your information, your risk is (Insert patient's risk score)
- What this means is that if we put 100 people just like you, with the same risk factors for heart disease, (Insert patient's risk score) of these people will have a heart attack or stroke in the next 10 years.
- Let's talk about what we can do to prevent one of them from being you (refer to checklist and risk assessment tool to develop individualized plan)

Checklist and script adapted from:

Martin, S. S., Sperling, L. S., Blaha, M. J., Wilson, P. W. F., Gluckman, T. J., Blumenthal, R. S., & Stone, N. J. (2015). Clinician-patient risk discussion for atherosclerotic cardiovascular disease prevention: importance to implementation of the 2013 ACC/AHA Guidelines. *Journal of the American College of Cardiology*, 65(13), 1361-1368. Retrieved from <https://www.ncbi.nlm.nih.gov/pubmed/25835448>

Mayo Clinic. (n.d.). *Cardiovascular Primary Prevention Choice*. Retrieved from Mayo Clinic Shared Decision Making National Resource Center: <https://shareddecisions.mayoclinic.org/decision-aid-information/decision-aids-for-chronic-disease/cardiovascular-prevention/>

Appendix V

CVD Prevention Toolkit Contents

CVD Prevention Toolkit

- ❖ **Clinician Tool: Tobacco Cessation for Patients with Cardiovascular Disease**
From “2018 ACC Expert Consensus Decision Pathway on Tobacco Cessation Treatment,” by Barua et al., 2018, *Journal of the American College of Cardiology*, 72(25), (<https://doi.org/10.1016/j.jacc.2018.10.027>). Copyright 2018 by Elsevier Inc.
- ❖ **NJ Quitline Provider Toolkit**
From *New Jersey Quitline: Provider Toolkit*, by The NJ Department of Health, n.d. (www.njquitline.org). In the public domain.
- ❖ **American Heart Association My Cholesterol Guide Booklet**
From *My Cholesterol Guide*, by The American Heart Association, 2018 (https://www.heart.org/-/media/files/health-topics/cholesterol/cccc_mycholesterolguide.pdf?la=en&hash=D2615F014E44766A96EDEE2EF81633BE162B10D0). In the public domain.
- ❖ **Myth or Fact: The Truth about Cardiovascular Medications Patient Education Handout**
From *About Million Hearts*, by The U.S. Department of Health and Human Services, n.d. (<https://millionhearts.hhs.gov>). In the public domain.
- ❖ **Coronary Artery Calcium Testing Patient Education Handout**
From *Coronary Artery Calcium Testing*, by The National Lipid Association, 2018 (<https://www.lipid.org/node/1620>). In the public domain.

Appendix W

Budget

Expense ▼	Financier ▼	Budget ▼	Actual ▼	Difference (\$) ▼
Printed materials (surveys, consent forms)	Project Directors	\$ 50.00	0.00	\$ 50.00
Envelopes	Project Directors	\$ 10.00	\$ 1.00	\$ 9.00
Printed materials for CVD Prevention Toolkit	Project Directors	\$ 100.00	0.00	\$ 100.00
Refreshments for education sessions for staff and providers	Project Directors	\$ 100.00	\$ 80.00	\$ 20.00
Refreshments for debriefing session	Project Directors	\$ 50.00	\$ 50.00	\$ -
Online access to ASCVD Risk Assessment Tool	Site	Free	0.00	0.00
Folders for CVD Prevention Toolkit (7, \$5.10 each)	Project Directors	\$ 36.00	\$ 30.90	\$ 5.10
Patient participant incentives (100, \$10 gift cards)	Project Directors	\$ 1,000.00	\$ 240.00	\$ 760.00
Staff wages	Site	No additional cost predicted	0.00	0.00
Staff and provider incentives (11, \$10 gift cards)	Project Directors	\$ 110.00	\$ 70.00	\$ 40.00
Rutgers SPSS license	Project Directors	\$ 35.00	0.00	\$ 35.00
Poster and manuscript printing	Project Directors	\$ 200.00	\$ 200.00	\$ -
Total Expenses		\$ 1,691.00	\$ 671.90	\$ 1,019.10

Project Timeline

[illegible]