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Lipid Management of Patients with Probable Familial Hypercholesterolemia by a Nurse Practitioner

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LIPID MANAGEMENT OF PATIENTS WITH PROBABLE FAMILIAL HYPERCHOLESTEROLEMIA BY A NURSE PRACTITIONER

By

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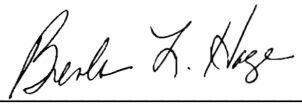	
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Abstract

Heart disease remains the number one killer of Americans. Patient's high cholesterol numbers are a major risk factor for the development of heart disease. Studies performed by the Centers for Disease Control (CDC) and the U.S. Department of Health and Human Services (DHHS) have recognized this as an area in need of improvement. Strategies for improvement of patients' serum cholesterol and adherence to the recommended therapies have been explored. The purpose of this evidence based project is to compare cholesterol management outcomes in patients cared for by a nurse practitioner, with lipid management certification, to patients cared for by their usual providers, in a population with severe hypercholesterolemia. The population samples, non-pregnant adults, aged 20 years old or greater, will be obtained from patients with a minimum baseline low density lipoprotein cholesterol (LDL-C) of $\geq$190. Levels will be accessed through an electronic health record database, on blood work previously ordered by a network provider. All patients in both groups will receive the same standard care available. The difference will be the provider only; the nurse practitioner holds a certification in lipid management. Data analysis will be on the percent change in LDL-C, from baseline at 4 to 12 weeks, as well as provider adherence to the guidelines. The benefit of this investigation is that it may demonstrate a successful treatment strategy for the management of high cholesterol.

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Chapter One: Introduction and Overview of the Problem of Interest

Sixty-seven years ago, the Framingham Heart Study (FHS), a prospective cohort trial, set in Framingham, Massachusetts, was established initially as a 20 year epidemiological investigation to evaluate heart disease. The study continues today, as an Offspring cohort as well as a Third Generation cohort, and includes an examination of the role of genetics. Analyses over the years have disclosed hypertension and high cholesterol among the risk factors for the development of atherosclerotic cardiovascular disease (ASCVD) in both men and women, and not simply a normal phenomenon of aging (Castelli, Anderson, Wilson, & Levy, 1992; Mahmood, Levy, Vasan, & Wang, 2014). Critics however, note that the Framingham study investigated a population of Caucasians and question its generalizability.

The INTERHEART study investigators, in contrast, sought to examine cardiovascular risk factors across varied ethnic groups and geographic areas. This investigation was a large international case control study, which demonstrated that smoking and abnormal lipids were the two strongest modifiable predictors of myocardial infarct (MI) in men and women and across all ethnic and geographic regions (Yussuf et al., 2004).

As heart disease globally remains the leading cause of death, (World Health Organization, 2015), it is recognized that one out of three people have cardiovascular disease (CDC, 2014). The American Heart Association (AHA) has identified an ideal total cholesterol level to be <200 mg/dL. The National Health and Nutrition Examination

Survey (NHANES) data from 2011 to 2012 demonstrated that only 46% of adults met that criteria (Mozaffarin, et al., 2015).

The AHA has identified metrics of health for varied cholesterol levels. An ideal TC level is <200 mg/dL, intermediate: 200-239 mg/dL, and poor: ≥240 mg/dL (Mozaffarian et al., 2015). The prevalence of high cholesterol remains relatively high. The "percent of adults age 20 years and over with high serum total cholesterol (greater than or equal to 240 mg/dL): 13.4% (2009-2012)", while the "mean serum total cholesterol level for adults age 20 years and over: 196 mg/dL (2009-2012)" (Centers for Disease Control, 2014a, FastStats Cholesterol). Further, "the mean level of LDL cholesterol for American adults > 20 years of age was 115.8 mg/dL in 2009 to 2012" (Mozaffarin et al., 2015, p.e108).

Despite the high prevalence, screening efforts to identify those at risk and in need of treatment, remains inadequate. According to the Centers for Disease Control (CDC) (2014b), the 2010 National Ambulatory Medical Care Survey (NAMCS) reported that only 15.7% of office visits were recorded in the medical record for hyperlipidemia and only 7.8% of the office visits were for diagnostic and screening purposes for blood lipids that were either ordered or provided. The AHA has outlined policy solutions for improvement, including ensuring national guideline use to increase adherence (Mozaffarian et al., 2015). Federally, they recommend exploring prospects to assimilate mobile technologies and applications to improve outcomes (Mozaffarian et al., 2015).

Therefore, there is room for improvement in the management of patients' serum cholesterol levels. The World Health Organization (2015), as well as the AHA,

(Mozaffarian et al., 2015) identify two levels of intervention: population-wide, and individually-focused. Ideally, these levels of intervention should be enmeshed to optimize outcomes. The World Health Organization suggests that individual, targeted therapy be employed to those with the highest risk, and in the most cost-efficient manner, including care with "non-physician health workers" (World Health Organization, 2015, How can the burden of cardiovascular diseases be reduced?).

Background

Recently, the American College of Cardiology (ACC) and the American Heart Association (AHA) released the 2013 ACC/AHA Guideline on the Treatment of Blood Cholesterol to Reduce Atherosclerotic Cardiovascular Risk in Adults (Stone et al., 2014). The guideline is based on randomized controlled trials (RCT), meta-analyses, and high quality observational studies only (Stone et al., 2014).

According to the authors, the purpose of the guideline is to disseminate a tool for ASCVD population risk reduction, and is not intended as a guide for the management of complex lipid disorders as "it is anticipated that clinicians with lipid expertise can contribute to their management" (Stone et al., 2014, p. 10). However, it is conveyed that four groups of patients would benefit from statin therapy, one of which is people with "primary elevations of LDL-C $\geq$190 mg/dL" (Stone et al., 2014, p.13). Notably, with respect to individuals with severe LDL-C ($\geq$ 190 mg/dL), the Blood Cholesterol Guidelines indicate the following:

> The guideline recognizes that adults ≥21 years of age with primary, severe elevations of LDL–C (≥190 mg/dL) have a high lifetime risk for ASCVD events.

> This is due to their lifetime exposure to markedly elevated LDL–C levels arising from genetic causes. Thus, at age 21, these individuals should receive statin therapy if they have not already been diagnosed and treated before this age. Although in most clinical trials, individuals with LDL–C ≥190 mg/dL were not included due to their need for treatment, extensive evidence shows that each 39 mg/dL reduction in LDL–C by statin therapy reduces ASCVD risk by about 20% (Stone et al., 2014, p. 28).

Familial hypercholesterolemia (FH) is "the most common dominantly inherited disorder in humans" (Watts et al., 2014, p. 153), with a genetic mutation of lipid metabolism, causing severe elevations of LDL cholesterol, that if left untreated, can lead to premature death from cardiovascular disease. The problem is underdiagnosed and undertreated: "There are probably more than 15 million people with FH worldwide, but less than 10% have been detected and only 5% adequately treated" (Watts et al., 2014, p.153). Further, "without treatment, more than half of all men with FH and 30% of women with FH are expected to have a myocardial infarction before 60 years of age"(Goldberg et al., 2011b, p.48).

Generally, two forms of FH exist: homozygous FH, which carries an incidence of 1 in one million and heterozygous FH, which carries an incidence of about 1 in every 300 to 500 people and is more common than type 1 diabetes or cystic fibrosis (Defesche, 2010). FH can be due to a defective LDL receptor, defective apolipoprotein B-100, or mutations in the pro-protein convertase subtilitsin/kexin type 9 (PCSK9) gene (Goldberg

et al., 2011a). Heterozygous FH is determined when the mutation is inherited from one parent.

FH is defined as having an LDL-C $\geq$ 190 (Third Report of the National Cholesterol Education Program Expert Panel on Detection, Evaluation, and Treatment of High Blood Cholesterol in Adults, 2002). In addition, according to the International FH Foundation, "a plasma LDL cholesterol of 5.0mmol/dL or greater indicates high probability of FH in the absence of a positive parental history of hypercholesterolemia or premature CHD" (Watts, 2014, p.150). (Utilizing the conversion factor of x mg/dL cholesterol = x mmol x 38.7; 193.5mg/dL = 5.0 mmol, Watts et al., 2014). This is a clinically relevant point for population screening.

The focus of this evidence based practice (EBP) project will be on probable heterozygous FH, in populations with an LDL-C $\geq$ 190. Specifically, "heterozygous familial hypercholesterolemia (FH) is a dominantly inherited disorder caused by mutations of the low-density lipoprotein (LDL) receptor locus on the short arm of chromosome 19" (Williams et al., 1993, p. 171). Traditionally, there have been three well known diagnostic tools to help clinicians make a diagnosis of FH –the Dutch Lipid Clinic Network Diagnostic Criteria (DLCN), the U.S. Make Early Diagnosis Prevent Early Death (MED PED) criteria, and the Simon Broome Register Diagnostic Criteria (Willard, 2011). These methods combine criteria, physical findings, family history and genetic testing. Based on these criteria, often one could be placed in categories of *definite, probable, or possible* FH. However, the more current literature identifies FH categorically as those with an LDL-C $\geq$ 190 (Stone et al., 2014; Third Report of the

National Cholesterol Education Program Expert Panel on Detection, Evaluation, and Treatment of High Blood Cholesterol in Adults, 2002; Watts et al., 2014).

Heterozygous FH (HeFH) patients have LDL cholesterol levels often twice normal with an increased cardiovascular risk for atherosclerosis (Williams et al., 1993). This heightened risk is due to prolonged elevations in cholesterol levels, since birth. It is commonly associated with physical findings of the skin such as tendon xanthomas, xanthelasmas, or a premature corneal arcus, however, the physical findings may not always be present. Genetic testing may be performed, however, it is expensive, not always available, and is unnecessary, as elevated lipids can be categorical, physical exam findings and a positive family history (Goldberg et al., 2011a). Further, it is unclear how health insurance companies may view genetic testing results that disclose a criterion that is associated with premature morbidity and mortality.

Significance to health care, financing, and advance nursing practice

High quality scientific trials have demonstrated a clear benefit of statin therapy in the primary and secondary prevention of ASCVD (Stone et al., 2014). It has been noted however that there has been a dearth of literature reporting the social and economic value of statin therapy. Grabowksi et al. (2012) explored the social value of statins on a population level, within the U.S. Social value weighs the total cost of treatments to the cost of the disease, from a societal and economic perspective. Investigators reported that:

> National survey data suggest that statin therapy reduced low-density lipoprotein levels by 18.8 percent, which translated into roughly 40,000 fewer deaths, 60,000 fewer hospitalizations for heart attacks, and 22,000 fewer hospitalizations for

> strokes in 2008. For people starting statin therapy in 1987–2008, consumers captured $947.4 billion (76 percent) of the total social value of the survival gains (Grabowski et al., 2012, p. 2276).

While progress has been made, the authors note that if all identified patients eligible to be on statin therapy were treated as per the guidelines, additional societal gains might be demonstrated.

Further benefits can be made from a population perspective, if identified patients were treated. According to data from 2009-2012 presented by the AHA, " >100 million US adults $\geq$ 20 years of age have total cholesterol levels $\geq$ 200 mg/dL; almost 31 million have levels > 240mg/dL" (Mozaffarian et al., 2015, p.e32). The U.S. Department of Health and Human Services (U.S.DHHS) has identified population wide goals for 2020, titled *Healthy People 2020 (HP2020).* An objective of the agency is to "improve cardiovascular health and quality of life through prevention, detection, and treatment of risk factors for heart attack and stroke; early identification and treatment of heart attacks and strokes; and prevention of repeat cardiovascular events" (U.S. DHHS, 2015, Goals).

Astoundingly, the expenses of heart disease and stroke combined, cost the country more than $320 billion, in 2011, including direct and indirect costs (Mozaffarian et al., 2015). The cost of cardiovascular disease remains higher than any other diagnostic group (Mozaffarian et al., 2015).

Therefore, in light of the high incidence of cardiovascular disease with known modifiable risk factors, and the continued high prevalence of undertreated elevated cholesterol levels, much work is yet to be done to improve the health status of

individuals. The current methods of management are unsatisfactory. One can turn to an EBP change for amelioration.

Melnyk and Fineout-Overholt (2010) describe EBP as clinical practice occurring within the context of external evidence from research, expert opinion leaders, and evidence based theory as well as clinical expertise and patient preferences. The purposes of EBP are multifold: high quality, cost-effective care, improved outcomes, and clinician satisfaction (Melnyk & Fineout-Overholt, 2010). It is within the mission of the development of EBP that the following clinical question is derived.

Question Guiding Inquiry: PICO-T

The clinical question is displayed in a PICO-T format *(P*atient *P*opulation, *I*ssue of *I*nterest, *C*omparison group, *O*utcome and *T*imeframe). The PICO-T question developed in the setting of patients with high cholesterol is: In non-pregnant adults aged 20 years old or greater, with a diagnosis of probable heterozygous familial hypercholesterolemia, would treatment in a lipid clinic by a nurse practitioner certified in lipid management, compared to usual care, lead to an improvement in the LDL cholesterol at the end of a 3 month period? Usual care references treatment by any provider, including primary care, or cardiology, that is not certified in lipid management.

Lipid Certification

A clinical lipid specialist (CLS) is a clinician who holds an advanced certification in the field of lipidology as conferred by the Accreditation Council for Clinical Lipidology (ACCL, 2015a). Traditionally, the certification was open to professionals such as nurses, nurse practitioners (NPs), physician assistants (PAs), dieticians, exercise

physiologists, and pharmacists, who were board eligible based on the satisfaction of specified rigorous academic, clinical and educational requirements (ACCL, 2015b). Recently, eligibility has been expanded to physicians. Generally, most physicians are certified by the American Board of Clinical Lipidology (ABCL) and are called lipidologists upon successful exam completion. Lipid certification demonstrates one's credibility to the discipline and serves as a benchmark of competency.

System and Population Impact

For the reasons outlined, national as well as international goals for improvement of patients' blood cholesterol and the improvement of cardiovascular risk factors have been established. The CDC has identified a national goal to prevent one million heart attacks and strokes by the year 2017 (CDC, 2014a) while the U.S. DHHS has specifically established HP2020 goals for the management of cholesterol (U.S. DHHS, 2015). These include Heart Disease and Stroke Goal 13 (HDS-13), to: "increase the proportion of adults with elevated LDL cholesterol who have been advised by a heath care provider regarding cholesterol-lowering management, including lifestyle changes and, if indicated, medication" and HDS-14, to "increase the proportion of adults with elevated LDL-cholesterol who adhere to the prescribed LDL-cholesterol lowering management lifestyle changes, and, if indicated, medication" (U.S. DHHS, 2015, Heart Disease and Stroke Objectives). Similarly, the AHA has established a goal of reducing CVD mortality by 20% by 2020 (Mozaffarian et al., 2015). Therefore, in summary, an emphasis on advisement and adherence to treatment of LDL-cholesterol, is recommended. Internationally, the WHO established a global non-communicable disease target that "at

least 50% of eligible people should receive drug therapy and counseling (including glycaemic control) to prevent heart attacks and strokes" between 2013-2020 (World Health Organization, 2015,WHO Response).

Purpose, Aims, Objectives

The purpose of this EBP is to describe a successful treatment strategy, designed to reflect a modern care model, by a nurse practitioner (NP) practicing within a lipid clinic, to treat patients with excessively high cholesterol levels. The model, of an advanced practice nurse caring for patients with risk factors for chronic disease, is consistent with the model of team-based care, as supported by the ACC (Brindis, Rodgers, & Handberg, 2011). Barriers, such as adherence to recommended treatments, have been acknowledged, and remain a challenge to overcome.

Further, in team-based care, there is effective utilization of resources, where physicians can provide complex tasks that require medical training. This model is consistent with Bauer's observation (2010) that nurse practitioners have been underutilized resources for healthcare reform. The proposed model exemplifies the economic principle of *input substitution* where cost effective, quality care can be provided (or *substituted*) by an alternative means than traditional approaches. This is defined further: "It is the cost of different labor inputs for producing the same service" (Bauer, 2012, p.230).

In addition, this model of an EBP will demonstrate linkage to all of the Eight Essentials of Doctoral Nursing Practice (American Association of Colleges of Nursing, 2006). It will also meet the competencies for improved clinical education as a part of

healthcare reform, as suggested by the Institute of Medicine (2001, 2003), to provide patient centered care, to work in interdisciplinary teams, and employ evidence based practice.

Chapter Two: Review of the Evidence/Literature

Due to the high cardiovascular risk, where "the risk of premature coronary heart disease (CHD) is elevated about 20-fold in untreated FH patients," and the fact that FH is a treatable disorder affecting many undiagnosed young patients, an opportunity exists for improvement (Goldberg et al., 2011a, p. S135). To identify if a lipid certified NP treating a population of probable FH patients would improve outcomes, a review of the literature was undertaken. It should be noted that in the proposed project, the NP will be working collaboratively with an experienced lipidologist who has extensive training and expertise in this area. Team-based care has been supported in the literature, and will be included in the review.

Topics of interest for research include the components of the PICO (*P*opulation, *I*ntervention, *C*ontrol group, *O*utcome) question: In non-pregnant adults aged 20 years old or greater, with a diagnosis of probable heterozygous familial hypercholesterolemia, would treatment in a lipid clinic by a nurse practitioner compared to usual care (by non-lipid-certified clinicians), lead to improvement in the LDL cholesterol at the end of a 3 month period? Specifically, the component topics of *P*-probable heterozygous familial hypercholesterolemia (FH) patients, the *I*-a group of patients treated by a lipid certified NP, the *C*-a comparative group of patients managed by usual care, and the *O*-improved lipids, were researched.

The best available evidence was sought, based on the hierarchy of evidence, searching for systematic reviews of randomized controlled trials (RCT) first, followed by individual RCTs, cohort studies, case control studies, and finally, case reports. In

addition, available guidelines for the treatment of blood cholesterol as well as FH and lifestyle management were sought to frame the EBP. Further, scientific evidence supporting the diagnosis of heterozygous FH (HeFH) as well as treatments will be reviewed. It should be noted that the literature search is not exhaustive and is meant to support the PICO-T.

Methodology

A literature search was conducted using the term familial hypercholesterolemia, with Boolean modifiers limiting the search to English studies published between 1985-2015, utilizing the databases of EBSCO HOST, MEDLINE, and CINAHL Complete. This returned 5,428 articles. The search was narrowed to FH AND lipid clinic, yielding 265 articles. The search was further narrowed by adding AND heterozygous to the search, returning 75 articles which were all reviewed for applicability. Additional searches were conducted using hypercholesterolemia AND lifestyle management returning 64 hits, while combining FH and National Lipid Association returned three. The 2013 AHA/ACC Guideline on Lifestyle Management as well as Make Early Diagnosis Prevent Early Death were also searched separately. Clinical Trials.gov as well as EBM Reviews were searched for the ENHANCE and IMPROVE-IT trial information. Bibliographies were also examined to obtain pertinent articles. In addition, personal communication with lipid experts aided in trial analyses and understanding of FH.

Population

The population, *non-pregnant adults aged 20 years old or greater, with a diagnosis of probable heterozygous familial hypercholesterolemia*, was not random.

First, the treating practitioners work in an adult practice, limiting the population. Statins are contraindicated in pregnancy, and pregnant FH patients are not an aim of this project. Second, the screening guidelines from the National Lipid Association (NLA), identify a population greater than or equal to 20 years old (Goldberg et al., 2011a). Consistent with the objective of an evidence based project, age will be a limiting factor.

Intervention: Treatment by a Nurse Practitioner

Guidelines for blood cholesterol.

Individual approaches as well as population strategies have been recommended to improve cardiovascular health (Mozaffarian et al., 2015). Advocacy and policy solutions as suggested by the AHA include ensuring "adherence to clinical guidelines and treatment protocols" (Mozaffarian et al., 2015, p. e51). The 2013 ACC/AHA Guideline on the Treatment of Blood Cholesterol to Reduce Atherosclerotic Risk in Adults was reviewed to determine applicability to the proposed EBP project. Given that the guideline facilitates a strategy for risk assessment, it is not useful in a population, in isolation, with excessively high cholesterol numbers who are at high cardiovascular risk to begin with and where "risk stratification algorithms should not be used" (Goldberg et al., 2011a, p. 136). Therefore, alternative guidelines were sought. In addition, the evidence to support utilization of an LDL-C of $\geq$ 190 was provided initially by the National Cholesterol Education Program Adult Treatment Panel III, in 2001, and reinforced by the NLA in 2011 and the International FH Foundation in 2014, as previously discussed (Goldberg et al., 2011a; Third Report of the National Cholesterol

Education Program Expert Panel on Detection, Evaluation, and Treatment of High Blood Cholesterol in Adults, 2002; Watts et al., 2014).

Guidelines for screening and treatment of FH.

The NLA offers clinical guidance from an Expert Panel on the screening, diagnosis and treatment of FH that will be used to facilitate this project. The aim of the recommendations is to provide guidance for the primary care specialist as well as the lipidologist caring for FH patients. The document provides a framework for treatment, and recommends adherence and persistence to recommended therapies, to reduce cardiovascular risk. The recommendations are clear and concise for use as a tool in the aforementioned EBP and is highly applicable. Authors are all lipid specialists and members of the National Lipid Association who have written extensively on the subject and are considered experts within the lipid community. It is noted the development of the document was supported by a grant from many pharmaceutical companies, however, it was noted that the NLA had full scientific control over the content of the paper. Most investigators have received honoraria from various drug companies, and disclosed this information.

It has been noted that the document was not meant to be a "comprehensive examination of the published literature" (Goldberg et al., 2011a, p.S134). It is not clear if there were external reviewers, and there was no mention about future updates, however attention to future research needs was noted. Specifically envisioned was "methods to enhance healthcare provider adherence to guidelines" (Goldberg et al., 2011a, p. S139),

which is consistent with recommendations from the 2015 Heart Disease and Stroke Update of 2015 from the AHA (Mozaffarian et al., 2015).

Additionally, the NLA devoted an entire supplement to the *Journal of Lipidology* in 2011, to FH (Supplement 5). Several articles, written by different authors, deal with the same issues: management, treatment, prevalence, and screening of FH patients. The Executive Summary was a compilation of the work (Goldberg et al., 2011a). This methodology is cumbersome to review and to use clinically, with noted redundant effort.

Heterozygous FH studies.

In searching for the highest level of evidence, it is noted that there is a dearth of double-blind, placebo-controlled, randomized trials of FH patients. It is acknowledged that "in most clinical trials, individuals with LDL-C $\geq$ 190 were not included due to their need for treatment" (Stone et al., 2013, p. 28). However, as the next investigation reveals, studies have been done with patients *on* treatment.

Smilde et al. (2001) investigated 325 FH patients, both men and women aged 30-70 between 1997 and 1998. Baseline characteristics were similar in both groups. This was a prospective, randomized, double-blind trial, from the Netherlands. The aim was to see whether a potent high dose statin regressed carotid intimal media thickness (CIMT), over 2 years, compared to a less potent statin. Atorvastatin 80mg, the high dose statin, was compared with simvastatin 40mg, a less potent drug. Patients were randomized by computer, with concealment. Power, >80%, was noted; validity was high. This was a very well designed study, approved by an ethics committee. B-mode ultrasound, a reliable and valid tool, was used for measurement of CIMT.

Evaluation was on an intention to treat analysis, limiting bias. After 2 years, the CIMT "in the atorvastatin group decreased (-0.031mm [95% CI -0.007 to -0.055]; p=0.0017), whereas in the simvastatin group it increased (0.036 [0.014-0.058]; p=0.0005" (Smilde et al., 2001, p. 577); results were statistically significant. A limitation of this investigation was using CIMT as a surrogate for coronary artery disease (CAD). Notwithstanding, Smilde et al. (2001) convey: "in prospective studies, carotid IMT was able to predict coronary artery disease (CAD)" (p. 577). Results demonstrated that aggressive LDL-C reduction regresses atherosclerosis in FH patients, while less aggressive treatment does not. The study is highly applicable to the proposed PICO-T.

Friedrich (2010), a doctorally prepared NP who is a clinical lipid specialist (CLS), offers a very thorough case study of a patient with HeFH that was identified and treated in a primary care practice setting. Although low level evidence, the case presentation is highly applicable to the PICO-T question and provides a basic explanation of FH, as well as a historical perspective. HeFH is further defined scientifically, and differentiated from homozygous FH (HoFH), exceedingly rare, occurring in 1 in a million people (Friedrich, 2010). Friedrich offers credence to the proposed methodology of a lipid certified NP treating FH patients, emphasizing the benefits of NP care including patient education, underscoring both pharmacotherapy and lifestyle changes necessary for management. The chronic disease of this cohort is recognized and acknowledged it as a public health issue as well.

Lifestyle management.

The 2013 AHA/ACC Guideline on Lifestyle Management to Reduce Cardiovascular Risk will be used to guide lifestyle recommendations to the population in the proposed project, as lifestyle modifications are recommended by the NLA guidelines on FH (Goldberg et al., 2011a). Patients who would benefit from LDL-C lowering are advised to follow a heart healthy prudent diet.

Food plans aligned with this recommendation include the Dietary Recommendations to Stop Hypertension (DASH) dietary plan, the American Heart Association (AHA) Diet, or the U.S. Department of Agriculture (USDA) Food Pattern diet (Eckel et al., 2013). All of these diets advise patients to "consume a dietary plan that emphasizes intake of vegetables, fruit, and whole grains; includes low-fat dairy products, poultry, fish, legumes, nontropical vegetable oils and nuts; and limits intake of sweets, sugar-sweetened beverages and red meat" (Eckel et al., 2013, p. 13, p.18). For those with comorbid medical conditions such as diabetes, modifications are recommended. The strength of this recommendation is Level A, developed from multiple populations, RCTs and meta-analyses with an NHLBI Grade A (Strong) treatment effect (Eckel et al., p. 5). Further, adults who are advised to lower their LDL-C are encouraged to "aim for a dietary pattern that achieves 5-6% of calories from saturated fat," "reduce percent of calories from saturated fat," and "reduce percent of calories from transfat" (Eckel et al., 2013, p. 20).

Additionally, the Lifestyle Guideline advises "adults to engage in aerobic physical activity to reduce LDL-C and non-HDL-C: 3 to 4 sessions a week, lasting on average 40

minutes per session and involving moderate-to-vigorous intensity physical activity" (Eckel et al., 2013, p. 29). Again, the strength of this recommendation is ACC/AHA Level A, developed from multiple populations, RCTs and meta-analyses, with an NHLBI Grade B/Moderate treatment effect (Eckel et al., 2013, p. 29).

The aim of the Lifestyle Guideline is to provide guidance for the prevention and treatment of cardiovascular disease through lifestyle modifications. The recommendations are based on rigorous scientific systematic reviews and the highest level of evidence available. In addition, recommendations were reviewed by expert panels. Further, a limited number of individual expert reviewers assisted in the process. However, there was an extensive peer review process already in place. The guideline was developed jointly by the ACC/AHA and NHLBI who have separate grading reports for strength of evidence. This makes interpretation of some recommendations cumbersome and confusing. It has been acknowledged that the authors did not review any evidence beyond 2011, and therefore will begin updating the guideline beginning in 2014.

The Lifestyle Guideline is highly applicable to the proposed project. Tools such as hyperlinks to recommended diet plans are provided. Recommendations are easily discernible in the text and clearly communicated. Diet plans will be reviewed and available for print at patient encounters in the EBP change.

Statins.

One way to reduce cholesterol biosynthesis is to inhibit the pathway of production. "HMG-coA reductase is the rate- limiting enzyme in the cholesterol

biosynthetic pathway" (Tobert, 2003, p.518), and is a target of therapy, with a category of drugs called the HMG-coA reductase inhibitors. All generic medications in this class end with the term "statin" and, thus, have been collectively and commonly referred to as *the statins.* Lovastatin was the first statin approved for use in the U.S. by the Food and Drug Administration in 1987, followed by simvastatin and pravastatin in 1991 (Tobert, 2003). Since then, several have followed.

The Cholesterol Treatment Trialists (CTT) collaborators joined in 1994 to perform prospective meta-analyses of data in a series of cycles. The first cycle included over 90,000 individual patients in a total of 14 randomised statin trials. Single trials often lacked the power to assess the effects of cholesterol lowering on morbidity and mortality particularly when individual subgroups were analyzed. Specifically, the authors relate: "by weighing the results in individual trials and subgroups by the size of the achieved LDL cholesterol reductions, we were able to adjust for the potential confounding effects of such differences" (Baigent et al., 2005, p. 1275). In the first cycle of study, participants were treated with statin therapy for a mean of five years, with a mean LDL cholesterol reduction of 1 mmol/L (38.6 mg/dL) at one year. There was a 21% reduction in any major vascular event (0.79, 0.77-0.81; $p<0.0001$), with benefits evident in the first year, but greater in subsequent years (Baigent et al., 2005). Taking all years together, "the overall reduction of about one fifth per mmol/L LDL cholesterol reduction translated into 48 (95% CI 39-57) fewer participants having major vascular events per 1000 among those with pre-existing CHD at baseline, compared with 25 (19-

31) per 1000 among participants with no such history" (Baigent et al., 2005, p. 1267). Most notably,

> The results of the present meta-analysis indicate that the proportional reductions in the incidence of major coronary events, coronary revascularizations, and strokes were approximately related to the absolute reductions inn LDL cholesterol achieved with the statin regimens studied, and that the proportional reductions in such major vascular events per mmol/L LDL cholesterol reduction were similar irrespective of the pretreatment cholesterol concentrations or other characteristics (eg. age, sex, or pre-existing disease) of the study participants (Baigent et al., 2005, p. 1277).

Therefore the results of the work by the CTT collaborators demonstrate that statin therapy can significantly reduce an individual's vascular risk, over prolonged treatment, which also has positive similar implications for population health.

In most of the contemporary lipid literature, it is commonly acknowledged that due to ethical reasons, randomized placebo-controlled trials are not performed in FH patients, as the patients are of high cardiovascular risk, and to withhold treatment from one group would not be morally sound. Despite this acknowledgement, one RCT in heterozygous FH patients was located, from the late 1980s. This was a double-blind, placebo-controlled multicenter trial that included five lipid clinics in the U.S. involving the first statin approved by the FDA. The aim was to evaluate the effectiveness of lovastatin in 101 patients with HeFH, as determined by physical and laboratory characteristics. There were 62 men and 39 women with a mean age of 44 years; both

groups were homogenous at baseline. Patients were randomized to either placebo or varying doses of lovastatin, once or twice daily, over the 18 weeks of the investigation. Blinding as well as randomization was performed and discussed. Standardization of laboratory analysis was ensured across all five clinics.

Statistical analysis among groups was performed by a one-way analysis of variance. T-tests or signed rank tests were used as needed. Correlation was assessed by Spearman's rank. All 101 patients completed the study and there were no significant adverse effects. Results were statistically significant:

> Significant reductions ($p<0.01$) in total plasma cholesterol and low-density lipoprotein cholesterol as compared with placebo were seen after 6 weeks of lovastatin therapy. Mean reductions in total plasma cholesterol and low-density lipoprotein cholesterol ranged from 14% to 34% and 17% to 39%, respectively, for patients receiving lovastatin 5 to 40 mg twice daily for 6 weeks (Havel et al., 1987, p. 611).

The study demonstrated that lovastatin, in varying doses, was effective at reducing total cholesterol as well as LDL cholesterol, in a small group of patients with HeFH. However, this was not a clinical outcomes study which is a limitation. In this small investigation, power and intention to treat analysis were not considerations. It should be noted that this study was performed at a time when statins were in the infancy stage, as well as the science of familial hypercholesterolemia. For these reasons, it is likely that additional RCT of FH patients did not occur. Study results, however are applicable to the proposed PICO question.

A large, long-term, prospective, cohort registry included patients on treatment. Investigators examined 3, 382 HeFH patients in 21 clinics in the United Kingdom from 1980 to 2006. The aim of the study was to assess all-cause, coronary and cancer mortality in FH patients before and after treatment with statins. In keeping with the purpose of this review, only the cardiovascular segment will be discussed.

Patients were identified as definite, or possible HeFH, based on the Simon Broome Register. Using this methodology, the presence of tendon xanthomas as well as demographic information were assessed and registered. Baseline demographics were similar, and available for review in table format. Lipid assay was by the customary and widely used Friedewald formula. Statistical analysis was performed by standard computer methodology for cohort studies.

Investigators noted: "there was a significant excess in mortality from all causes before, but not after, 1 January 1992" (Neil et al., 2008, p.2627). This finding correlates with the time frame when statins were being introduced. The standardized mortality ratio (SMR) was "derived from the ratio of the number of deaths observed to those expected, which was expressed as a percentage" (Neil et al., 2008, p. 2626). This key point assisted researchers in determining the number of expected deaths, which was used in data analysis. From 1 January 1992 on, there were 153 coronary heart disease deaths, and 72 expected, with an SMR of 213 (95% CI 181-250, $p<0.0001$), a statistically significant finding (Neil et al., 2008). Although a cohort study is mid-level evidence, this study is clinically relevant to the proposed project.

Other pharmaceuticals.

Statins are the mainstay of therapy for LDL-C reduction, as they have been proven to reduce morbidity and mortality, with strong scientific rigor (Stone et al., 2014). However, suboptimal reductions, drug intolerances, and continued cardiovascular events may necessitate a look at combination and alternative pharmacotherapy. The evidence to support this was examined.

Ezetimibe (trade name Zetia), has been studied in FH patients. Ezetimibe is a cholesterol absorption inhibitor, and therefore has a different mechanism of action than a statin. Two investigations utilizing ezetimibe will be reviewed. The first, called ENHANCE, the Ezetimibe and Simvastatin in Hypercholesterolemia Enhances Atherosclerosis Regression trial, was an international, double-blind, RCT over 24 months duration, from 2002-2006 and included 720 male and female HeFH patients. (Indeed the study dates were 2002-2006, and the investigation period was 24 months, as written.) Participants were from 18 centers in eight countries, including the Netherlands, Canada, the United States, South Africa, Spain, Denmark, Norway and Sweden.

The aim of the study was to compare the effectiveness of high dose simvastatin, 80mg, and placebo, to high dose simvastatin, 80mg plus ezetimibe 10mg and placebo on carotid intima media thickness (CIMT), a marker of atherosclerosis. The primary endpoint was the change in the mean of CIMT by B-mode ultrasound measurements. All participating centers required institutional review board (IRB) approval, and obtained informed consent from participants. There were strict inclusion and exclusion criteria, including either a genetically determined diagnosis of HeFH, or a strict clinical one,

necessitating meeting specified characteristics and parameters. Notably, 80 % of patients in both arms were already on some statin therapy at entrance. Additionally, compliance with the recommended therapy was accounted for by tablet count.

Randomization of patients occurred through a computer generated code. In addition, providers were rigorously trained and certified ultrasonographers were blinded to the patients. B-mode ultrasound, which is reliable, validated and widely available, was utilized to obtain CIMT measurements.

Evaluation was on intention to treat analysis, with a power of greater than 90%, to detect a difference of 0.05 mm in carotid measurements, limiting bias and improving the reliability of the results. However, authors disclosed that the study was not powered to assess clinical outcomes. The investigation was supported by the drug sponsors, Merck and Schering-Plough, however it was noted that all study components were of scientific merit, on the authors behalf.

Outcomes were obtained through covariate analysis models, using SAS software. "The primary outcome, the mean ($\pm$ SE) change in the carotid-artery intima-media thickness, was 0.0058 $\pm$ 0.0037 mm in the simvastatin-only group and 0.0111 $\pm$ 0.0038 mm in the simvastatin-plus-zetia (combined therapy) group, P=0.029" (Kastelein, 2008, p.1431). Therefore, the combination therapy did not decrease CIMT more than statin therapy with simvastatin alone. However, the authors also noted:

> After 24 months, mean levels of LDL cholesterol decreased from 317.8 ± 66.1 mg per deciliter (8.22 ± 1.71 mmol per liter) to 192.7 ± 60.3 mg per deciliter (4.98 ± 1.56 mmol per liter) in the simvastatin-only group and from

> 319.0 ± 65.0 mg per deciliter (8.25 ± 1.68 mmol per liter) to 141. 3± 52.6 mg per deciliter (3.65 ± 1.36 mmol per liter) in the combined-therapy group, a between-group difference of 16.5% (P<0.01; p.1437).

In addition, there were marked reductions in the levels of triglycerides, C-reactive protein, and apolipoprotein-B levels in the combined therapy group versus the simvastatin group that was statistically significant, but not a primary or secondary outcome (Kastelein et al., 2008).

Therefore, there was no significant decrease in CIMT despite higher degrees of reduction in LDL-C, triglycerides, CRP, and apolipoprotein-B compared to simvastatin only therapy. One wonders whether the study was poorly designed--in that there was no statistical difference in CIMT because patients were already on adequate therapy with statins, or perhaps because the study wasn't long enough, or some other unexplained reason. Notably though, this was a study about a drug effect on CIMT, not clinical outcomes, but held promise to those believers in "the lower, the better, hypotheses," referencing reductions in LDL-C, triglycerides, apolipoprotein-B, and CRP, which predicated future outcome studies with ezetimibe (personal communication, T. Dayspring MD, FACP, FNLA, NCMP, Director of Cardiovascular Education, Foundation for Health Improvement and Technology, February 16, 2015).

More recently, a randomized, placebo controlled trial titled IMProved Reduction of Outcomes: Vytorin Efficacy International Trial (IMPROVE-IT), sought to investigate the efficacy of simvastatin versus simvastatin and ezetimibe on clinical outcomes, in high risk patients. Final results were recently published in the New England Journal of

Medicine (Cannon et al., 2015). There were 18,144 high risk patients, with a recent acute coronary syndrome, randomized to receive either simvastatin 40 mg or simvastatin 40 mg and ezetimibe 10mg. It is known that ezetimibe when added to statin therapy provides an additional 20% LDL-C reduction (Canon, 2015). What was not known is whether the addition of ezetimibe would change clinical outcomes, i.e. cardiac events. Primary endpoints of the study were cardiovascular death, myocardial infarction, stroke, re-hospitalization for unstable angina, or coronary revascularization greater than or equal to 30 days post randomization.

There were strict inclusion and exclusion criteria, with similar baseline characteristics of both groups. There was sufficient power, >90%, to determine clinical outcomes. Data was evaluated on an intention to treat analysis, limiting bias. The study was drug company sponsored, however all academic rigor was given to the study authors.

Results demonstrated a statistically significant decrease in cardiac endpoints, at the end of 2.5 years of follow up in the simvastatin/ezetimibe group vs the simvastatin group (32.7% vs 34.7%, HR=0.94, 95% CI 0.89-0.99; p=0.016; Cannon, 2015). This supports the hypothesis that the lower the LDL-C, the better the atherosclerotic risk reduction. In addition, these results demonstrate a statistically significant reduction in clinical outcomes when ezetimibe was added to statin therapy, in high risk patients with established CAD. It is unclear if these results can be extrapolated to low risk patients. However, this investigation provides support for adding ezetimibe to high risk patients, to reduce LDL-C, and is applicable to the proposed EBP.

Additionally, there are two novel pharmaceutical agents that have been developed and approved by the FDA for treatment of FH patients: lomitapide and mipomersen. However, at this time, their use is restricted to treating homozygous FH (HoFH) patients. Studies are currently ongoing to expand the indications, and in the future, may be appropriate for treating HeFH. Therefore, at this time, these agents are not available for use in the population of patients in this project.

Team based care.

A systematic review of practice guideline dissemination and implementation for healthcare teams was analyzed, using the Joanna Briggs Institute's (JBI) approach, within a high level of the hierarchy of evidence. The aim was to evaluate the effectiveness of clinical practice guidelines for collaborative care and patient outcomes. Eighty-eight articles were included in the final analysis, starting from an initial pool of over 12,000, published between 1995 and 2007. Included were RCTs, descriptive/case series, or cohort/case control studies. Papers were reviewed by a minimum of two reviewers; a third was used if needed as a tiebreaker. This approach provided a high level of validity. In addition, a standardized critical appraisal instrument from the JBI was utilized, increasing the reliability of the results.

Overall, ten guideline dissemination and implementation strategies were gleaned from the 88 articles. Examples included laminating of guideline cards, mass media presentation, and distribution of educational material and poster displays. The descriptive analysis reported favorable results, with 72.7% of the studies reporting teams to have enhanced "knowledge, practice, and /or outcomes" (Medves et al., 2010, p.79).

Diagrams and tables complemented the presentation and discussion of the findings. Limitations were the varied and inconsistent methods of guideline dissemination amongst the studies.

In conclusion, investigators support the use of evidence based guidelines in team based care, to enhance patient and provider outcomes. This is highly consistent with the proposed evidence based project, using guidelines to identify and treat a specific patient population, under the care of an advanced practitioner collaborating with a lipidologist.

The ACC supports a vision to "dramatically reduce the incidence, severity and complications of cardiovascular disease as we promote prevention, reduce disparities in health care, and improve personal and population-based cardiovascular health" (ACC, 2015a). The College is strategic in formulating guidelines to lead and shape cardiovascular health across our nation. In recognition of that vision is the College's support of team-based care. On the ACC President's Page (Brindis, Rodgers & Handberg, 2011), an emphasis is placed on the value of the contributions of "non-physicians" [*sic*], including both physician assistants (PAs), and nurse practitioners (NPs), in providing high quality patient centered care. Additionally, the College recently published its 2015 Health Policy Statement on Cardiovascular Team-Base Care and the Role of Advanced Practice Providers (APP), providing a formal position on the issue (Brush et al., 2015). In fact, an APP functioning in a lipid clinic as a provider in a disease-state management, was an exemplar case of team based care in the health policy (Brush et al., 2015).

Although low level evidence, the College conducted a survey in 2010 of over 2,400 cardiovascular practices, representing 14,000 cardiologists across the U.S. The aim was to gain a better understanding of the benefits of team-based care. Results disclosed that team care enhanced patient education, as reported by 69% of respondents, while 63% related improved efficiency and 50% conveyed improved patient adherence (ACC, 2015b). Additionally, 33% percent suggested enhanced outcomes utilizing PAs and NPs to provide collaborative care in lipid clinics, device clinics, and anticoagulation clinics (ACC, 2015b). Notably, the landscape of cardiovascular care is changing, with opportunities on the horizon for the advanced practitioner. Reflective of the current status of clinical cardiovascular practice, the survey results do demonstrate clinical significance to the proposed PICO-T question.

Allen et al. (2002), in a RCT, tested the effectiveness of an NP in managing lipid abnormalities in patients with known coronary heart disease. Included in the study were 228 hospitalized patients from a large tertiary medical center, randomized by computer to either care by an NP, or usual care, by the primary care provider or cardiologist, after an acute coronary syndrome. Blinding however, was not discussed. In addition, it did not appear that the NP held a lipid certification.

Baseline characteristics of both groups were comparable. Interventions included the standard of care incorporating pharmacotherapy, diet instruction and a personalized exercise prescription. There was additional emphasis placed on lifestyle management in the NP arm, with a focused analysis on improvements in exercise and dietary habits.

Follow-up visits occurred up to a year after discharge, in person or by phone, in the intervention group. Lipid levels were reexamined at one year.

Data were assessed by an intention to treat analysis, decreasing potential bias. Results demonstrated a statistically significant achievement of an LDL-C goal of ≤100 more often in the NP group than in the usual care group (65% vs 35%, p=.0001; Allen et al., 2002, p.683). Limitations included the possibility of a type II error, with a narrow intention to treat analysis, with a moderate sample size.

The investigation by Allen et al. examined secondary prevention, with those known to have coronary heart disease (CHD), differing from the population of the proposed EBP. However, both are considered to be high cardiovascular risk groups. There is a high degree of correlation between the intervention and outcome of this RCT and the proposed project, supporting the suggested approach for treatment of lipids by an NP.

Another investigation, a cohort study by Shafer and Wexler (1995), compared treatment of lipids in a multidisciplinary lipid clinic with that of usual care. The convenience sample with age matched cohorts included 120 patients, 60 from the Cincinnati, Ohio, VA Lipid Clinic and 60 from a general internal medicine (GIM) clinic, in a retrospective chart review. The intervention group was treated by a multidisciplinary team including an NP, dietician, pharmacist, nurse and psychologist.

Lipids were examined after 12 months in the Lipid Clinic and after 18 months in the GIM clinic. Results demonstrated that patients in the Lipid Clinic were four times as likely to reach lipid goals as those in the GIM clinic with a relative risk ratio of 4.1

(95% C.I. 1.4-12.7; p<.001; Shafer & Wexler, 1995, p.2330). The results are statistically and clinically significant to the proposed project. Limitations were the design and non-random, convenience sample, which increases potential study bias. The prospective design predisposes the providers to bias as they are aware the patients are in a study.

Adherence and persistence.

Assessing adherence and persistence to treatment plans, particularly to medications such as statins, would be an important metric in RCTs examining mortality and morbidity in high risk patients. Simpson and Mendys (2010) performed a systematic review of the effects of adherence and persistence on clinical outcomes in patients treated with statins. They analyzed 19 total articles quantifying adherence (n= 15) and persistence (n=4) in treatment with statins to clinical outcomes, through a PubMed search of English articles published between 1999 and 2009. Investigations were performed either in Canada or the U.S. and excluded reviews and nonclinical studies. Three studies were primary prevention and eight were secondary prevention trials. There were inconsistencies in defining adherence and persistence among the studies examined which made data analysis difficult. In fact, no definition of persistence was disclosed. Adherence was defined as the portion of days covered (PDC), or the number of days medication is supplied, divided by the observation time interval. A commonly accepted threshold was defined as 80% or greater, over the period observed.

The reliability and validity of the investigation could not be verified; there was no valid tool used and patients self-reported if they were taking the medications. Investigators reported descriptive results in an easy to read table. In primary prevention

studies, benefits were derived at one year of therapy or longer. High levels of adherence were associated with a decrease in all-cause mortality, and nonfatal cardiovascular events with adherence >80% (Simpson & Mendys, 2010). A weakness of the analysis, is the number of studies examined and the lack of consistent definitions of critical concepts. This weakens the overall conclusions. Adherence to recommended treatments to reduce cholesterol levels is applicable to the PICO-T presented.

Darves (2003) described a retrospective study of 70 patient charts, assessing improvement in LDL cholesterol in an NP managed lipid clinic. An aim of the study was to indirectly assess medication adherence, as measured by improved lipids. In this small investigation, the average patient was 70 years old, and 67% were male. Patients had a 33% reduction in average LDL cholesterol and 75% of the patients met established goals (Darves, 2003). Limited information was available from the presented study abstract, however it was noted that limitations included the small sample size, and lack of baseline lipid levels in some patients. Despite the study's low level of evidence, it was included in the review, as it is highly applicable to the identified PICO-T and supports the EBP.

Control Group: Usual Care

Birtcher et al. (2010) performed a retrospective, cohort observational study, to determine if lipid management of patients with established CAD cared for in a multidisciplinary clinic (SPLC), would improve adherence to the established lipid guidelines, compared to usual care, as measured by the lipid profile, at the end of three years. A total of 1,433 people, 415 in the specialty clinic, and 1018 in comparative group, were recruited from a computer database and included in this investigation from a

large subspecialty practice in Texas. Patients in the multispecialty clinic were cared for by both cardiologists and pharmacists, and patients in the usual care group were provided care by cardiologists alone. Patients in the multispecialty clinic achieved "LDL-C goals more often than usual care cardiology patients (goal<100 mg/dL: 81.9%, vs. 72%, *P* <.001; optional goal, 70 mg/dL: 41.9% vs. 28.6 %, *P*< 001; Birtcher et al., 2010, p. 46). This was statistically significant.

By design, this study offers mid-level evidence in the hierarchy of scientific vigor. The applicability to the proposed project is in the analysis of the results of the performance of usual care, which will be similar, but not exactly to, the comparative group. Usual care in the proposed project will be by either the primary care provider or cardiologist. The results of the examined study do demonstrate that an alternative model of care can be more successful than usual care in treating patients with established CAD, who are high risk, when compared to usual care. Therefore, this investigation is highly applicable to the proposed project.

Another study examined lipid lowering therapy, as well as other clinical characteristics, in a prospective, cross-sectional analysis of a longitudinal cohort study, consisting of a total population of 1,852 patients from 19 lipid clinics in Spain. International FH guidelines provided the framework for this particular investigation which has been titled SAFEHEART, the SpAnish Familial HypErcHolEsterolemiA CohoRt STudy. Genetic testing with DNA assays was used to confirm the diagnosis of FH in this population.

Results disclosed that "only 3.4% of patients reached and [*sic*] LDL-c [*sic*] under 100mg/dL" (Mata et al., 2011, p. 1), however, 'half of this population were receiving treatment to reduce LDL-C ≥ 50%" (Mata et al., 2011, p. 6). The investigators did discuss the International FH guideline LDL-C goals: "the optimal LDL-c [*sic*] goal should be 100 mg/dL or to achieve at least a 50% reduction in LDL-c [*sic]* levels" (Mata et al., 2011, p. 6). Based on either goal, this investigation demonstrated that there is still significant room for improvement in the management of lipids in FH patients. This study is highly applicable to the proposed PICO project, and offers additional mid-level evidence from a well-designed cohort study.

Outcome: Improved Lipids

Goals of treatment of lipids for FH have been established. According to the NLA FH Expert Panel: "For adult FH patients, initial treatment is the use of moderate to high doses of high potency statins titrated to achieve an LDL cholesterol reduction ≥ 50% from baseline" (Goldberg et al., 2011a, p.138). However, some FH patients with other comorbidities, and those with established coronary heart disease, may require greater LDL cholesterol reductions, beyond 50% (Goldberg et al., 2011a). Modifications, including alternative therapies with other medications are recommended for those intolerant of stains. These pharmaceuticals may include ezetimibe, niacin, or a bile acid sequestrant or combination therapy (Goldberg et al., 2011a). Additional therapies such as LDL apheresis are available for specific cases, but will not be a part of this particular project.

Limitations

The limitations of the review are based on the studies examined, as the search was not an exhaustive one. It included studies available in the databases searched, under the particular key words.

Conclusions

There is strong evidence to support the need for better lipid management in patients with high cholesterol levels. The population in this project is well established, by the framework of the aforementioned guidelines. The NLA FH recommendations are moderately supported by the available evidence, as there are few scientific studies of high level evidence, with randomized, controlled and blinded studies in a population that is known to be high risk. The display of the recommendations from the NLA would be more clinically useful if combined into one document, instead of many papers in a supplement.

The diagnosis of HeFH is well supported and treatment goals are well delineated, with strong scientific support for the use of statins, and ezetimibe. However, there are no clinical outcome studies on other pharmaceuticals such as fibrates, niacin and bile acid sequestrants, although supported for use by the NLA recommendations, if clinically necessary. Therefore, there is scientific merit for treatment with statins, ezetimibe, and lifestyle management. Emphasis will be placed on these strategies for patients in the project. Other modalities will not be excluded however, if there are drug intolerances, or additional therapies are required to meet goals.

There is clinical support from field experts in cardiology, on behalf of team based care, by the ACC. In addition, there was an excellent systematic review using the JBI approach supporting healthcare teams, the use of guidelines and improved outcomes. There was moderately high evidence for the support of an NP treating lipids in a specialty clinic, compared to usual care. Furthermore, good studies on adherence and persistence to recommended treatments are lacking, and perhaps the available study in this review sought to examine two separate constructs in one study making analysis difficult. Further, the lack of clear definitions of adherence and persistence makes the prospect of scientific vigor less promising.

Chapter Three: **Organizational Framework/Conceptual Model for Evidence Based Practice Change**

According to the World Health Organization (2002), chronic conditions are the health care challenges of the 21st century. The World Health Organization offers a compendium of information and discussion about chronic conditions, as a call for action by policy leaders and decision makers who have the capacity to alter the course of chronic disease management in a positive fashion (2002). It is clear that without a better emphasis on preventive medicine, the cost of caring for those with chronic conditions, such as heart disease, cancer, diabetes and depression for instance, will be insurmountable. Elements for attention include: (a) a focus on prevention, (b) integrated health care, incorporating primary care, community resources, and inpatient as well as outpatient care, with facilitated shared information, (c) the utilization of health care professionals to the fullest extent of their education, and (d) an emphasis on patient centered care (WHO, 2002).

Defined, chronic conditions are "*health problems that require ongoing management over a period of years or decades* [*sic*]*,"* (World Health Organization, 2002, p.11) and are inclusive of heart disease. A call for innovation to manage chronic conditions is made. Further, a correlation across the conditions is made:

> Innovative care is not based on the etiology of a particular problem, but is based on the demands that the health problem places on the health care system. In the case of chronic conditions, the demands are similar regardless of the cause of the condition. Moreover, effective management strategies are remarkably

> comparable for many chronic problems, and chronic conditions management, inclusive of all chronic health problems, is developing an identity of its own in health care (World Health Organization, 2002, p.44).

A framework for organizing health care for chronic conditions is therefore introduced. Specifically, a model called the Chronic Care Model (CCM), will be used for this evidence based project.

Conceptual Definitions

The Chronic Care Model (CCM) was developed by Dr. H. Wagner, and colleagues at the Seattle based MacColl Center for Health Care Innovation at the Group Health Research Institute, in conjunction with the Robert Wood Johnson Foundation (RWJF), in the 1990s. It was designed as a utilitarian model with applicability to groups of patients in diverse populations with chronic illness. The model is "a synthesis of evidence-based system changes intended as a guide to quality improvement and disease management activities" (Wagner et al., 2001, p. 69). It has since been further modified with an international applicability to populations as a whole.

The original CCM has interacting components whereby "the system changes support the development of informed activated patients and prepared proactive healthcare teams whose interactions become more productive and satisfying around chronic illness" (Epping-Jordan, Pruitt, Bengoa, & Wagner, 2004, p.300). (See Appendix A for a diagram of the CCM; Wagner, 1998b.) When these integrated components function optimally, good chronic care is achieved, and customers, including the clinician as well as the patient, are satisfied, with improved outcomes.

Overall, there are six elements that comprise the CCM. The Health System is a part of the bigger Community, whereby community resources as well as the health care organization itself are two interacting components of the Model. The Health System organization includes four interacting elements: self-management, delivery system design, decision support, and clinical information systems (Epping-Jordan et al., 2004; Pearson et al., 2005). Self-management support incudes care to the patient and/or family, and includes empowering the client by providing proper tools and education for success. Further, it epitomizes patient centered care. Delivery system design entails a description of and setting of the encounter, as well as the specific provider. This is a key component of the *systems change* [emphasis added]. Team care is inferred, with innovative delivery system redesign.

Decision support refers to the evidence based guidelines that frame the care. In addition, it encompasses the integration of expert consultation that may be indicated, as well as educational tools to assist the clinician. Clinical information systems enhance the sharing of information between providers, and can create reminders for follow-up visits, lab work, and medication refills, for instance, to facilitate adherence. Furthermore, disease registries can offer a database to manage process improvement and performance evaluations. Critically, it is noted that "the improvement in the care of patients with chronic illness will only occur if system leaders, whether private or governmental, make it a priority and provide the leadership, incentives, and resources necessary to make improvements happen" (Epping-Jordan et al., 2004, p. 300).

Utility of Model

Coleman, Austin, Brach, and Wagner (2009) provide a review of evidence supporting the use of the model in guiding quality initiatives in ambulatory care over ten years. The Model has been used in over 1,500 medical practices, including primary care offices, patient-centered-care home models, and in the Heath Disparaties Collaboratives (HDCs) as well as the Improving Chronic Illness Care (ICIC) Collaborative (Coleman et al., 2009). It has also been the basis for many state, national, and international system changes. Clinically, several works have described it as a successful model for patients with congestive heart failure, diabetes, asthma, depression, and lipid management (Hallady et al., 2014; Khatana, Liang, & Wu, 2014; Pearson et al., 2005; Stock et al., 2014). Furthermore, use of the CCM has been described by U (2012) in conveying care provided by family nurse practitioners in family medicine. This underscores the applicability for use in the proposed EBP.

Relationship of Model to Project

The following will describe a correlation of the model elements to interventions in the proposed project.

1. *Self- management interventions*- Patients will be able to verbalize an understanding of their treatment goals, to facilitate adherence. Patient centered educational material, as produced by nationally respected organizations such as the National Lipid Association (NLA), the Preventive Cardiovascular Nurses Association (PCNA), the U.S. Department of Health and Human Services (U.S. DHHS) and the U.S. Department of Agriculture, for instance, will be integrated through the EHR and available for print at the closure of each

patient encounter, as ordered by the provider. Material will encompass lifestyle changes, exercise, diet and pharmaceutical information sheets, to strengthen self-management skills.

2. *Delivery system design*- Delivery system for the project population will be specifically with a nurse practitioner (NP) who is a clinical lipid specialist (CLS). Care will be provided through a team approach, with the NP working collaboratively with a board certified lipidologist. Encounter visits will be documented through the electronic heath record (EHR) to facilitate communication with the primary care provider as well as other specialists. Follow up phone calls will be made to promote adherence to the treatment plan.

3. *Decision support*- Guidelines offered by the NLA will be used to guide lipid treatment goals and pharmaceutical recommendations, while guidelines from the ACC/AHA will provide recommendations for diet and exercise. Expert clinician assistance will be available through the collaborative work with a lipidologist.

4. *Clinical information systems*- An electronic database will be used to identify those patients with probable familial hypercholesterolemia, to facilitate the patient population. All patient encounters with the NP will be documented within an EHR. Any required testing will be ordered through the EHR. Follow up visits will be coordinated through use of the EHR as well. In addition, ongoing, daily, electronic communication between the office staff and the NP will provide an avenue for patients' calls and questions to be answered in a timely manner.

5. *Health System Organization and Care*- The development of a lipid clinic, in which the proposed evidence based project is a part, has been supported by administration. The strategic plan in fact, was coordinated by the management team, with network wide communication marketing the notion, demonstrating commitment on behalf of the cardiac service.

6. *Community Resources and Policies*- Patients will be offered referrals for Medical Nutrition Therapy (MNT) to review recommended diets, on a one-on-one approach with a registered dietician. Recommendations for community agencies offering exercise facilities will be provided, including the Network's gyms, to facilitate compliance with local amenities. Participation in community resources will be encouraged.

7. *Improved functional and clinical outcomes*- Outcomes will be assessed by percent change in the TC and LDL-C at 12 weeks.

These interventions are consistent with those proposed by Wagner et al., (2001) and the Chronic Care Model.

Chapter Four: Project Design

The project will be conducted using a comparative design using a prospective intervention group and a retrospective comparison group. There will be a pre-intervention allocation to two groups, an intervention and a comparison group, based on an electronically identified LDL-C $\geq$190. Based on the setting of the comparison group, a true randomized intervention is not possible. However, the design will likely strengthen the project, minimizing bias, with analysis of results performed in a real-world setting. This is a feasible and alternative inquiry to randomization, in a practice based setting, as demonstrated by review of the literature (Bonell et al., 2011).

Protection of Human Subjects Research

Appropriate educational standards have been met to ensure the safety and protection of human subjects. Collaborative IRB Training Initiative (CITI) research modules were completed and achievement certificates presented, as required for human subject research. In addition, a web-based training course was completed as offered by the National Institutes of Health (NIH) Office of Extramural Research titled *Protecting Human Research Participants.*

Organizational consent on behalf of St. Luke's University Health Network was obtained by signature on the IRB application, from the Vice President of Operations of Cardiovascular Medicine, Kevin McGovern, as well as the Chairman of Cardiovascular Medicine, Raymond Durkin, M.D., and the collaborating physician, lipidologist Gerald Pytlewski, D.O. IRB approval as a Type I Exempt review was met, from both St. Luke's University Health Network, and Misericordia University (see Appendix B and D).

Additionally, St. Luke's provided a letter of support (See Appendix C), as the population of patients originates from the St. Luke's Network. Additionally, the St. Luke's standard Informed Consent Form will be used, as required by the collaborating institution (See Appendix E).

Data Collection Tools

Lipids will be assessed utilizing a standard 12 hour fasting lipid profile, which estimates the LDL using the Friedewald formula. In this method LDL cholesterol is estimated by figuring "the total cholesterol minus high-density lipoprotein (HDL) cholesterol minus very-low-density lipoprotein (VLDL) cholesterol (estimated as triglyceride ÷ 5)" (Warnick, Knopp, Fitzpatrick & Branson, 1990, p. 15).

> Because ultracentrifugation is unavailable in most routine laboratories and the procedure is expensive, time consuming, and technically demanding, the nearly universal approach in clinical laboratories (and that used commonly even in specialized lipid laboratories) has been to estimate LDL cholesterol from the formulas of Friedewald et al. (Warnick et al., 1990, p. 15).

Plan for Evaluation

Data analysis will be in percent change of LDL-C, at four weeks for the treatment group and 12 weeks for the comparison group. The 2013 ACC/AHA Guideline on the Treatment of Blood Cholesterol indicates lipids should be rechecked in 4-12 weeks after initiating statin therapy, to assess for patient safety and adherence (Stone et al., 2013). Additionally, a treatment goal for this population has been established: "for adult FH patients (>20 years of age), drug treatment to achieve an LDL cholesterol reduction

> 50% should be initiated" (Goldberg et al., 2011a, p.136). Therefore, outcomes will address provider adherence to the guidelines, as well as measurement of LDL cholesterol reduction. Data will be analyzed, with the assistance of Jill Stotltzfus**,** PhD., Director of Clinical Research of St. Luke's University Health Network. The time frame for the project was narrowed, based on the timing of IRB approvals, and patient recruitment.

Resources Needed

An organizational change such as the one planned, requires the support of administration, the Chief of Cardiology, cardiologists, and referring providers, as well as the support of information technology and medical assistants. Leadership champions such as Kevin McGovern, FACHE, Vice President of Operations at St Luke's University Health Network, and Raymond Durkin, MD, Network Chairman of the Department of Cardiovascular Medicine, have been instrumental in the development of a Lipid Clinic, of which this project is a component. Successful transformational leadership understands that "people need to be empowered to take charge of the design of their own learning and to alter their roles and behaviors in response to what they discover" (Porter-O'Grady & Malloch, 2015, p. 480). As visionaries, they are able to anticipate and plan for the changes in healthcare, based on recent statutes.

The 2009 Health Information for Economic and Clinical Health Act of 2009 (HITECH) Act was legislation passed by the Federal government that has brought about widespread use of health technology. This regulation financially incentivizes institutions for using electronic health records (EHR) as components of "meaningful use," whereby patient safety, quality and care coordination are enhanced and use of Clinical Decision

Support Systems (CDDS) are integrated into the EHR. The aim is to improve outcomes and quality, based on evidence based care (Murphy, 2014), as well as encourage patient engagement (Beaty & Quirk, 2015). Given this regulation, providers and institutions will be held accountable if process outcomes are substandard. In this fashion, population health and preventive medicine can be improved. The Clinical Quality Solutions (CQS) program by the Team Praxis available through St. Luke's Allscripts EHR provides a tool to identify populations of people with probable FH.

Regulatory efforts emphasize commitment to the cause. The Office of the National Coordinator for Health Information Technology (ONC) performs ongoing research and data analysis related to the use of health information technology (HealthIT). Case studies, data briefs and exemplar analyses are disseminated widely on a HealthITDashboard by the ONC (HealthIT.gov. 2015). Despite governmental regulations, it has yet to be firmly established that the promise of enhanced health IT will reduce costs, and improve quality (Sherer, 2014). Sherer (2014), a professor of Information Systems at Lehigh University, whose research interests include health IT, advocates for action designed research (ADR), using existing theory as a framework. Sherer suggests that traditional methods of research, in retrospective analyses, will miss opportunities for influencing current practice changes. She underscores the importance this work be accomplished in a multidisciplinary fashion, with economic experts, information technologists, providers, payers, and healthcare managers. Sherer's reflections are notable in this vastly changing environment of the Digital Age in healthcare. One needs to consider endpoints and economics.

Key stakeholders in the project are the cardiologists, referring providers and patients themselves. Patients have developed relationships with their usual providers and intrusion into that relationship can cause apprehension for some. Kennedy & Nordrum (2015), discuss the successes and barriers of population health management in a family practice setting. While it has been recognized that NPs provide cost-effective, quality care, patients remain loyal to their doctors. A call for managers and administrators to employ practice redesign to ensure NPs function at the highest level of their education, have been made by several authors (American Association of Nurse Practitioners, 2015; Bauer, 2010; Kennedy & Nordrum, 2015). The design of the proposed EBP is consistent with these goals.

Additional resources such as personnel support by the medical assistants and information technology experts are invaluable. The support of individuals familiar with the outpatient electronic health record will ease the burden of use by a new user, and will assist with printing of documents such as medication profiles, educational materials and lab requisitions. The Director of Allscripts Data Entry, Bonnie Smith, was instrumental in integrating all of the educational materials and inputting them into the electronic health record, centrally located, in a Lipid Care Guide. The need for integrating this information was supported by the Vice President of Operations of Cardiovascular Medicine, who facilitated meetings to accomplish this goal.

Budget Justification

There is no specific budget justification necessary for the implementation of this project. However, use of the electronic health record will generate the medication profile

and side effect list, as well as educational materials such as the diet instruction, and recommended lifestyle modifications. This will require paper and ink to print. These materials are expenses incorporated into general office visits of the practice, and will not contribute to excessive paper and ink, requiring a budget justification. Medical assistants function to help all providers, and electronic record support from Allscripts EHR are all part of routine office care.

Conclusion

The proposed EBP compares measurements of patients' lipids with probable FH, treated by an NP in collaboration with a lipidologist in a lipid clinic, to usual care. It is grounded on a chronic care model, with an emphasis on the use of integrated, evidence-based care using informatics.

Chapter Five: Implementation Procedures and Processes

An EBP vision was developed based on the clinical and personal experience of the investigator, which includes a strong interest in risk factors associated with the development of cardiovascular disease. Why young people in particular die from heart disease, stimulated further inquiry as well as certification in lipidology. An idea for a PICO-T question was subsequently developed. Would treatment of patients with excessively high lipids (probable FH) by a lipid certified NP, improve management, when compared to usual care? The premise was that the NP is specialized in lipid management, and that usual care refers to providers taking care of patients with a number of medical illnesses and concerns. Therefore, dedicated treatment to a modifiable risk factor would appear plausible, particularly based on the education and role of a doctorally prepared nurse practitioner. Therefore, a formal PICO-T question was developed: In non-pregnant adults aged 20 years old or greater, with a diagnosis of probable heterozygous familial hypercholesterolemia, would treatment in a lipid clinic by a nurse practitioner with a specialty in lipid management, compared to usual care, lead to improvement in the LDL cholesterol at the end of a 4 week period?

Setting

The patient selection is from St. Luke's University Health Network, a large in-patient and out-patient network, located in eastern Pennsylvania and western New Jersey (St. Luke's University Health Network, 2015). The Network consists of six hospitals, situated over 200 sites in two states. It has been named one of the top 50 cardiovascular

hospitals in the nation, and provides a comprehensive cardiac service line (St. Luke's University Health Network, 2015).

Population

Eligible patients were populated from the Clinical Quality Solutions (CQS) database, as previously described. Initially, inclusion criteria were non-pregnant adults, greater than 20 years old with an age-related LDL cholesterol cut off of ≥220, consistent with the MED PED criteria (Willams et al., 1993). Recruitment of the treatment group was difficult. Several patients were contacted, two were scheduled, and then subsequently cancelled. After consulting with lipid experts in the field of lipidology at a national lipid conference, reconsideration of the LDL cholesterol cut off criteria was performed. By general expert opinion, the EBP was being based on old criteria, the MED PED criteria (Williams, 1993). In 2001, an LDL cholesterol of ≥190 was considered very high, by the National Cholesterol Education Panel (NCEP) Adult Treatment Panel (ATP) III:

> *Very high LDL cholesterol (190 mg/dL).* Persons with very high LDL cholesterol usually have genetic forms of hypercholesterolemia: monogenic familial hypercholesterolemia, familial defective apolipoprotein B, and polygenic hypercholesterolemia (Third Report of the National Cholesterol Education Program (NCEP) Expert Panel on Detection, Evaluation, and Treatment of High Blood Cholesterol in Adults (Adult Treatment Panel III) final report, 2002, p. 17).

Given the most recent guidance from the International FH Foundation (Watts, 2014), the 2013 ACC/AHA Guideline on the Treatment of Blood Cholesterol (Stone et al., 2014), as well as the NLA FH Recommendations (Goldberg et al., 2011a), the LDL cholesterol cut point for this EBP was lowered to ≥190; rescreening then took place.

Steps to Implementation

There were several steps to consider in the planning phase, including creating a project vision, identifying a model of care and communicating regularly and collaboratively with information technology (IT). Notably, early in the planning phase of this EBP, a meeting was held with the EHR Director to trial run an acquisition of a population of patients with probable FH, without patient identifiers, or provider information. Based on this information, the project seemed feasible. Further, establishing a collaborative relationship with IT, enabled evidence based educational material regarding diet, exercise, and medical therapy, to be integrated into a Lipid Care Guide through the electronic record. At the completion of a patient encounter, this material could be printed for each patient, enhancing self-management.

Working with dieticians and fitness center personnel allowed the integration of community services, available at St. Luke's, into the full treatment algorithm. The process for referrals for medical nutrition therapy was streamlined and free coupon vouchers from the St. Luke's Fitness Centers were offered to promote regular physical activity. Integrating community resources into the treatment is consistent with elements of the Chronic Care Model, as suggested by Wagner et al., (2001). Most notably, identifying stakeholders and obtaining administrative support was integral to the

development of a new Lipid Clinic, not previously available at St. Luke's, of which this project is a component. Several cardiology office sites were offered throughout the network for clinic visits to accommodate patients' geographic location and to increase patient access to the provider.

The CQS program, by Team Praxis, identified through the Allscripts EHR, was the data source utilized to determine patient eligibility for both groups. The prospective group, which included patients to be treated by the NP, would emanate from St. Lukes' Cardiology Associates (SLCA), a subsidiary of the St. Luke's Network, where the NP is employed. Given that the NP functions in a team environment, this method would facilitate the informed consent process, while adhering to patient confidentiality, consistent with human subject research. In this fashion, a *Pursuit List* was queried from the *Quality* database of Allscripts. From a dropdown selection of the *Pursuit List*, *Cardiovascular Disease* was selected as a focus.

The selection criterion was further narrowed by selecting current cardiology providers, and excluding the two practicing lipdologists from SLCA. Columns of criteria were chosen to be included in the populated list. Inclusion criteria were the patient name, age, medical record number, attributing provider, and LDL cholesterol. From the inputted criteria, a population was created. The patients could then be sorted by populating the LDL in a descending list. However, at the time of implementation, that function was not working properly, therefore a manual search of 213 pages in the database was undertaken. Patients with an LDL-C $\geq$190 were obtained, and placed in a spreadsheet.

A similar approach was undertaken to obtain the comparison group, deselecting cardiology providers as inclusion criteria. The appropriateness of the identified patients was then ascertained, first by seeking permission from the patient's usual cardiologist to consider the patient for the EBP. Communication in this fashion was performed through *Tasking* in the individual patient's EHR. Some patients were excluded in this process, as not good candidates, per the usual cardiologist. Other patients were excluded who reside In New Jersey, as the provider is not licensed in that state. All appropriate patients were then called by the investigator personally, to invite the patient to participate. Overall, forty-six patients were screened, and 37 patients were contacted. Patients unable to be reached the first time, were phoned at a different time, in the evening, to enhance facilitation of successful communication. Additionally, patients unable to be reached in this fashion were mailed a letter. Therefore, three attempts were made to reach identified patients. Several patients who responded, declined. Others did not respond at all.

Comparison group patients were obtained in a similar fashion, excluding patient names, and any identifiers. Medical record numbers however, were included in order to reassess LDL levels in 4-12 weeks for comparison. Since comparison patients are not current SLCA patients, recruitment for a prospective project was not possible, given patient confidentiality and the informed consent processes.

Task List with Time Line- For specific dates of tasks, please see Appendix F.

Chapter Six: Evaluation and outcomes

Data Analysis

To review, the clinical question the EBP proposed to answer was: *In non-pregnant adults aged 20 years old or greater, with a diagnosis of probable heterozygous familial hypercholesterolemia, would treatment in a lipid clinic by a nurse practitioner certified in lipid management, compared to usual care, lead to an improvement in the LDL cholesterol at the end of a 3 month period?* An important consideration in analyzing the results, is an indicator of provider adherence to the guidelines. Therefore, results will analyzed to reflect provider adherence to rechecking lipids four to twelve weeks after initiating statin therapy, to assess for patient safety and adherence, as recommended (Stone et al., 2014). Further, the percent change in LDL-C will be assessed, with an ultimate goal, as established in the literature, "for adult FH patients (>20 years of age), drug treatment to achieve an LDL cholesterol reduction > 50% should be initiated" (Goldberg et al., 2011a, p.136).

Results

In consideration of provider adherence to the guidelines, and in reassessing patients' lipids four to twelve weeks after the initiation of statin therapy, the EBP change met this criteria 100% of the time. Contrastingly, in the comparison group, only 5% of the time, were lipids reassessed in four to twelve weeks. The minimum time frame lipids were rechecked after the first assessment, was four months, and the longest was two years. Given, it was assumed that if a provider checked a patient's lipids, and an LDL $\geq$190 were obtained, treatment was initiated. That is not absolutely known, however, but

certainly recommended. Further, to check the lipids and not to initiate therapy, is still not consistent with the guidelines. In summary, provider adherence to the guidelines in the comparison group, was strikingly low.

In the treatment group, four patients were enrolled. The first patient achieved a 22% LDL cholesterol (LDL-C) reduction on a non-statin product, over-the-counter red rice yeast, along with lifestyle modifications. Consistent with patient centered care, the patient was educated and advised regarding the recommended statin therapy, however the patient declined. A second patient achieved a 55% LDL-C reduction, a third patient, a 58 % reduction, and the fourth patient, a 39 % reduction, all on conventional statin therapy, as well as individualized lifestyle modifications, at four weeks. In summary, at 4 weeks 50% of the treatment group met the goal of an LDL-C $\geq$ 50%. It is anticipated that if the EBP project time frame were extended, one might see additional LDL reduction, given the short study period of four weeks.

In the comparison group, four of the 20 patients, 20%, had a documented reassessment of their lipids, anywhere from four months to two years after the first lipid profile was obtained. One patient's lipids were reassessed at 12 weeks, within the guidelines. Four of the five patients exceeded the recommended goal, a 50% reduction from their baseline LDL-C, while one patient's LDL cholesterol dropped 3%, over six months. In summary, of the 25% of the comparison patients who had a reassessment of their lipids at *any* time, one patient, .05%, had a reassessment of lipids within the recommended guidelines of four to twelve weeks. Four patients achieved an appropriate level of LDL-C reduction anywhere from four months to two years after the initial lipid

assessment. Given the few number of participants in the treatment group, as well as the few numbers of patients who had a reassessment of lipids in the comparison group, further statistical analysis between groups is not feasible.

Relationship of Results to Framework and Objectives

Results demonstrate a successful treatment strategy, designed to reflect a modern care model of a lipid certified NP practicing within a lipid clinic, to treat patients with high cholesterol levels. This strategy is consistent with prior research (Allen et al., 2002; Birtcher et al., 2010; Darves 2003; Shafer & Wexler, 1995). Further, the EBP meets all of the elements of the Chronic Care Model (Wagner, 1998a). These elements include self-management, the delivery design as described, decision support by the use of evidence based guidelines, and the integration of clinical information services. Additionally, the project was supported by the organization's administration. Community resources were offered, such as referrals to medical nutrition therapy and physical fitness centers. Finally, functional and clinical outcomes were measured by a percent change in LDL–C. These indices all reflect the Chronic Care Model.

"There are probably more than 15 million people with FH worldwide, but less than 10% have been detected and only 5% adequately treated" (Watts et al., 2014, p.153). The EBP demonstrates patient centered care, evidence of interdisciplinary team work, and evidence based practice, towards the ultimate goals of reducing population wide cardiovascular risk as well as individuals' risk. It is an example of input substitution, where the work of a cost-effective, quality NP can be substituted for the work of a physician, who can then be freed up to perform procedures and tasks for which

he or she is specifically trained (Bauer, 2010). Additionally, results demonstrate promise as a mechanism to increase patient adherence to therapies, although this was not specifically measured.

Recently, The Institute of Medicine (IOM) formulated a workgroup called the Committee on Core Metrics for Better Health at Lower Cost (IOM, 2015). The work was funded by the collaborative efforts of the Robert Wood Johnson Foundation, the Blue Shield of California and the California Healthcare Foundation, whose mission was to "promote the effectiveness of the measurement enterprise in the United States by identifying a parsimonious set of core metrics that deserve widespread implementation and to suggest how that implementation might occur" (IOM, 2015, Preface).

The recommendations of the Committee have been published by the Institute of Medicine and is titled *Vital signs: Core metrics for health and health care* (IOM, 2015). The Committee developed 15 core measures that constitute the *vital signs* of the health of the nation. Applicable to this EBP project are the following IOM core measures: (a) preventive services, (b) care match with patient centered goals, (c) individual engagement, and (d) evidence based care (IOM, 2015). Further, related priority measures have been developed, which include cardiovascular risk reduction. In the future, the use of the core measures may be integrated into the government's EHR incentive program as Meaningful Use metrics and be compared to benchmarked goals, as a measurement of preventive care. As a successful treatment strategy to improve patient's lipids, the EBP is in alignment with the latest IOM recommendations to improve

population health, specifically reducing cardiovascular risk, by adhering to guidelines and measuring LDL cholesterol reduction.

Chapter Seven: Implications for Nursing Practice

Implications for Nursing Practice

The proposed EBP project is consistent with the goals established of a DNP: "practice-focused doctoral programs are designed to prepare experts in specialized advanced nursing practice" (American Association of Colleges of Nursing, 2006, p.3). In addition, it is consistent with the American Association of Colleges of Nursing Position Statement established on DNP preparation: to cultivate needed competencies for advanced clinical practice, enhance knowledge to improve nursing practice, and to prepare advanced practice nurses to provide evidence based care to improve patient outcomes (American Association of Colleges of Nursing, 2004).

Strengths and Limitations

There were several limitations of this project. Initially, the project was designed for two groups of patients with probable HeFH, with an age-related LDL cholesterol cut-off of a minimum of 220 in the general population (age >20), based on U.S.MED PED criteria, one of the many ways of identifying this cohort clinically. Patient recruitment, however, was difficult. Many of the patients were already being treated by one of the two lipidologists in the practice. Further, these patients are often young, and working. They generally feel well, and may not see the benefit of seeing another provider to treat a medical issue that they may not recognize as significant. Therefore, an adjustment was made in the inclusion criteria, with an LDL cholesterol minimum cut-off of $\geq$ 190, based on the guidance from the International FH Foundation (Watts et al., 2014), as well as the 2013 Guidelines on the Treatment of Blood Cholesterol (Stone et al., 2014) and the

National Cholesterol Education Program Adult Treatment Panel III (Third Report of the National Cholesterol Education Program Expert Panel on Detection, Evaluation, and Treatment of High Blood Cholesterol in Adults, 2002).

The fact that there are a number of ways of identifying patients with either probable, possible, or definitive FH is problematic, in discerning the most appropriate criteria for patient recruitment in a project of this sort. Given this, one might wonder how a diagnosis of FH would change treatment. A diagnosis of FH would suggest cascade screening of family members, as it is a genetically transmitted disorder. Providers then could make a more robust impact on population health. In addition, a diagnosis of FH may enhance patient adherence to therapy, as FH is known to increase cardiovascular risk and premature heart disease. Ultimately, a population with an LDL $\geq$ 190 carries a high lifetime cardiovascular risk, constitutes severe hypercholesterolemia and probable FH, and therefore should be treated aggressively (Stone et al, 2014, Watts et al., 2014).

The time frame of the project was shortened due to an unanticipated late IRB approval from Misericordia University, as well as the need to readjust the inclusion criteria, and screen for patients a second time. Due to these issues, the time frame of the project was shortened from twelve weeks to four. Notwithstanding the brevity, based on the ACA/AHA Blood Cholesterol Guidelines, it is recommended that one should recheck LDL cholesterol levels anywhere from four to twelve weeks after initiating statin therapy, to assess for adherence and patient response (Stone et al., 2014). Therefore, four weeks was felt to be an acceptable time period for the treatment group.

The current EHR is a limitation. At the time of patient selection, the Allscripts dashboard was not functioning appropriately. The LDL column could not be populated in a descending fashion. Therefore, patient selection was performed manually, and 213 pages of patient data were reviewed. Further, the inpatient and outpatient EHR systems do not cross talk. This makes data collection cumbersome and potentially unreliable.

Several scheduling issues were evident. The timing of the year was a limitation. Some patients stated they could not participate because they were traveling to other parts of the country for the summer, and would be gone for a number of weeks to months. Others found transportation issues difficult, as St. Luke's encompasses a large geographic network, covering six hospitals in two states, and many patients did not desire to travel a great distance to be treated. To ameliorate access issues and enhance patient participation, multiple site locations for the project were offered.

Overall, patient participation was a significant barrier. Whether due to feeling well, traveling for the summer, noting prior statin intolerance, access issues, or general lack of desire, participation was low. A limitation was the small sample size of the treated group. Perhaps these responses represent the community at large; this may contribute to the status of the population's cardiovascular health, as noted by the CDC and U.S. DHHS (CDC, 2014a; U.S. DHHS, 2015).

A significant strength of the project is the impact that an NP lipid specialist can make on reducing cardiovascular risk. Results of Cholesterol Treatment Trials (CTT) meta-analyses have demonstrated "that each 39mg/dL reduction in LDL-C with statin therapy reduced ASCVD events by 22%, and the relative risk reductions in ASCVD

events were consistent across the range of LDL-C levels" (Stone et al., 2014, p. 24). Therefore LDL cholesterol reduction of this magnitude can positively impact both individuals' lives, as well as improve population health.

The model of team-based care demonstrates strength of the project as well. An organizational change in a model of care that has been described cannot be undertaken without the support of administration and the department chief. Further, the encouragement from physician colleagues was welcoming and quite supportive. The described EBP, of an NP performing disease management in a lipid clinic is consistent with an example of cardiovascular team-based care, as discussed in the 2015 Team-Based Care Health Policy Statement by the ACC (Brush et al., 2015).

Linkage to DNP Essentials

Elements of the proposed EBP meet all Eight of the Essentials of Doctoral Nursing Practice (AACN, 2006). The Essentials are listed below, noting how the elements were met.

- I. Scientific Underpinnings for Practice. The project is evidence based, with a scholarly review of the literature and supported by the Chronic Care Model.
- II. Organizational and Systems Leadership for Quality Improvement and Systems Thinking. The project exhibits an organizational change of care delivery for lipid patients. In addition, it showcases an exemplar of team-based care.
- III. Clinical Scholarship and Analytical Methods for Evidence-Based Practice. A scholarly review and critical appraisal of the literature was performed focusing on new knowledge from recent guidelines and recommendations.

- IV. Information Systems/Technology and Patient Care Technology for the Improvement and Transformation of Health Care. The project demonstrates strong integration of interdisciplinary work with information technology integrating evidence from the 2013 Lifestyle Management Guidelines and recommendations for treatment of severe hypercholesterolemia and probable HeFH into the EHR. Population samples were derived from a data source through the EHR.
- V. Health Care Policy for Advocacy in Health Care. The project exhibits conformance with the 2015 American College of Cardiology (ACC) Health Policy Statement on Cardiovascular Team-Based Care and the Role of Advanced Practice Providers (Brush et al., 2015). As all patient material is available in several languages, the project provides a mechanism to decrease health disparities.
- VI. Interprofessional Collaboration for Improving Patient and Population Health Outcomes. The project was a culmination of work with stakeholders, administration, physician colleagues, dieticians and fitness experts.
- VII. Clinical Prevention and Population Health for Improving the Nation's Health. The project demonstrates evidence that an advanced practice nurse can improve outcomes, and therefore is capable of improving the cardiovascular risk of patients and a population with severe hypercholesterolemia. As a pilot, it is a model for organizational change.

- III. Advanced Nursing Practice. The project demonstrates the role of a DNP, functioning in an area of specialization, working in an interdisciplinary team, to improve the cardiovascular health of individuals and a population with severe hypercholesterolemia.

Chapter Eight: Summary of Project and Conclusions

Given that heart disease remains the number one killer of Americans, and that hypercholesterolemia, as a known modifiable and treatable risk factor, is underdiagnosed and undertreated, the proposed EBP change was examined to determine if a nurse practitioner certified in lipid management could improve patients' lipids, over an established time period, compared to care provided by non-lipid certified providers. Familial hypercholesterolemia (FH) affects young people with an associated high lifetime cardiovascular risk, therefore, the population was selected as a personal choice, as treatment can afford a considerable beneficence on patients' lives, as demonstrated in the literature.

The EBP change is well supported. The NLA, as a specialty organization, poses several resources for the diagnosis, screening, and treatment of FH, among all other dyslipidemias, and is a valuable aide. Other organizations, such as the AHA/ACC and the International FH Foundation, provide similar guideline evidence for the diagnosis of FH. However, the number of ways one can characterize a patient as probable, possible, or definite FH can be ambiguous to the novice. As discussed, the National Cholesterol Education Program/ Adult Treatment Panel III (NCEP ATP III) in 2001, established that an LDL-C $\geq$190 was consistent with probable FH, and should be aggressively treated as such, to decrease one's lifetime risk for vascular events. For the purpose of population health, this is an accepted cut point for the diagnosis, as reinforced by multiple organizations in the literature.

Recommended strategies for treatment of FH are well documented. The ACC/AHA provide strong evidence and recommendations for lifestyle management for LDL cholesterol reduction, both in terms of diet and exercise. Ample evidence exists regarding the benefits of treatment with statins, and more recently, ezetimibe (Zetia). Additionally, the role of an NP managing patients in a lipid clinic is in alignment with the role of an advanced practice provider functioning as a member of team-based care, as conveyed by the most recent 2015 ACC Health Policy Statement on Cardiovascular Team-Based Care and the Role of Advanced Practice Providers (Brush et al., 2015). Further, the practice of an NP managing patients in a lipid clinic has been established by published literature as well.

Dissemination Plans

This EBP will be disseminated by presentation to a population of cardiovascular nurses, as well as other interested healthcare personnel, at a hospital network cardiovascular symposium in the fall of 2015. It will also be presented at a cardiovascular educational meeting, attended by cardiologists, fellows, residents and advanced practice providers. Further, it may be submitted to *The Journal of Cardiovascular Nursing*, which is the official journal of the Preventive Cardiovascular Nurses Association (PCNA), either as a model of a pilot, or as a presentation of 4 patient case studies. Alternatively, and more likely, however, the EBP will be continued, as an organizational change as described in

the next section, with additional data collection and subsequent delayed submission for publication.

Future ideas or next steps related to project

As an organizational change, the EBP will be continued. This process has had the support of both administration as well as the Department Chief. Pending submission and acceptance of a new IRB application to St. Luke's IRB, additional patients will be recruited and data will be collected, to assess effects of implementing the change on a more widespread level. Given the nature of the Network's geographic location of over eight counties and 60 miles, the hours and location of the Lipid Clinic will be expanded to additional sites. Increasing provider access and clinic hours will facilitate additional patient recruitment for the project. Further, Network cardiologists will be reeducated about the availability of the Clinic, the expanded hours, and additional site offerings, to increase in-house referrals and patient recruitment of this population.

Results also demonstrate a need for provider education to enhance adherence to evidence based practice and implementation of the guidelines. The difficulty in patient recruitment likely represents an area for additional patient education as well, to reinforce the high lifetime cardiovascular risk that FH patients carry, and to reiterate the need for early and aggressive treatment. Additionally, results infer a need to increase FH awareness globally, which has been advocated for by the NLA.

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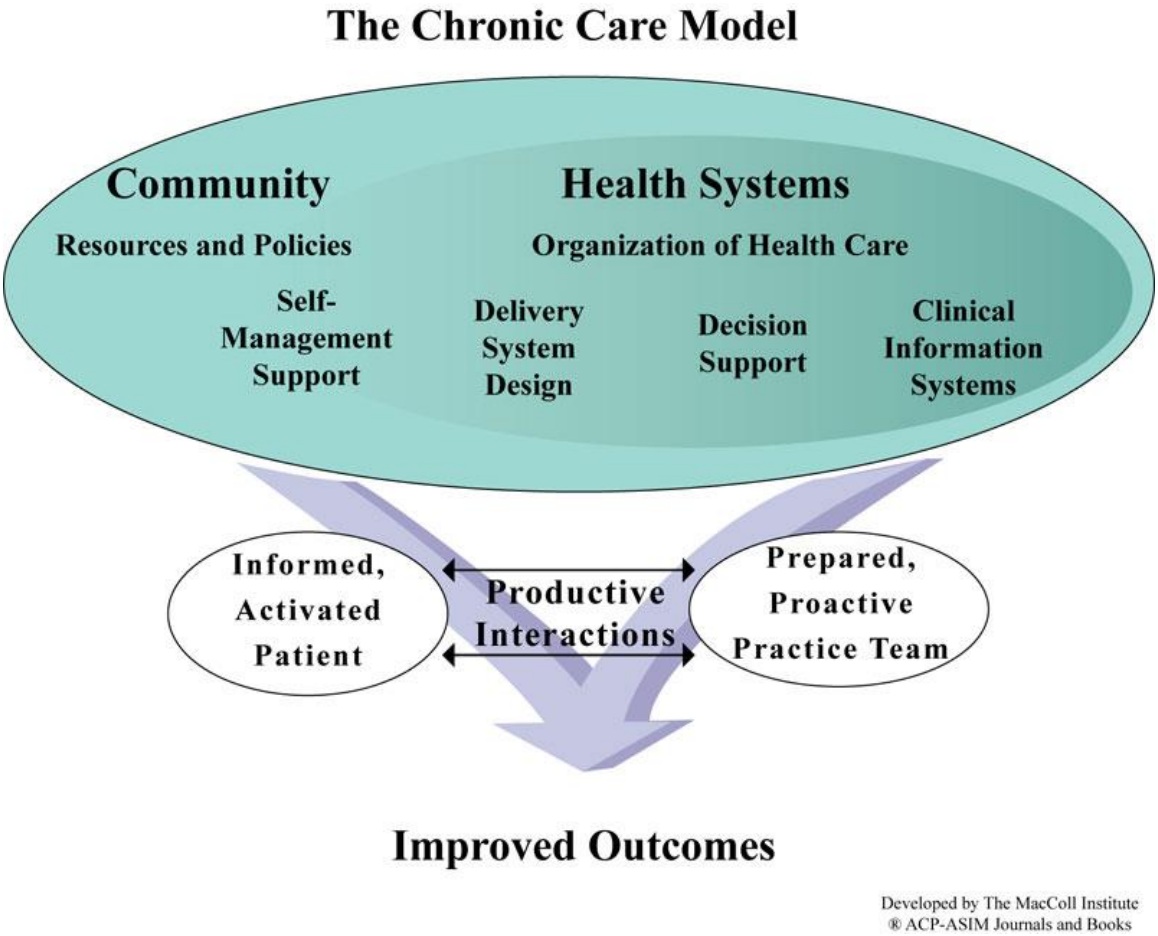
Appendix A



Developed by The MacColl Institute, © ACP-ASIM Journals and Books, reprinted with permission from the American College of Physicians.

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Appendix B

From: Murtaugh, Holly
Sent: Monday, February 16, 2015 9:00 AM
To: Weidner, Carla
Subject: FW: Documents have been IRB reviewed: SLHN 2015-10 IRB No.: SLHN 2015-10
Please see below. The IRB study you submitted titled "Lipid Management of Patients with Probable Familail Hyperlipidemia" (SLHN # 2015-10) was reviewed and deemed exempt from IRB Review.
**Please note this is the only notification you will receive from the IRB Office regarding this study **
From: do_not_reply@ddots.com [mailto:do_not_reply@ddots.com]
Sent: Tuesday, February 10, 2015 3:38 PM
To: Murtaugh, Holly
Subject: Documents have been IRB reviewed: SLHN 2015-10 IRB No.: SLHN 2015-10

An event for Protocol SLHN 2015-10 has been marked as having completed review.
Local ID: SLHN 2015-10
Protocol: SLHN 2015-10
Type of Submission: New Studies
IRB Meeting Date: 03/03/2015
Action: Not Approved
Reviewed By: Exempt
Action Date: 02/10/2015
Agenda: new study - IRB Exemption

Studies involving prospective data collection are not exempt. Please revise study dates and re-submit as retrospective, or submit as prospective for full board review. Full board review will require different submission form.

List Documents and Comments for each Document:
Download File: slhn 2015-10 - application & exempt request form.pdf
Download File: slhn 2015-10 - article and cvs.pdf
Download File: slhn 2015-10 - icf form.pdf
Download File: slhn 2015-10 - protocol.pdf

Review Completed By: Stawicki, Stanislaw P.
Completed Date: 02/10/2015

Email sent to: Murtaugh, Holly; Pytlewski DO, Gerald Confidentiality Notice: This e-mail message, including any attachments, is for the sole use of intended recipient(s) and may contain confidential and privileged information. Any unauthorized review, use, disclosure or distribution is prohibited. If you are not the intended recipient, please contact the sender by reply e-mail and destroy all copies of the original message.

Appendix C

StLuke\s
UNIVERSITY HEA TH NETWORK

Stanislaw P. Stawicki, M.D.,F.A.C.S.
Chair, Department of Research & Innovation
Medical Director, Institutional Review Board
Associate Professor, Temple University School of Medicine
NW2 Admin ., 801 Ostrum Street, Bethlehem, PA 18015

DEPARTMENT OF RESEARCH & INNOVATION

January 23, 2015

To Whom It May Concern,

This letter is in support of a Misericordia University Doctoral Research Project proposed by Ms Carla Weidner. The project's title is *Lipid Management of Patients with Familial Hypercholesterolemia by a Nurse Practitioner.*

Ms Weidner is well qualified to conduct the proposed project, and has formed a research team that includes one of the foremost area experts in the field of lipidology, Dr. Gerald Pytlewski.

I recommend, without reservations, that the project be considered favorably by the Misericordia University Doctorate of Nursing Practice (DNP} faculty. Please do not hesitate to contact me with any questions or concerns.

Sincerely,

Stanislaw P. Stawicki, M.D., F.A.C.S. Chair,
Department of Research & Innovation Medical
Director, Institutional Review Board
Associate Professor, Temple University School of Medicine NW2
Administration
801 Ostrum Street
Bethlehem, PA 18015
Phone (484) 526-4426
Email: stanislaw.stawicki@sluhn.org

Appendix D

MISERICORDIA UNIVERSITY.

May 13, 2015

Carla Weidner, MSN

Brenda Hage, Ph.D. Nursing Department Misericordia University Dallas, PA 18612

Dear Ms. Weidner and Dr. Hage:

Thank you for submitting the modifications to your IRB application, *Lipid Management of Patients with Probable Familial Hypercholesterolemia by a Nurse Practitioner,* number 13-15-Tl . Your study is now approved by the IRB.

As part of the approval, the IRB has received and accepted the consent form as submitted. The attached consent form with a valid period of eligibility is the only consent form to be used. Any modifications must be approved by the IRB. The date stamp indicates the eligible period.

You will be reminded one month prior from the expiration date of your research protocol to complete an End-of-Project Report. You also have the responsibility to notify the IRB of any changes in the conduct of this study or injury to study subjects and to retain all approved application documents and signed consent forms for a minimum of three years following completion of the study (this includes student research). Please refer to the IRB Policies and Procedures document for specific details on what is expected.

Ifyou have any questions, please feel free to contact me. Sincerely,

McKinley H. Manasco, Ph.D. Chairperson, IRB

Appendix E

St. Luke's University Health Network

Department: Cardiology

Principal Investigator: Carla Weidner, MSN CRNP **Telephone**: 484-503-0600

Co-Investigator(s): Gerald Pytlewski DO **Telephone**: 610- 435-5913

Medical Title: Lipid Management of Patients with Probable Familial Hypercholesterolemia by a Nurse Practitioner

Lay Title: Lipid Management of Patients with High Cholesterol by a Nurse Practitioner

Sponsor: Misericorda University

You are being asked to take part in a medical research study. As required by federal regulations, this research study has been reviewed and approved by an Institutional Review Board (IRB), a committee that reviews, approves and monitors research involving humans. Before you can make a decision about whether to participate, you should understand the possible risks and benefits related to this study. This process of learning and thinking about a study before you make a decision is known as *informed consent* and includes:

- Receiving detailed information about this research study;
- Being asked to read, sign and date this consent form, once you understand the study and have decided to participate. If you don't understand something about the study or if you have questions, you should ask for an explanation before signing this form;
- Being given a copy of the signed and dated consent form to keep for your own records.

Study Purpose and Procedures

You are being asked to participate in this clinical research study by donating a sample of your blood. The blood sample will be used for the following:

Purpose of the Study:

Significantly elevated blood cholesterol levels can be hereditary, and is one of the risk factors for
Hardening of the arteries, or atherosclerosis. Untreated, or inadequately treated blood cholesterol can promote the formation of heart disease. National agencies have done studies indicating there are a lot of people with cholesterol numbers that are too high. Strategies to improve people's blood cholesterol have been explored. This study will

compare patient's blood cholesterol treated by a nurse practitioner to patient's blood cholesterol treated by their usual provider, or doctor.

Description of the Study:

Patients who obtain blood work at any St. Luke's network facility review and sign a General Consent form prior to their blood being drawn. Line item 3 reads:

- I authorize the facility to use and disclose my health information: (1) to other health care professionals who are involved in my treatment, either now or in the future.

Within the realm of this permission, it has been identified that the blood work you recently had drawn showed blood cholesterol levels that were elevated.

In this study, there will be 2 groups of 20 patients each. One group will be cared for by their usual provider, or doctor. The other will be cared for by me, a nurse practitioner. Each group will receive the same standard care that is available for patients with high cholesterol. At the end of 12 weeks, all patients will have their fasting blood cholesterol levels rechecked, which is a part of the routine standard care. A comparison will be made in the percent change from baseline to 12 weeks. No other data will be collected or examined.

You have been told that, as a participant in this study, you will have blood drawn. The amount of blood drawn will be about one teaspoon.

You will be in this study for two blood draws over a period of 12 weeks.

What Are the Risks of Drawing Blood?

You have been told that certain risks may be associated with the drawing of blood. The known risks are discomfort as the needle is inserted, bleeding, bruising and discoloration around the site of the blood draw, infection at the site, and, rarely, fainting. Risks will be minimized by having the blood drawn by an individual who is trained to perform this procedure.

Are there benefits to me for being in this study?

You will not personally benefit from taking part in this study. However, the information gained may be of benefit to society in general or to certain individuals in the future.

Confidentiality

Care will be taken to preserve confidentiality of all protected health information (PHI) collected about you during the course of this study. PHI is information such as your name, address, social security number and any other information that could identify you personally. PHI that is collected for this study may be reviewed by the researchers at St.

Luke's University Health Network who are conducting this study, the Institutional Review Board (IRB), and appropriate offices of St. Luke's University Health Network. You are also allowing the research team to share your PHI with your health insurance company (if necessary for billing for standard medical care).

In addition, the following organizations or individuals may request and will be given access to your PHI: None

Certain information about you and your blood will be kept in the study records. This includes the following:
Cholesterol numbers

Identifiers will not be maintained with this data, and there will be no way to link it to you.

This information will be kept in a locked filing cabinet or password-protected computer database, and only the investigator and his or her research team will have access to this information. This information will be kept indefinitely.

The information from this study may be published in scientific journals or presented at scientific meetings but you will not be personally identified in these publications and presentations.

You will not be told of the research results obtained using your blood sample unless the research tells us important information about your health. In this case, we will ask for your permission to inform your personal physician. You will be asked to sign a separate authorization for this.

You may revoke this authorization to use and share your PHI at any time by contacting the principal investigator, in writing, at: weidnerc@misericordia.edu or Carla Weidner NP, St. Luke's Cardiology, 1700 Riverside Circle, Suite 301, Easton, PA 18045

If you revoke this authorization, you will no longer be able to participate in this research study, and the future sharing of PHI will be stopped. However, the PHI that has already been collected and shared may still be used.

Will I be Paid for Being in the Study?

You will not be paid for your blood sample.

In addition, you will not be paid if inventions and/or patents are developed from the blood you provide for this study or the study results.

What is my Alternative to Participation?

This study does not involve treatment, and provides no benefit to you. Your alternative is not to participate in this study.

Will I be told about any new findings?

Anything learned during the study, beneficial or not, that may affect your health or your willingness to continue in the study, will be told to you and explained.

Who Should I Contact if I Have Any Questions or Concerns?

If you have questions related to your rights as a participant in a research study, you may call the St. Luke's University Health Network Institutional Review Board (IRB) at 570-674-1483.

If you have any questions about the study, or problems or if you feel you have experienced a research-related injury as a result of being in this study, you may call Carla Weidner NP at 484-526-0600 or Dr. Pytlewski at 610- 435-5913.

In the event that you experience a research-related injury, comprehensive medical and/or surgical care (including hospitalization) to the extent needed and available will be provided. However, St. Luke's University Health Network cannot assure that this comprehensive medical and/or surgical care will be provided without charge. The costs will be billed to your insurance carrier but they may ultimately be your responsibility. A research-related injury is a physical injury or illness resulting to you as a direct result of the experiments, treatment(s) and/or procedure(s) used in this study that are different from the medical treatment you would have received if you had not participated in this study.

Are There Costs to me for being in this Study?

There is no cost to you for participating in this research. If you receive a bill that you think is wrong, please discuss it with the study investigator/clinician or coordinator.

Voluntary Consent and Subject Withdrawal

You voluntarily consent to be in this study by providing a sample of your blood. You have been told of the possible risks that might occur, and you are aware that you will not benefit from your participation in this study.

You may refuse to participate in this investigation, and this will not affect your future medical care at St. Luke's University Health Network.

You may discontinue study participation without penalty or loss of benefits to which you are otherwise entitled and without affecting your future care at St. Luke's University Health Network.

By your agreement/your permission to participate/ in this study, and by signing this consent form, you are not waiving any of your legal rights.

You affirm that you have read this consent form. You have been told that you will receive a copy.

_____
Your Name *(please print or type)*

_____ _____
Your Signature Date

_____
Name of Person Conducting Consent

_____ _____
Signature of Person Conducting Consent Date

Appendix F

Task List Timeline

Project component	**Date of completion**
Developed an evidence based practice (EBP) vision and identified a mentor	9/8/14
Site visit with a Lipid Clinic in Berkely Heights, N.J.	9/25/14
Administrative Strategic Planning meeting for the Lipid Clinic	10/17/14
Initial meeting with staff from electronic health records (EHR); discuss population screening and plans for integrating educational materials into EHR	10/18/14
Submitted a final PICO-T question	10/18/14
Administrative Strategic Planning meeting for the Lipid Clinic	10/22/14
Identified patient educational material to be incorporated into the EHR	10/23/14
Completed the NIH program "Protecting Human Research Participants" and obtained a certificate of completion.	11/4/14
Met with Network Service Line Administrator and Supervisor of EHR to discuss integration of patient education materials into a Lipid Care Guide	11/12/14
Submitted final table of evidence /literature review to support the PICO-T	11/15/14
Met with Supervisor of the EHR to discuss implementation of the Lipid Clinic Care Guide and to again discuss EHR screening of the EBP population	11/21/14
Received formal letter of support from St. Luke's Network for EBP	1/23/15
Submitted Chapter I: Introduction	2/2/15
Obtained signature support from key stakeholders for IRB submission	2/6/15

Received IRB approval from St. Luke's University Health Network	2/16/15
Submitted Chapter II: Review of the Evidence	2/22/15
Attended St. Luke's Network EHR workshop	3/2/15
Submitted Chapter III: Organizational Framework	3/3/15
Received IRB approval from Misericordia University	5/13/15
Accessed the CQS Quality Dashboard through the EHR, to ascertain a comparison group of patients	5/27/15
Continued to seek eligible patients for the EBP	process began 6/01/15
Submitted Chapter IV: Project Design	5/31/15
Submitted Chapter V: Implementation Procedures and Processes	6/10/15
Planned implementation of the practice change	6/24/15
Submitted Chapter VI: Evaluation and Data Analysis	7/24/15
Submitted Chapter VII: Implications for Nursing Practice, Strengths and Limitations and Applicability to the Eight DNP Essentials	6/22/15
Project end	7/31/15
Measure clinical outcomes	7/23/15
Analyze outcomes	7/23/15
Submitted Chapter VIII: Summary and Plan for Dissemination	7/28/15