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Use of structured educational program to improve patient's adherence to lipid-lowering medication

A Scholarly Project Presented to the Faculty of the
Nicole Wertheim College of Nursing and Health Sciences

Florida International University

In partial fulfillment of the requirements
For the Degree of Doctor of Nursing Practice

By

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Date: _____

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Abstract

Medication adherence has been defined as the process by which patients take their medications on how they are prescribed (Ruppar et al., 2015). Medication nonadherence has become a critical healthcare issue. Several interventions have been tried to increase adherence. Therefore, the objective of this review is to assess if a structured educational program directed to providers and staff could increase medication adherence among patients who are prescribed lipid-lowering medications for primary and secondary prevention of cardiovascular disease. The gathered evidence led to the development of a quality improvement project. Three databases were screened to answer the clinical question, and six articles were included in the review. The educational programs ranged from 90 minutes of training up to 2-day educational sessions. The programs included scientific updates, clinical guidelines, feedback, and communication skills. Five out of the six studies found a significant increase in medication adherence after the intervention. Even when different approaches were used, it is feasible to create an educational program targeting providers and their staff to increase lipid-lowering medication adherence. A Quality Improvement (QI) project was implemented in a local Primary Care practice. The project was designed as a pre-post intervention survey. The purpose of the QI was to increase the skills and awareness of the provider's staff to increase the patient's adherence to lipid-lowering medication. After the educational intervention, there was an improvement in staff knowledge, awareness, and skills to assess, educate, and engage patients to promote patients' adherence to lipid-lowering medication. More research is needed to prove the efficacy of different types of intervention targeting providers over medication adherence in other chronic conditions.

Keywords: medication adherence, lipid-lowering medication, providers, educational intervention

Introduction

Background

Hypercholesterolemia has been recognized as a significant risk factor for cardiovascular disease. Total serum cholesterol below the 200 mg/dl is considered one of the critical elements of good cardiovascular health. However, more than 28 million adults in the United States have serum cholesterol over 240 mg/dl (Benjamin et al., 2019). The United State Preventive Services Task Force (USPSTF) recommends that adults with more than one risk of developing cardiovascular disease (CVD) from 40 to 76 years old, and with a greater than 10 % in the 10-year risk assessment of cardiovascular events should be on statins for primary prevention (USPSTF, 2016). Moreover, the American College of Cardiology (ACC) recommends the use of high-intensity statins therapy for secondary prevention on patient younger than 76 years old that have a clinical CVD (Grundy et al., 2019).

Statins and other lipid-lowering medications have been commonly used for both primary and secondary prevention, yet, patient's nonadherence usually deters the role of statins. Nonadherence to medicine is a prevalent issue with a diverse range of negative consequences. Between 30% to 50% of patients with chronic conditions such as diabetes and hypertension do not take the medications as prescribed. Studies have demonstrated that after the first year of treatment, about half of the patients stop using them, and it is estimated that by the second year, only 25 % of the patients continue been adherent (Rash, Campbell, Tonelli, & Campbell, 2016). In the United States, medication nonadherence is considered a significant public healthcare problem. About half of the patients with chronic diseases are nonadherent, and it is estimated that more than \$100 billion are spent on issues associated with poor medication adherence (Kini & Ho, 2018).

Medication adherence is a complex process that involves elements from both the patients and the providers (Kini & Ho, 2018). Several factors have been associated with statins and other lipid-lowering medication discontinuation, for instance, low socioeconomic status and high copayments. Likewise, factors such as side effects, low self-efficacy, statins used for primary prevention, or depression, increase the rate of withdrawal (Rash, Campbell, Tonelli, & Campbell, 2016). Patient's self-care characteristics, beliefs, socioeconomic status, or health literacy are associated with the patient's discontinuation of treatment (Rash, Campbell, Tonelli, & Campbell, 2016). Additionally, complex prescription regimes, inappropriate follow up, inadequate patient-provider relationships, weak communication, and lack of patient-centered care can also deter the adherence process (Hickson et al., 2017).

Different approaches to assess medication adherence includes self-report, pharmacy claims for refills, and electronic drug monitors (Kini & Ho, 2018). In some instances, serum levels of cholesterol, triglycerides, and low-density lipoproteins (LDL) could be a good indicator of medication adherence (Deichmann et al., 2016). However, one prevalent issue is the lack of a standard tool to measure nonadherence and lack of consistent interventions (Van Driel et al., 2016). Several initiatives have been proposed to increase patient adherence. For instance, improvement of patient/provider relationship, follow up guidelines, generating clinical pathways to guarantee appropriate decision-making, strengthening of healthcare delivery, adequate follow-up, simplification of medical regimen, and the use of technology (Lee et al., 2016).

Even when different interventions have been implemented, only complex interventions that included active provider involvement and close patient follow up demonstrated significant improvement (Van Driel et al., 2016). Moreover, a study designed to evaluate the effect of

financial incentives on lipid levels shown that only when physicians and patients shared incentives, a significant reduction on the lipid levels was achieved (Asch et al., 2015).

Rationale

Primary care providers play an essential role in the assessment, management, and treatment of hyperlipidemia for primary and secondary prevention of cardiovascular disease. Proper communication between providers and patients can have a positive influence on patients' adherence to different medication regimens, especially when managing chronic conditions. The likelihoods of poor medication adherence are significantly higher when patient-provider communication lacked focus on the discussion about medication, patients' preferences, and patients' psychosocial characteristics (Schoenthaler, Knafl, Fiscella, & Ogedegbe, 2017).

Provider-patient communication is considered an essential reason why a vast number of patients become nonadherent (Brinton, 2018). The Understanding Statin Use in America and Gaps in Education (USAGE) survey exposed how poor communication leads to a lack of patients' understanding of the benefits of statin use, becoming a crucial factor in patient's discontinuation of treatment (Brinton, 2018). Interventions at the patient, provider, and health system levels tend to have a positive effect on the management of cardiovascular events. Hence medication adherence becomes an essential issue when considering primary or secondary prevention.

Several studies agree that providers should assess adherence in every encounter and that lack of patient-provider communication is a negative factor in the process of adherence (Ruppar et al., 2015). Nevertheless, the lack of consensus on how to address nonadherence and the absence of a definite clinical guideline could affect the effectiveness of the provider's role. Some studies suggest different strategies to approach this subject. In some instances, educational and

behavioral approaches have been successful. Besides, other studies provide recommendations to improve patient-provider communication, not only addressing the patient but also the providers. However, there is not a single algorithm that could aid providers to discuss nonadherence topics (Ruppar et al., 2015).

Nevertheless, the collaboration between patients and providers toward a common goal is more effective than individuals' efforts. Providers play a crucial role in shaping patients' attitudes and beliefs regarding self-efficacy, medication adherence, and chronic disease management. Lack of practitioners focus on adherence issues at the time of prescribing, and their positions regarding statin therapy and nonadherence management are known to affect patients' adherence negatively (Barfoed et al., 2016).

Prior systematic reviews have shown that quality improvement projects can be useful to manage chronic conditions and to improve medication adherence in patients with cardiovascular events (Lee et al., 2016). Changes at the patient/provider relationship include abiding by the guidelines or creating clinical pathways to ensure appropriate decision-making, intensification of healthcare delivery, proper follow-up, simplification of medical regimen, and use of technology (Lee et al., 2016).

Objective

The purpose of this review is to assess if a structured educational program directed to providers and the staff could increase medication adherence among patients who are prescribed lipid-lowering medications for primary and secondary prevention of cardiovascular disease. The objective of the systematic review is to gather evidence for the development of a quality improvement project (QI). The goal is to increase patients' adherence to lipid-lowering medication through a structured intervention targeting primary care providers and their staff as

well as identify tools and guidelines that could be implemented in the primary care setting to improve patient adherence.

Methodology

Information sources

After formulating the clinical question and determined the PICO concepts, a preliminary literature review was performed. Three different electronic databases were screened: Medline ProQuest, Embase, and the Cumulative Index of Nursing and Allied Health Literature (CINAHL). Embase produced a higher number of articles; however, most of the reports did not include some elements of the clinical question. Hence, Medline ProQuest was the primary database regarding the number of useful articles after the initial screening with the features of the PICO question.

Search strategy

The screening process used the concepts of "medication adherence," "lipid-lowering medication," and providers to answer the elements of the clinical question. Other terms were included, such as "medication compliance," "drug adherence," "medication nonadherence," or noncompliance, statins, physicians, "general practitioners," "advanced practice nurses," and "nurse practitioners." The use of Boolean operators, MeSH terms, CINAHL headings, and Emtree were included in the research phrases to identify the studies addressing the impact of an intervention on medical providers on lipid-lowering medication adherence.

Each database was screened using the keywords and the specific Boolean operators to increase the possible items to be considered. In Medline ProQuest, MeSH terms were added to the research keywords as follow:

Medline ProQuest: (Adher* or complian* or comply or noncomplian* or nonadher* or MESH.EXACT("Medication Adherence") or MESH.EXACT("Patient Compliance")) AND (MESH.EXACT("Hydroxymethylglutaryl-CoA Reductase Inhibitors") or MESH.EXACT("Rosuvastatin Calcium") or MESH.EXACT("Atorvastatin") or MESH.EXACT("Simvastatin") OR MESH.EXACT("Ezetimibe, Simvastatin Drug Combination") or "lipid-lowering medication*" or "lipid-lowering drug*" or statin* or Crestor or Lipitor or simvastatin) AND (MESH.EXACT("General Practitioners") OR MESH.EXACT("Family Nurse Practitioners") or MESH.EXACT("Health Personnel") or MESH.EXACT("Nurse Practitioners") or MESH.EXACT("Nurses") or MESH.EXACT("Medical Staff") or provider* or "general practitioner*" or physician* or nurse* or doctor* or "medical staf*").

The CINAHL database was screened adding the CINAHL headings to the keywords as follows: ((MH "Medication Compliance") OR (MH "Patient Compliance") or Adher* or complian* or comply or noncomplian* or nonadher*) AND ((MH "Antilipemic Agents") or (MH "Statins") OR (MH "Atorvastatin") OR (MH "Rosuvastatin") OR (MH "Simvastatin") or "lipid-lowering medication*" or "lipid-lowering drug*" or statin* or crestor or Lipitor or simvastatin) AND ((MH "Advanced Practice Nurses") OR (MH "Nurse Practitioners") OR (MH "Adult Nurse Practitioners") OR (MH "Family Nurse Practitioners") OR (MH "Gerontologic Nurse Practitioners") or (MH "Physicians, Family") or provider* or "general practitioner*" or physician* or nurse* or doctor* or "medical staf*").

Lastly, Embase's Emtree's term were included this way: ('medication compliance'/de OR adher* OR complian* OR comply OR noncomplian* OR nonadher*) AND ('hydroxymethylglutaryl coenzyme a reductase inhibitor'/de OR 'antilipemic agent'/de OR

'rosuvastatin'/de OR 'atorvastatin'/de OR 'simvastatin'/de OR 'lipid-lowering medication*' OR 'lipid-lowering drug*' OR statin* OR crestor OR lipitor OR simvastatin) AND ('general practitioner'/de OR 'nurse'/de OR 'nurse practitioner'/de OR 'pharmacist'/de OR 'physician'/de OR 'medical staff'/de OR provider* OR 'general practitioner*' OR physician* OR nurse* OR doctor* OR cardiologist* OR pharmacist* OR 'medical staf*').

The initial search comprised journal articles and systematic reviews from 1989 to 2019. Then inclusion and exclusion criteria were applied to find full-text articles, peer-reviewed, and published only in English between January 2014 and September 2019. The reports retrieved were exported to RefWorks as a database management tool. Depending on the relevance, according to the PICO question, the articles were assigned to three different folders. After eliminating duplicates articles, an exhaustive analysis of titles and abstracts was performed. A total of 339 articles were excluded because they did not address the elements of the PICO question and were included in the irrelevant to the PICO question folder.

Eligibility criteria

Only those articles written in English, published in peer review journals in the past five years (January 2014-December 2019), were included. Those articles with interventions directed to clinical providers and measuring the effect on a statin or other lipid-lowering medication adherence were included. All the pieces were screened, and those that did not include an intervention addressing clinical providers were excluded. The primary outcome was to assess the effect of educational intervention on providers over the adherence to lipid-lowering medication.

Results

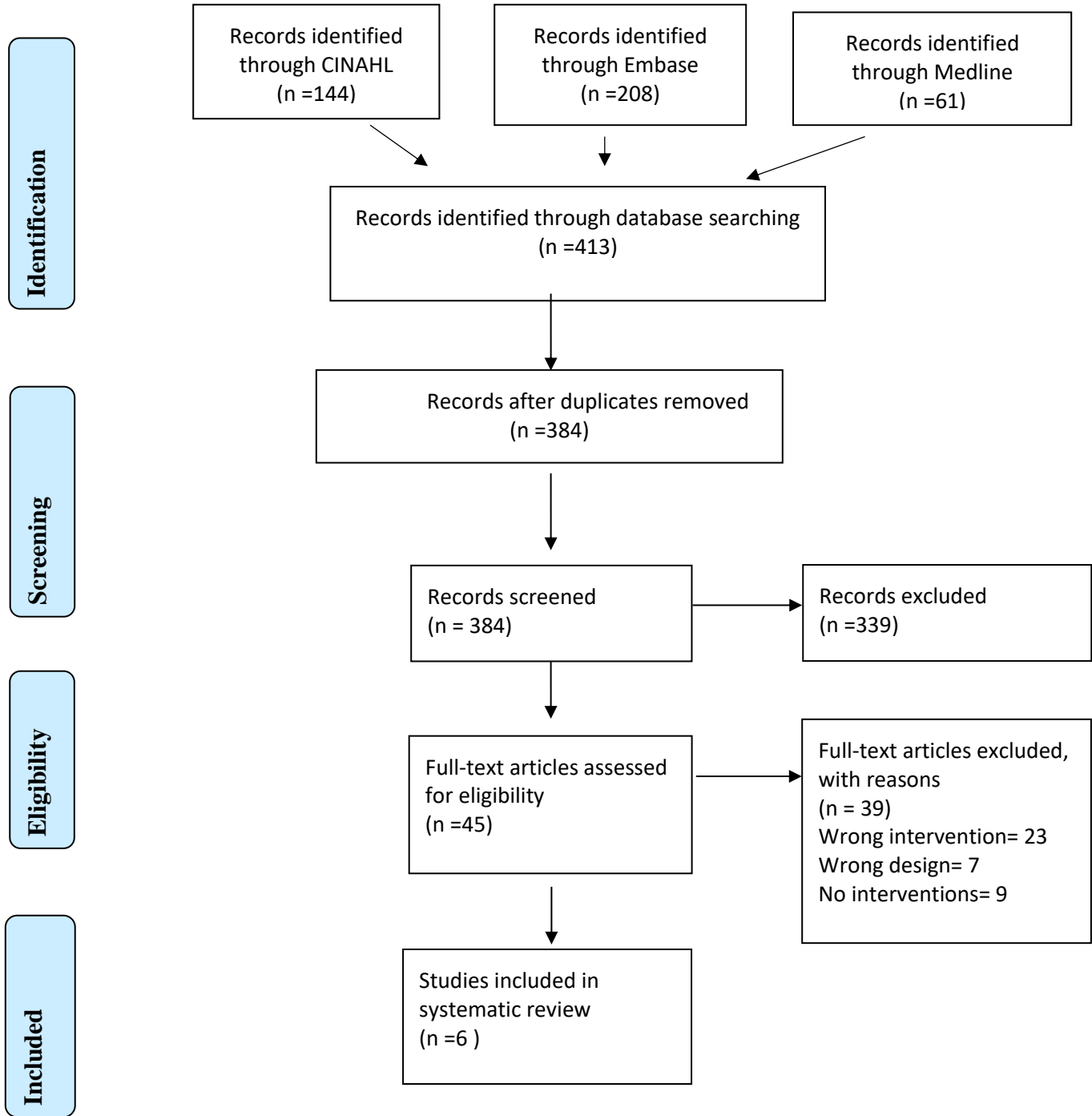
Study selection

After the initial search, a total of 2568 items were retrieved. Out of that total, 1228 articles were found on Embase, 353 in CINAHL, and 987 in Medline ProQuest. After applying selection criteria such as full-text articles, peer-reviewed, and published in English only between January 2014 and September 2019, a total of 413 articles were identified. Out of that total, 29 pieces were eliminated because of duplication. The 384 articles were screened by a thorough analysis of the abstract, methodology, and interventions leading to exclude 339 because they did not address the elements of the PICO question. The rest of the articles' abstracts were thoroughly reviewed. Those that did not include interventions involving providers were excluded. The full text of the articles was then analyzed, and only six items met the inclusion criteria (see Figure 1 for the PRISMA flow chart).

Data collection process and data items

For the data collection, a chart was created to include information regarding methodology, participants, type of interventions, and outcomes. Each article was analyzed to gather data such as type of study, sample, type of intervention, randomization, outcomes, results, discussion, limitations, relevance, and risk of bias. The risk of bias was assessed on methodology design, randomization, blinding, and report of findings as recommended by the Cochrane tool to assess the risk of bias in systematic reviews.

Figure 1: PRISMA Flow Diagram



Study characteristics

Only two studies were carried on in the United States (USA), another one in Argentina and the other three in Europe (one in the United Kingdom (UK) and two in Italy). A total of 16,243 patients were included in the studies, as well as about 835 providers that included general practitioners, nurses, nurse practitioners, and office staff. Out of the six studies, two are randomized control trials (RCT) and four quasi-experimental.

All the studies included an intervention with clinical providers and staff. All the interventions involved a tailored educational session performed by a pharmacist or more specialized professionals with the focus on updated cholesterol management guidelines, assessment and management of hypercholesterolemia, feedback, and communication skills. Educational intervention ranges from a 90 minutes session (Olomu, Hart-Davidson, Luo, Kelly-Blake, & Holmes-Rovner, 2016; Olomu et al., 2016) up to a 2-day intensive training (Gulayin et al. (2019), or coached pharmacist-led interventions (Lowrie, Lloyd, McConnachie, & Morrison, 2014). One study also included outreach visits and the incorporation of a smartphone decision making application (Gulayin et al. (2019). In the studies carried on in the USA, patients were also trained in communication skills. The focus of the intervention relied on the patient-centered care model. The follow-up visits included the use of a checklist tool that improved patient engagement and decision making (Olomu, Hart-Davidson, Luo, Kelly-Blake, & Holmes-Rovner, 2016; Olomu et al., 2016).

Patients in the study were adults older than 18 years old, except for the research performed by Gulayin et al. (2019) that included patients between 40-74 years. Four of the studies included patients with a confirmed history of cardiovascular disease, diabetes mellitus, and hypercholesterolemia, or high risk of developing cardiovascular disease (Gulayin et al.,

2019; Lowrie, Lloyd, McConnachie, & Morrison, 2014; Olomu, Hart-Davidson, Luo, Kelly-Blake, & Holmes-Rovner, 2016; Olomu et al., 2016). Meanwhile, the other two studies included patients receiving statin prescription regardless of whether they were for primary or secondary prevention (Arcoraci et al., 2014; Casula et al., 2016).

Adherence was measured differently in the studies. Two studies assessed adherence by using the medication possession ratio (MPR) (Arcoraci et al., 2014; Casula et al., 2016). Another one used a self-reporting tool, the Morisky-Green questionnaire (Gulayin et al., 2019). The other two used patients self-reporting (Olomu, Hart-Davidson, Luo, Kelly-Blake, & Holmes-Rovner, 2016; Olomu et al., 2016) and the last one measured level of cholesterol and LDL (Lowrie, Lloyd, McConnachie, & Morrison, 2014).

In four of the studies, the interventions led to a significant increase in medication adherence (Arcoraci et al., 2014; Casula et al., 2016; Olomu, Hart-Davidson, Luo, Kelly-Blake, & Holmes-Rovner, 2016; Olomu et al., 2016). They also found a significant improvement in serum cholesterol levels, which was directly related to the enhancement in adherence — overall, the percentage of patients who received the correct dose of statin increased. Two of the studies also focus on the engagement of patients in the decision-making process. The improvement in the communication between providers and patients resulted in a significant increase of adherence (Olomu, Hart-Davidson, Luo, Kelly-Blake, & Holmes-Rovner, 2016; Olomu et al., 2016).

Results from individual studies

The study by Casula et al. (2016) aimed to assess how effective an educational program addressed to providers could be on improving statin therapy adherence. They prepared an intervention that included a document focused on a scientific update on dyslipidemia—diagnosis,

monitoring, drug utilization, healthy lifestyle modification, and how to improve adherence and persistence to treatment. They also facilitated information about accumulated statistics on statin use and adherence benchmarked to other providers in the area.

The study was designed as pre-post interventional quasi-experimental research. It included a total of 705 general practitioners in the region of Lombardy (Italy) that have patients on lipid-lowering medications and their 10,621 patients. The variables considered were adherence and persistence. In this study, adherence was measured by calculating the medication possession ratio (MPR). It was calculated by dividing the number of drug coverage' days by the number of days in the observation period. Persistence was assessed by determining the time elapsed between prescriptions.

Most of their initial data were obtained from the pharmacy's database. They identified two cohorts. One cohort received their first statin prescription before the intervention (PRE-i), and the other had their first prescription after the intervention (POST-i); each patient was followed up for one year. An analysis of adherence and persistence was conducted in both cohorts and the results compared using Student *t*-test, 1-way ANOVA, or Mann-Whitney test (Casula et al., 2016).

Most of the patients in both cohorts were male (51%) and between 40 to 79 years old. The main finding demonstrated a significant increase in adherence in the POST-i group as well as an increase in the number of prescriptions filled (persistence). According to Casula et al. (2016), these results were relevant because only healthcare providers can modify their prescriptive practice. Skilled and well-informed providers can have a positive influence on patients' perceptions and trust, leading to stronger patient-provider relationships and improvement on patients' adherence. However, the assessment of adherence was based on

pharmacy data, which is not always accurate and should be complemented with other tools such as serum cholesterol values. The strength of this study is the large sample included; however, the authors did not consider the presence of other associated comorbidities or additional therapeutic. Moreover, the lack of a control group makes it difficult to assess how effective the intervention is concerning the usual care.

Similarly, Arcoraci et al. (2014) evaluated the effect of an educational program offered to general practitioners on the patient's adherence to lipid-lowering medication. The study was designed as a quasi-experimental study with pre-post intervention analysis. The sample included all 25-general practitioners in the local unit of Caserta (Italy) and 877 patients under their care. This study comprised a retrospective analysis of the patient's medical records, and a prospective follow up of the patients after the intervention; the observational period was 36 months (18 months before and 18 months after the intervention). The sample included patients older than 18 years, receiving at least one lipid-lowering medication regardless of the prescription as primary or secondary prevention.

The variables analyzed included drug utilization (medication adherence), clinical targets (serum cholesterol and low-density lipoprotein (LDL) values), and process indicators (LDL follow up, and risk factors assessment). Like in the study performed by Casula et al. (2016), Arcoraci et al. (2014) used the MPR to measure medication adherence. The authors collected retrospective data from the Caserta health agency's database and the longitudinal prospective data from the practitioners' medical records. The statistical analysis was carried on by means and standard deviation, as well as chi-square tests, considering values of $p < 0.05$ statistically significant.

In the study, the intervention included a 1-day intensive training focused on three main topics: first, an educational update on clinical recommendations, secondly, clinical case discussions, and lastly, strategies and tools to monitor medication efficacy and safety. After the intervention, Arcoraci et al. (2014) found that the educational program did not have any significant effect on the levels of serum cholesterol or LDL levels or in the quality of care (process indicators). However, there was a small but significant increase in adherence given by and improvement in the MPR indicators. The difference in outcomes with the study performed by Casula et al. (2016) may lie in the fact that in this study, the patients were already taking statins. That could explain that serum cholesterol, and LDL levels did not show a significant improvement despite the increase in medication adherence.

Nevertheless, the point that providers accepted to be included in the research voluntarily and the lack of a control group can hinder the generalizability of the results. Also, because the educational program was partially effective, Arcoraci et al. (2014) claim that it was probably because of lacking focus on communication skills training. The authors also emphasized the need for a multidisciplinary approach aiming to provide tools to assess and monitor medication adherence and lifestyle counseling.

In contrast, the quasi-experimental study conducted by Olomu et al. (2016) over 12 months in two federally qualified health centers (FQHC) in Michigan (USA) aimed to measure the impact and feasibility of implementation of the Office-Guidelines Applied to Practice (Office-GAP) program on medication use. The study included all providers and staff of both centers (six doctors, three nurse practitioners, and 18 office staff) and 243 patients (older than 18 years) with the diagnosis of diabetes mellitus (DM), coronary heart disease (CHD), or both.

Centers were randomly allocated (coin toss) in and intervention (120 patients) and control group (123 patients).

The Office-GAP program is composed of three main elements: providers and staff training, patient group visit, and the use of an Office-GAP checklist at the time of follow up. During the 90 minutes of providers training, the cardiovascular secondary prevention guidelines and improvement on communication skills were addressed. The goal was to entitle providers with the tools to engage and empower patients on a shared decision-making process. Patients intervention also included educational information about lifestyle changes, medication facts, and shared decision-making strategies. During the follow-up visits, providers and patients used the Office-GAP checklist to complete the intervention.

The variables measured were the feasibility of the intervention and the medication usage at baseline, 3, 6, and 12 months after the intervention. Surveys completed by the patients were the primary source of the data. Unlike the two previous studies (Arcoraci et al., 2014; Casula et al., 2016), the patient's self-report was the assessment method used for medication adherence, which was verified at each visit because patients should bring their medications bottles. The quality of the data collected was assured because of the training of the research assistants and by standardized methods of data collection, maintaining reliability higher than 98%.

The statistical analysis was performed by using t-Test and chi-square. Besides, to analyze the overtime changes in medication usage, they used algorithms, sensitive analysis, and a logistic regression model to control variables such as age, race, or gender. Results demonstrated a change from baseline use of medication, and statins adherence improved at 3 and 6 months. The strength of this study resulted from the easy to use tools provided and the teamwork approach. Engagement and empowerment of patients have been proved influential in medication adherence

(Olomu et al., 2016). The intervention was performed in two small centers. The lack of meticulous randomization might prevent the generalizability of results.

Similarly, Olomu, Hart-Davidson, Luo, Kelly-Blake, & Holmes-Rovner (2016), carried on a one-group pretest-posttest quasi-experimental study to assess the effect of the implementation of the Office-GAP program on patient satisfaction about patient-provider communication and the use of medication for secondary prevention of CVD according to the ACC guidelines.

They recruited a group of patients with diagnoses of DM, CHD, or both in a designated FQHC in Michigan, USA. All the providers and office staff on the center were included in the study, too, for a total of two doctors, one nurse practitioner, eight staff members, and 95 patients. The Health Literacy Care model serves as a conceptual framework to develop Office-GAP intervention. The program was constructed on the basis that a strong provider-patient relationship promoted safe and effective delivery of care. The program included three elements: training targeted to providers and staff, patient group visits, and the application of the Office-GAP checklist tool during patient and provider encounters.

Likewise, during the training, the providers and staff received a 90 min informative session with an updated review of the current guidelines, and communication skill tools. The latter focuses on the patient-centered model of care with the final goal of promoting patient empowerment and engagement. The patients received shared decision support and communication skills training. During the patient's group visits, scientific information about secondary prevention of CHD was provided to the patients.

The Office-GAP checklist, written at a 6th-grade level, was used in the patient-providers encounters at 3, 6, and 12 months follow up to improve share decision making and help in the

communication process. The COMRADE survey was used to gather data about patient satisfaction and decision confidence. Equally, to the study by Olomu et al. (2016), medication usage and adherence were measured by patient self-report. Descriptive statistics were used to analyze the data collected. The authors found an increase in medication use at the time of follow up when compared to baseline. Adherence to statins was significant at 12 months following the implementation of the program.

The main difference between both studies was the design and the assessment of patient's satisfaction in the latter. By the implementation of the same intervention in a different setting, the authors demonstrated that interventions targeting providers should also address patients' preferences and education, and an improvement in patient-provider relationship to attain desired healthcare outcomes.

In contrast, in the RCT conducted by Gulayin et al. (2019), they could not find an improvement in serum cholesterol levels or medication adherence. In this trial, ten primary care practices were randomly selected to participate in a study aimed to document if a program directed to clinical providers could improve high cholesterol management. They performed a structured intervention that encompasses a 2-day intensive provider training, three educational follow up visits, and the use of mobile evidence-based decision support applications. The sample included all the primary care physicians and the patients between 40-79 years old with a history of cardiovascular disease (CVD), high risk of developing CVD, LDL values of 190 mg/dl or higher, or diabetes type 2.

Five practices were allocated in the intervention group and received an update in CVD assessment, risk stratification, medication monitoring, and adherence management. During the follow-up educational visits, specialized professionals identified prescription barriers and

provided feedback. Besides, the mobile application included evidence-based guidelines and CVD risk estimator tools.

The objective of the study was to achieve a change in LDL levels at 12 months after the intervention. The research also looked for an increment in patients with the proper dose of statins. Additionally, the patient's adherence was assessed through a patient's self-report using the Morisky-Green questionnaire. Trained, certified research nurses performed data collection. The statistical analysis takes into consideration the cluster design to provide a 90 % statistical power (Guyalin et al., 2019).

After the patient screening, they randomly selected 357 patients and allocated 178 in the control group and 179 in the intervention group. After the intervention, they accounted for an increase in the number of appropriate doses of prescribed medication in the intervention group. However, the study failed to demonstrate a significant improvement in the serum levels of cholesterol or patient adherence to statins by 6 and 12 months follow up. Lack of adherence was comparable to other studies that demonstrate that statin adherence tends to decrease over time (Rash, Campbell, Tonelli, & Campbell, 2016). Also, failure to achieve the desired outcomes could be in part because the intervention was focused on providers following the guidelines and enhancing prescription skills but lacked focus on communication tools and patient-centered care.

Lastly, in contrast with the rest of the studies, the RCT carried on by Lowrie, Lloyd, McConnachie, and Morrison (2014) was based on the hypothesis that a pharmacist-led intervention addressed to primary care providers could improve statin prescription and serum cholesterol levels. In doing so, out of the 238 primary care practices in Glasgow (UK), 49 were randomly requested to join the study, but only 31 practices agreed to participate. Patients included in the study should have been diagnosed with cardiovascular disease. Baseline data was

collected from practices patients records, completing a subset of 4,040 patients. After clustering the practices in two separate groups considering if they were group practice or single-handed practices, they paired them according to similar characteristics. Then, they randomly selected one practice out of each pair for the intervention arm and the other for the control group.

The intervention included a pharmacist working at the clinical practice providing organizational support, identifying providers' barriers for prescriptive changes, finding solutions to overcome those barriers and to provide general practitioners scientific evidence for each patient management. The pharmacist was also responsible for following patients to improve medication adherence. The purpose was to measure how many patients attained normal levels of serum cholesterol, and the relationship between those levels and the prescription of statins.

Data collection was performed by two researchers that were blinded to practices allocation to prevent collection bias. Blinding was strictly followed to avoid performance and detection bias. The study established that a higher number of patients in the intervention group accomplished serum cholesterol target levels. A follow-up analysis demonstrated an increase in prescribing practices that have persisted over the years (Lowrie et al., 2014). Lower levels of cholesterol in the patients in the intervention group suggested an increase in medication adherence. Furthermore, the study highlights the importance of pharmacists, healthcare providers, and patients to achieve a positive outcome in medication management.

Risk of bias

The analysis of the risk of bias was performed following the recommendation of the Cochrane collaboration tool to assess the risk of bias in systematic reviews that include six main areas—selection, performance, detection, attrition, reporting, and other types of bias (Higgins et al., 2011). The overall risk of bias among the studies was low. The sampling selection was

carefully determined, and in some instances, the whole population was included in the studies, allocation of subjects among the studies preclude selection bias, which allows the possibility of generalizability of findings. The randomization process and the recollection of data were carefully designed to prevent biases.

Table 1

Analysis of individual studies

Articles	Purpose	Methodology /Intervention	Sample/location	Outcomes	Results
Arcoraci et al. (2014)	To compare CVD prevention before and after the implementation of an educational program targeting GP.	Pre-post intervention Quasi-experimental Retrospective-prospective analysis 1-day training program focused on clinical guidelines on the use of lipid-lowering medication for the prevention of cardiovascular disease (CVD).	25 GP, 887 patients >18y taking lipid-lowering medications/ Italy	Measuring clinical outcomes: target cholesterol and LDL levels Drug-utilization: medication adherence Process indicators: Identification of risk factors, proper follow-up	Partial achievement on cholesterol and triglyceride blood levels which that was not significant. Adherence increased significant and no difference in the quality of care (process).
Casula et al. (2015)	Assess how effective an informative and educational program targeting providers could be on improving medication adherence and persistence to statin	Quasi-experimental pre and post-intervention Two activities. First, a scientific document focusses on clinical management of dyslipidemia— diagnosis, education, adherence, statin use. Secondly, aggregated data information with	705 GP 10,621 patients 5833 preintervention 4788 postintervention/ Italy .	Medication adherence and persistence	They found a significant increase in adherence in the post-intervention cohort and an increase in effective prescriptions. Clinically and statistically relevant

		data about their patient use of statin compared to other practices			
Gulayin et al. (2019)	Test if a complex intervention aiming to providers can improve treatment and control of hypercholesterolemia among patients with moderate to high CVD risk	Cluster RCT Three components intervention: Intensive 2-day training based on guidelines, CV risk assessment, diagnostic, management, monitoring and dealing with adherence issues Three quarterly educational outreach visits: onsite face to face, feedback, identification of barriers Mobile health application to facilitate EB decisions support	10 centers 5 intervention 5 control 357 patients 179 intervention 178 control/ Argentina	The net change in LDL levels at 12 months, the number of at-risk patients with the correct dose of statins. Level of medication adherence	No difference in LDL levels at the end of the trial Increase in better prescription patterns. No significant difference in patients with high adherence to statins after 6 and 12 months follow up.
Lowrie Lloyd, McConnachie & Morrison (2014)	To assess if a pharmacist-led complex intervention delivered to primary care providers (doctors and nurses) could improve statins prescription and attain target cholesterol levels beyond one year.	RCT matched cluster design Pharmacies provided organizational support, identify barriers and potential candidates for statins, assist GP, and NP. overcome barriers, identify suitable patients according to guidelines. Prepared	30 practices, and 4040 patients (15 singles, 16 group practice) 15 practice 2373 patients, 37 GP, 20 nurses in the intervention group 15 practices, 3352 patients, 35 GP, 18 NP in the control group	Achieve cholesterol targets and proper follow up	The intervention group had a higher proportion of patient with target levels of cholesterol and improvement in prescription patterns

		individualized written EB recommendations, educational support, and face-face training, feedback, and cost-effectiveness to GP and nurses			
Olomu, Hart-Davidson, Luo, Kelly-Blake & Holmes-Rovner (2016)	Evaluate the feasibility of implementing the Office-GAP program and its impact on patients and physician satisfaction with communication and decision making, and the use of guideline medication for CHD prevention	Pretest-posttest Quasi-experimental Physicians and staff training (90 min) in the secondary prevention of CHD and communication skills. Patient group visits. Use of Office-GAP checklist tool at follow up	2 doctors, 1 NP, 8 staff members, and 95 patients/ Ingham County, Michigan, USA	The feasibility of model implementation measured by: Efficacy of the program measured by the patient's satisfaction (COMRADE survey) Medication use and adherence by self-report	Significant increase in the drug utilization and adherence to statins at 6 and 12 months
Olomu et al. (2016)	Determine the feasibility of implementation of the Office-GAP program and its impact on the implementation of current guidelines for CHD prevention as well as prediction of medication use (adherence and persistence)	Quasi-experimental Physicians and staff training (90 min) in the secondary prevention of CHD and communication skills. Patient group visits. Use of Office-GAP checklist tool at follow up	6 MD, 3 NP, 18 staff, 243 patients/ Michigan, USA	Feasibility of model implementation Drug utilization measured by improvement in prescriptions and patient self-report adherence at each visit	Increase the use of medication in the intervention group, adherence to statin improved by 3 and 6 months

Discussion

Summary of the Evidence

Medication nonadherence is a very prevalent healthcare issue. Health care professional intervention can be beneficial to achieve patient's adherence to statins as well as for maintaining healthy levels of cholesterol and improvement in lifestyle. General practitioners are in an advantageous position to deliver the necessary education to increase patient adherence and consequently improve healthcare outcomes (Oñatibia-Astibia et al., 2019). The overall evidence gathered in this review shows the importance of educational and informative intervention targeting providers over lipid-lowering medication adherence. In the databases examined, there was not a previous systematic review that addresses the effect of such interventions.

In the six studies appraised, the tools to assess medication adherence varies. Two studies used the medication possession ratio (MPR) (Arcoraci et al.,2014; Casula et al.,2016). This method to determine adherence relies on the dispensing records provided by the pharmacy databases, and it is calculated by dividing the days covered by a drug by the days in the observation period. Ratios over 80 % are considered ideal (Arcoraci et al.,2014; Casula et al.,2016). This method's limitation depends on the fact that there is no guarantee that the patients are taking the medication as prescribed; but that they are receiving the refills on time. One study (Gulayin et al., 2019) used the Morisky-Green questionnaire to assess medication adherence. The Morisky-Green questionnaire, also known as MMAS-8, is an easy to use, cost-effective validated tool to evaluate medication adherence; however, it should be used with other methods of validation due to consistency issues regarding overestimation of patients' responses (Sison, 2018). Two other studies (Olomu et al., 2016; Olomu, Hart-Davidson, Luo, Kelly-Blake, & Holmes-Rovner, 2016) measured adherence by patient's self-report and by checking the pills

bottles for validation. Counting the pills left in the containers prevented the effect of patients overreporting. In contrast, Lowrie et al. (2014) did not measure adherence as a variable, yet, they assessed serum cholesterol levels as an indirect indicator of adherence. These results are like a systematic review that found that in 98 % of the studies, there was not a consistent method to measure medication adherence or persistence (Deshpande et al., 2017).

Simplification of the medication regimen and better communication between patients and providers can be promising to achieve better outcomes. Based on that premise, Casula et al. (2016) implemented an informational, educational intervention directed to providers to increase adherence to lipid-lowering medication. In this pre-post intervention quasi-experimental study, they compared the patient's adherence to lipid-lowering medication between two cohorts (pre and post-intervention cohorts), and they found a significant increase in patient's adherence to statins. In this study, the intervention intended to increase providers' awareness of updated clinical guidelines and benchmark their data with other providers in the area. That simple intervention produced a change in the provider's attitude toward patients, leading to an increase in adherence by the end of the trial. A change in practitioners' attitudes has a positive influence on patients' behavior because when prescribers are involved, that means improving the prescriptive activity at the source and more patient education and monitoring.

However, the study has some limitations. First, the lack of a control group does not allow to compare the effect of the intervention against the usual care to make more reliable conclusions. Secondly, they did not consider other comorbidities or any additional medications. The patients included in the study were first-time statin users, making it difficult to measure the impact of different factors over the attained results.

Meanwhile, Arcoraci et al. (2014) implemented an educational program directed to general practitioners with the objective to measure quality of care by increased patient adherence to lipid-lowering drugs, decrease serum levels of cholesterol, and identification and monitoring of other risk factors for cardiovascular events. The intervention consisted of a 1-day training with actualization on clinical guidelines and the analysis of tools and strategies to monitor the lipid-lowering medication efficacy and adherence. By the end of the study, there was an increase in adherence, given by higher MPR values. Though, the authors considered the study partially successful regarding the effect on serum cholesterol and LDL level. This study was performed in patients that were already on statins, and it is probably that they already were on the target level or that the degree of improvement would not be so significant. Besides, the intervention only focuses on providers' training, lacked focus on improving communication skills, and did not offer the tools to monitor and empower patients to be more adherent. That could be the reason why the intervention was just partially effective. Anyhow, the characteristics of the sample considered in this study and the way the educational program was structured could make generalizability of the results questionable.

The studies performed by Olomu et al. (2016) and Olomu, Hart-Davidson, Luo, Kelly-Blake, and Holmes-Rovner (2016) have similar interventions and objectives. The intervention took place in two different settings, with two different sample populations. The interventions carried on in these two studies were more structured than the interventions performed in other studies (Casula et al., 2016; Arcoraci et al. 2014). The study was designed around the application of the Office-GAP (guidelines applied to practice) program. The framework for these two studies was based on the patient-centered care model. Moreover, it included the empowerment and engagement of patients in the decision-making process.

In the study by Olomu et al. (2016), the two practices chosen were randomly assigned either to the intervention or control group. The intervention included a 90-minutes of training to providers and staff, offering an update on the clinical guidelines for secondary prevention of cardiovascular disease in consonance with the recommendations of the American Heart Association (AHA). Patients were also educated on decision-making, the establishment of goals, and scientific data about diabetes mellitus (DM) and coronary heart disease (CHD). The follow-up visits included the application of the Office -GAP checklist. It is an easy to use instrument that allows patients and providers to review treatment options and patients' preferences. The overall adherence to statins and other medication for cardiovascular prevention increased in the intervention group. Statin use increased at 3 and 6 months related to an improvement in providers' prescriptions after the intervention. However, at 12-months, the percentage of adherence was not statistically significant. This behavior correlates with previous studies that demonstrate the decrease in adherence over time (Rash, Campbell, Tonelli, & Campbell, 2016). According to Olomu et al. (2016), the strength of this study relies on teamwork, the ability to engage patients, and the usefulness of the checklist as a reminder of proper follow-up. However, sample size and the characteristics of the site makes generalizability of results uncertain. Nevertheless, this study highlights the importance of patient engagement and the need to establish a partnership between patients and providers to attain the desired healthcare outcomes.

Similarly, the study performed by Olomu, Hart-Davidson, Luo, Kelly-Blake, and Holmes-Rovner (2016) was based on the premise that when patients are involved in the management of their chronic conditions, they are more proactive and attain better healthcare outcomes. They implemented a shared decision-making intervention that included communication skill training for both patients and providers. Their primary focus was to create a

stable patient-provider relationship. The providers' intervention included a discussion of prevention guidelines and communication skills. The latter was based on the Patient-Centered Care Method of Communication, aiming to enhance patient engagement and empowerment.

The intervention produced an increase in the number of patients using statins and other medication for secondary prevention of CHD (Olomu, Hart-Davidson, Luo, Kelly-Blake, & Holmes-Rovner, 2016). Statins adherence increased by 6 and 12 months with a probability of adherence of 52 % at 6-months and 34% at 12-months. The overall results of this study demonstrated that the use of a simple checklist, such as the Office-GAP, enables providers to thoroughly contemplate the use of evidence-based tools to deliver a higher quality of care. The authors explained that the improvement in medication adherence could be the result of better patient-provider relationships and communication and enhanced prescribing practices. Despite the strength of the study, the design lacking control group and randomization, as well as the small sample, prevent generalization of the results. Additional research should be conducted to validate the effect of such intervention in the improvement of statin adherence and the consequent prevention of cardiovascular events.

Similarly, the pharmacist-led intervention conducted in the RCT by Lowrie et al. (2014) achieved an improvement in the appropriate prescriptions of statins, and the consequent decrease in LDL and serum cholesterol at the 12 months follow up, suggesting an increase in adherence. This study included a pharmacist collaborating, educating providers, assessing for barriers to implementation, detecting the patients needing therapeutic changes. The effect of adding a pharmacist to the healthcare team positively impact the patient's adherence because pharmacist can produce more follow up, patients' education, and practitioners counseling. However, even when adding a pharmacist to the project would be ideal for decreasing nonadherence, it is not

always a viable and cost-effective solution due to the differences in the economic and structural organization of the healthcare system in any given setting.

Unlike the other studies appraised, the RCT performed by Guyalin et al. (2019) did not demonstrate an improvement in lipid-lowering medication adherence. In this RCT, the sample was composed of the practitioners of ten centers in different locations in Argentina. Patients included in the study were 40-74 years old, who have at least one of the following inclusion criteria: DM, high cardiovascular disease (CVD) risks, an established CVD, or LDL levels above 190 mg/dl. The authors used a three-component intervention and evaluated the effect of such intervention on the control of hypercholesterolemia in patients at risk.

The intervention included a 2-day training followed by three educational visits and the use of a mobile evidence-based decision-making application. The training included guidelines updates, information on risk assessment tools, management, and monitoring of hyperlipidemia and adherence topics. Meanwhile, in the quarterly visits, the practitioners received feedback and help to identify possible barriers. Other additional support tools were provided to the intervention group, such as weekly text messages and training to pharmacist assistants on patient counseling and adherence.

The intervention proved significant to reduce cardiovascular risks after the first six months; however, this change did not continue at 12 months. Also, the percentage of patients receiving the appropriate dose of statin increased, yet no difference between the two groups was identified regarding adherence. These results are like other studies that demonstrate a decrease in adherence rates over time (Deshpande et al., 2017). It is possible that the type of intervention strongly focused on scientific data was not enough to achieve the desired outcomes, mainly

because of the lack of patient involvement or the lack of training in better communication pathways.

Different interventions have been tried to increase medication adherence with mixed results. In a systematic review conducted by Rash, Campbell, Tonelli, and Campbell (2016), including 25 randomized control trials (RCT), they found that a well-structured education-based intervention had a significant impact on statin adherence. However, not all the education trials were successful. Only those studies that depicted vigorous risk factor counseling sessions, lifestyle modification, and visual representation of coronary atherosclerosis improved the proportion of adherence. Furthermore, when a multifaceted intervention was used—education, pharmacist follow up, counseling, behavioral intervention, and medication reminders—there was improved adherence. In this systematic review, simplification of medication—using a polypill—was by far the best intervention leading to better adherence.

Patients' education and close patient monitoring interventions have been tried to increase the patient's adherence. It is a fact of the role that providers play in modeling patients' behavior through a strong patient-provider relationship, proper communication, and close monitoring (Brinton, 2018). Overall, providers recognized that excellent communication, patient-centered care, and patient education are crucial to achieving long term adherence; however, in some instances, they avoid discussing those issues, omit the use of statins in primary prevention, or do not involve patients in the decision-making process (Kruger et al., 2018)

Limitations

This review has some limitations. First, only two of the included studies are RCT. It is known that RCTs are considered the most reliable source of evidence (Mastrian & McGonigle, 2017) and usually is the best approach to demonstrate causality (Holly, 2014). Secondly, the

heterogeneity of the interventions and the different designs decrease the likelihood of generalizability of the results. Furthermore, the small samples, lack of control group, or randomization hinders the reliability and strength of the findings. Lastly, this review focused on intervention to primary providers or general practitioners and did not focus on the role that pharmacists play in the education, monitoring, and follow up to decrease nonadherence among patients at risk.

Studies included have their specific limitations. For instance, some of the interventions only included scientific updates to providers (Arcoraci et al.,2014; Casula et al.,2016; Guyalin et al., 2019), which proved only partially advantageous in part because of a lack of patient involvement. In two studies, the intervention also included patients as recipients of decision-making skills and communication techniques (Olomu, Hart-Davidson, Luo, Kelly-Blake, & Holmes-Rovner, 2016; Olomu et al., 2016). However, the small samples and the specific characteristic of the setting limits the generalizability of the results precluding the need for further studies.

Besides, most of the studies focused on statins used for secondary prevention (Guyalin et al., 2019; Lowrie et al., 2014; Olomu, Hart-Davidson, Luo, Kelly-Blake, & Holmes-Rovner, 2016; Olomu et al., 2016) and the other two included the patients regardless of the purpose of statin prescriptions (Arcoraci et al.,2014; Casula et al.,2016). Therefore, it is challenging to link adherence with the intention of primary or secondary prevention based on these findings. Besides, the lack of a standard tool to measure patient adherence hinders the ability of providers to address and monitor nonadherence adequately. Furthermore, only in one of the studies, the effect of the intervention has been considered in the long term, making it harder to analyze the impact of such interventions in the adherence-persistence process.

However, the review also has some strengths. First, there is no other review in the databases screened that addresses the effect of an educational intervention to providers on patient's medication adherence. Secondly, it highlighted the critical role that providers play in attaining a higher level of adherence. Finally, it emphasized the importance of educating providers and improving patient-provider communication as the right approach to address nonadherence.

Conclusions

Six studies were included in the review: two RCT and four quasi-experimental studies. In all the studies, there was an educational intervention targeting providers to increase lipid-lowering medication adherence, reduction of serum cholesterol levels and risk of CHD, and improvement in the provider's ability to prescribe and follow guidelines to manage patients with dyslipidemias. The structure of the educational program was diverse but mostly focused on scientific updates and feedback. In two of the studies, patients were also educated on decision making and communication strategies (Olomu, Hart-Davidson, Luo, Kelly-Blake, & Holmes-Rovner, 2016; Olomu et al., 2016).

The population studied mostly included patients on secondary prevention of CHD. However, two of the studies included all the patients with statins prescription without regard to whether they were for primary or secondary prevention (Arcoraci et al., 2014; Casula et al., 2016). Additionally, there was not a standard tool to assess medication adherence across the studies. Nevertheless, five out of the six studies found a significant increase in medication adherence after the intervention (Arcoraci et al., 2014; Casula et al., 2016; Lowrie, Lloyd, McConnachie, & Morrison, 2014; Olomu, Hart-Davidson, Luo, Kelly-Blake, & Holmes-Rovner,

2016; Olomu et al., 2016). Overall in the six studies, the authors found enhanced providers' performance abiding by the AHA guidelines.

It is feasible to increase medication adherence on the patient with dyslipidemia through interventions addressing providers; however, patients should be engaged in the decision-making process. Interventions should include not only scientific updates but also communication skills and tools to engage, empower patients in a patient-centered model of care. When patients and providers are equally involved in the process of care, it is possible to achieve better healthcare outcomes. More research is needed to prove the efficacy of intervention targeting providers over medication adherence in other chronic conditions and different settings to establish generalizability of findings.

Quality improvement project

Patients' adherence to lipid-lowering medication is often related to different factors. Patients' beliefs and health literacy, providers' attitudes, patient-centered care, and simplification of medical regimen have been invoked among the principal factors that facilitate adherence behavior (Rash, Campbell, Tonelli, & Campbell, 2016). Prescription patterns have been used lately as a measure of the quality of care; therefore, medication adherence and its relationship with positive health outcomes have been linked with a better quality of care (Seabury, Dougherty, & Sullivan, 2019).

The finding of the systematic review showed that it is feasible to improve patient adherence through a process of education and engagement of primary care providers. A change in the attitude of general practitioners with more emphasis on providing patients with the appropriate information lead to an increase in adherence and persistence. Besides, better prescribing practices and more providers' expertise enhance patients' trust and consequently

promote a change in patients' attitudes and better adherence (Casula et al., 2016). Primary care providers are in an advantageous position to influence patients' attitudes and increase adherence to lipid-lowering medication, which will contribute to decreasing the mortality due to cardiovascular disease.

Primary Aim

Therefore, the primary aim of this quality improvement (QI) project was to increase patient adherence to lipid-lowering medication through a structured educational intervention in a local primary care center. The QI project aimed to provide an educational intervention to healthcare staff to increase awareness and assessment skills on lipid-lowering medication adherence. Besides, it was also expected to improve healthcare providers' communication and patient education skills to increase the patient's adherence to lipid-lowering medication.

Goals and outcomes

The goals of the educational intervention addressed three crucial areas related to and associated with the patient's adherence to lipid-lowering medication. In this regard, the proposed educational program would promote the healthcare team's involvement in the identification of patients who will benefit from lipid-lowering medication, promoting patient's engagement in the decision-making process, and addressing lipid-lowering medication adherence.

The short-term goals included promoting the healthcare team's involvement in the identification of patients who will benefit from lipid-lowering medication (guidelines), promote patient's engagement in the decision-making process (education), and assess and educate on medication adherence (adherence). Additionally, the long term goals of the QI project included the introduction of a systematic assessment and education on patients with hypercholesterolemia that will reduce the incidence of adverse cardiovascular events and an improvement in the

healthcare indicators. The QI project outcomes included an improvement in the center healthcare team skills to manage patient's nonadherence to lipid-lowering medications. Those skills would empower the team to provide patient education in a patient-centered care environment

Rationale

Patient's nonadherence to medication usually hinders the role of lipid management for primary and secondary prevention of cardiovascular disease (CVD). Several factors play an essential role in patient's nonadherence, such as ineffective communication between provider and patient, insufficient education, improper follow-up, and perceived need from a patient perspective (Casula et al., 2015). Although the importance that lipid-lowering medications play in the prevention of CVD, there is a lack of consensus about how to address patient's lack of adherence in the long term in primary care, and there is no standardized method to measure and address adherence (Van Driel et al., 2016).

Interventions should be tailored according to the population's characteristics. For instance, suggested strategies approach nonadherence by emphasizing educational and behavioral approaches. Others provide recommendations to improve patient-provider communication, not only addressing the patient's beliefs but also the providers' attitudes (Ruppar et al., 2015). Thus, it is essential to implement interventions involving providers in devising strategies to improve patient's perception about the benefit of adherent behaviors to reduce the risk of adverse CVD events. Therefore, considering the critical role of providers and staff in modeling patients' beliefs and perceptions, it is essential to increase their understanding of how to address nonadherent patients.

Medication nonadherence is considered a significant public health problem because it leads to reduced healthcare outcomes with a consequent increase in healthcare costs. In the

United States, about \$100 billion are disbursed to services that are related to poor medication adherence (Kini & Ho, 2018). More than \$300 billion of unnecessary healthcare expenses—10% of healthcare budget—are the consequence of nonadherence (NEJM Catalyst, 2019). Therefore, interventions to increase medication adherence could have a beneficial effect on population health more significant than any specific treatment.

Evidence shows that it is feasible to increase lipid-lowering medication adherence through a comprehensive educational intervention. Based on the evidence gathered, this quality improvement project was implemented to increase healthcare team awareness of the need to assess and monitor for patient's adherence to lipid-lowering medication, to promote and reinforce patient education and patient engagement on the decision-making process.

Quality Improvement Method

The QI project took place in a Primary Care Center, which is composed of two physical facilities. All members of the staff were invited to participate in the QI project. The proposal was submitted to the Institutional Review Board (IRB) of Florida International University for approval. Once approved, the DNP student in agreement with the office manager established a date for the implementation of the project.

The program was designed as a pretest-posttest intervention. It encompassed three main components. Firstly, an initial assessment of staff and providers' knowledge regarding guidelines for lipid-lowering medication, medication adherence, and patient education was performed by the application of a pre-intervention questionnaire. Secondly, the educational program was carried on. Lastly, the post-intervention questionnaire was given to all the participants. All data collection, data analysis, and storing were performed at the clinical site. The pretest and posttest data were recorded in excel. Both surveys were scored individually and as a group with a

percentage. Results from pre- and post-intervention questionnaires were compared for improvement in group score.

Program Structure and Outline

The program included a pretest survey. The survey was composed of twenty questions that addressed the main objectives of the QI project. Answers from this survey provided any gap of knowledge and the degree of understanding about the primary topics addressed in the QI project. The questions assessed knowledge about lipid management latest guidelines, the ability to assess for medication adherence, and the readiness to provide patients education.

The educational program was structured in a way that responded to the three main topics of the QI project (guidelines, adherence, and education). The educational intervention was carried on in a face to face program that lasted 60 minutes and focused on the latest guidelines published by the American Heart Association (AHA) to manage hypercholesterolemia for primary and secondary prevention, medication adherence, and patient education. Additional resources on how to promote patient engagement through patient education were also provided.

Two different sessions were offered, one in each physical facility, to accommodate the staff according to their location and schedule, and to keep social distancing. The program was designed as an interactive activity, including a PowerPoint Presentation (PPP) and distribution of informative handouts. Emphasis on patient education and empowerment was a priority. The final step was a follow-up post-intervention survey.

Both pre- and post-intervention questionnaires were anonymous to protect participants' privacy. They were scored individually with a percentage, and then the group average was calculated. Then, results were compared for any improvement in group scores. The DNP student was responsible for applying both the pretest and posttest and the data collection and analysis.

Evaluation

The completion of the post-intervention questionnaire accomplished the evaluation of the QI project. The short-term impact of the educational program was evaluated by their responses in the post-intervention test, expecting an improvement in the skills to assess, monitor, and educate patients regarding lipid-lowering medication adherence. The long-term impact of the program should be accomplished and monitored afterward by the Center's management. The implementation of a systematic process to assess and monitor patients for lipid-lowering medication adherence and patients' feedback will provide structure to the delivery of healthcare.

Plan for sustaining change

Periodic evaluation of the QI project impact should continue to guarantee long-term goals. Education reinforcement, creation of a checklist that addresses the three crucial objectives of the QI project will be carried on in the Center to assure the sustainability of changes

Results

The QI project population included eight members of the staff who are involved directly with patient care. Demographic characteristics are included in Table 2. The staff was composed of 4(50%) medical assistants and 4(50%) patient care coordinators. All were the Hispanic (100%), mostly female (7= 87.5%), and over 40 years old (5= 62.5%).

Overall, there was an improvement in the individual scores when pretest and posttest results were compared (Figures 1-3). As a group, there was a 24 % improvement after the intervention. It was also found a 30 % improvement in guidelines knowledge, 29% in medication adherence knowledge, and 14 % in patient education, as shown in Table 3.

Pretest analysis**Guidelines knowledge**

While 75 % of the respondents believed they are familiarized with the latest guidelines for cholesterol management, only 25% could identify the patient who would be a perfect candidate for lipid-lowering medication for primary prevention. Additionally, only 50% identified the patients at high risk or recognized the target LDL levels on high-risk patients. Regarding risk identification, only 50 percent of the participants recognized that diabetes mellitus and smoking are considered significant risks for cardiovascular events. Meanwhile, 87.5 % identified HTN as a risk factor too.

Medication adherence knowledge

Only 50% of the respondents are familiarized with the concept of medication adherence. While 87.5 % consider it is essential to assess medication adherence in every encounter, they do not use a standardized assessment tool. Out of the total, 62.5 % consider that the best method to assess for adherence is to measure serum cholesterol and LDL level regularly. Lack of knowledge about the consequence of nonadherence was considered the most important reason why patients fail to take the lipid-lowering medication as prescribed, followed by impaired memory and forgetfulness with 62.5%.

Patient education

Regarding patient education, 62.5% states that they always provide patient's education about cholesterol management, 50 % educate patients about medication adherence, and 50 % often involve patients in the process of decision making. Besides, 75 % considered that patients should have an active role and should be included in creating the treatment plan, as well as be provided with the necessary skills. They all agree that discussing lifestyle and medication side

effects should be included in the education plan. However, only 50 % consider that assessing for medication adherence in every encounter will be a beneficial intervention to increase adherence among the patients, and 62.5% will include the use of technology (automatic reminders) and interactive educational activities to improve adherence.

Posttest analysis

Guidelines knowledge

After the educational intervention, 87 % of the subjects were able to identify the perfect candidate for lipid-lowering medication, and 62.5% were able to recognize the target LDL levels on high-risk patients. Regarding risk factors, all the participants (100%) recognized hypertension and smoking as significant risk factors, meanwhile 87.5 % identified DM as a risk factor too.

Medication adherence knowledge

All participants (100%) considered essential to assess for medication adherence in every encounter, and 87.5% could adequately define the concept of medication adherence. Out of the total, 87.5 % considered that measuring the serum cholesterol and LDL levels are the best method to assess for patient's adherence. Side effects of the lipid-lowering medication were considered by 75 % of the respondent as the main reason for patients' nonadherence.

Patient education

All the respondents agree that education should be provided in every encounter and that patients should play an essential role in the decision process. The 100 % agree that education should include changes in lifestyle, medication adherence, and side effects. They also agree that assessing adherence in every encounter and the use of some sort of technology could help to improve patient's adherence to lipid-lowering medication.

Discussion

Although the systematic review addressed interventions targeting mainly primary care providers, this QI project included mainly the ancillary staff that is directly related to patients. The supporting staff is in a perfect position to reinforce education, assist with medication adherence assessment, and engage patients. Healthcare delivery is a complex process, which is carried on by members of a multidisciplinary team. The quality and safety of that process are closely related to the characteristic of teamwork (Rosen et al., 2018). Teamwork can be helpful not only to identify barriers and modify patient behavior (Olomu et al., 2016), but also to improve patient education and engagement. The implementation of the QI project improved the staff skills and knowledge to carry on a more inclusive role in the patient's care.

Assessment for lipid-lowering medication, monitoring for adherence, and educating patients should be included in every encounter and followed up. Advanced practice nurses at the forefront of the healthcare team in primary care are in a position to influence team perspective and awareness. Their role in the assessment, education, and engagement of patients also entitles educating and empowering the healthcare team.

Conclusions

It is feasible to increase lipid-lowering medication adherence for primary and secondary prevention by targeting providers and staff. Increasing staff knowledge and skills increase the likelihood of better quality of care, providing comprehensive support to providers in the patient's care. Improving assessment tools, increasing patient engagement, and broadening patient education can be achieved with a team effort. More research is needed to assess the effectiveness of such interventions in the patient's adherence.

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Table 2

Demographic

Gender	Number (<i>n</i>=8)	Percentage
Male	1	12.5 %
Female	7	87.5 %
Age	Number (<i>n</i>=8)	Percentage
Under 40	3	37.5 %
Over 40	5	62.5 %
Ethnicity	Number (<i>n</i>=8)	Percentage
Hispanic	8	100 %
Position	Number (<i>n</i>=8)	Percentage
Medical Assistant	4	50 %
Patient care coordinator	4	50 %

Table 3

Group scores: Pretest/posttest analysis

Average scores	Pretest	Posttest	Improvement
Guidelines knowledge	48%	78%	30%
Medication adherence	51%	80%	29%
Patient education	78%	92%	14%
Group average	48%	72%	24%

Figure 2

Guideline knowledge individual scores

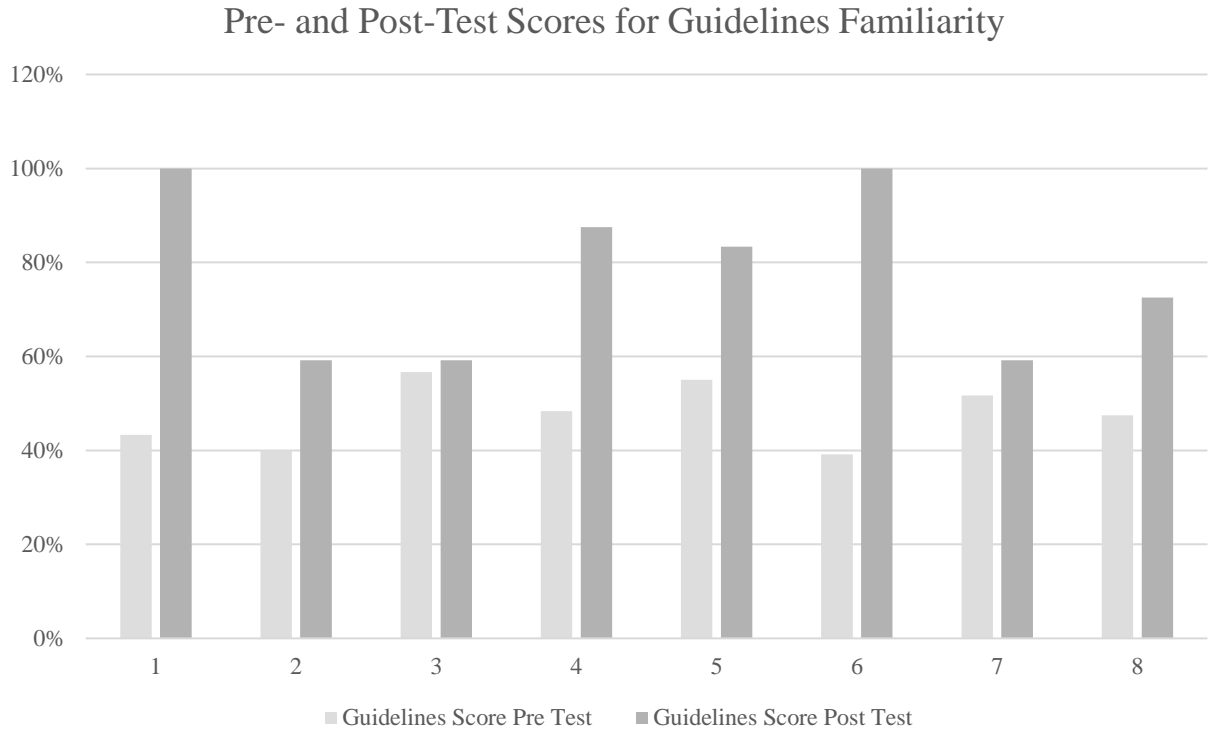


Figure 3

Medication adherence individual scores

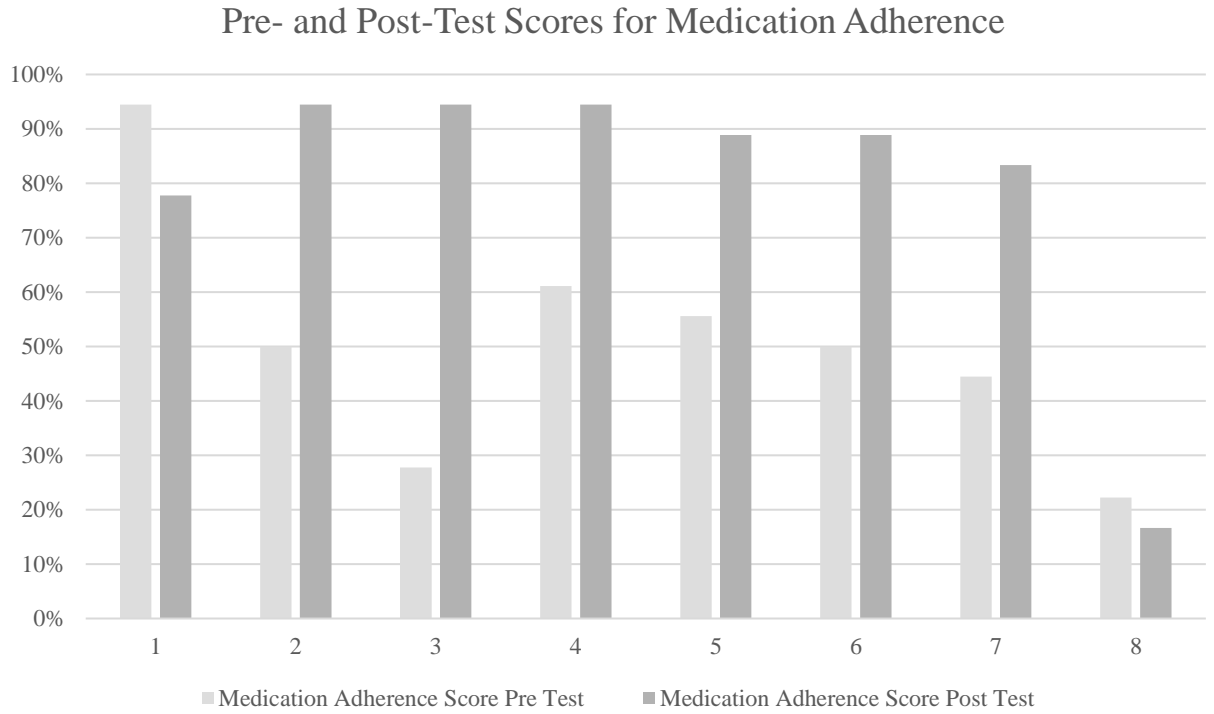
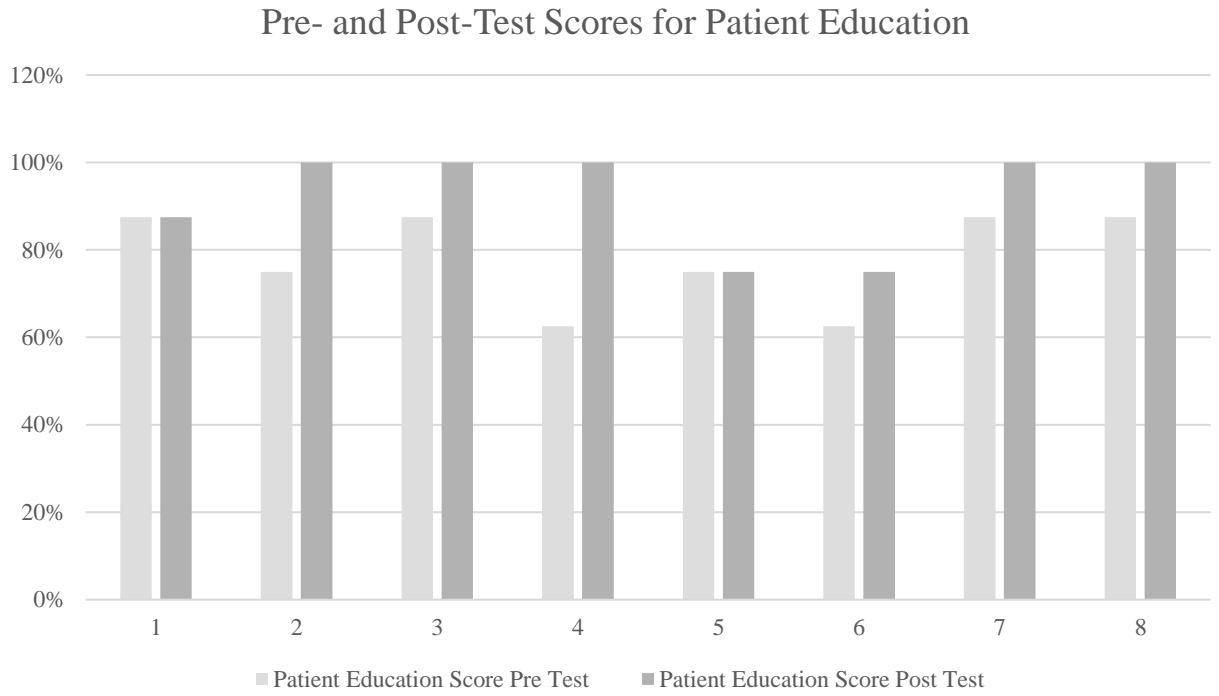


Figure 4

Patient education individual scores



Appendix A: Dissemination plan

Cardiovascular disease (CVD) continues as a leading cause of death in the United States (Kochanek, Murphy, Xu, & Arias, 2019). Statins and other lipid-lowering medications have been proven effective in reducing the risk of cardiovascular events. However, it is estimated that half of the patients prescribed statins cease their use within their initial year of treatment, and it continues falling in the subsequent years (Rash, Campbell, Tonelli, & Campbell, 2016).

Medication adherence is a complex process that involves elements from both the patients and the providers (Kini & Ho, 2018). Different factors lead to patient nonadherence. However, there is no consensus on how to measure and address nonadherence in primary care (Van Driel et al., 2016). Instead, medication adherence has been linked to the quality of care (Seabury, Dougherty, & Sullivan, 2019). Hence, primary care providers are in an advantageous position for modeling patients' behavior through a strong patient-provider relationship, proper communication, and close monitoring (Brinton, 2018).

Several initiatives have been proposed to increase patient adherence. For instance, improvement of patient/provider relationship, follow up guidelines, generating clinical pathways to guarantee appropriate decision-making, strengthening of healthcare delivery, adequate follow-up, simplification of medical regimen, and the use of technology have been proposed (Lee et al., 2016).

The findings of the systematic review demonstrated that it is feasible to increase patient adherence by increasing providers' awareness and engagement. Those results led to the proposal of a quality improvement project (QI) in the primary care setting. All the studies reviewed have in common the lack of a standard method to assess medication adherence. However, all of them apply different types of educational interventions targeting providers to increase medication

adherence. Interventions were dissimilar in structure, but conceptually they focus on increasing provider's knowledge about current guidelines, improving communication skills, and implementing a better follow up.

The QI implemented in the primary care office targeted the ancillary staff. Each member of the healthcare team plays an essential role in the delivery of care. The intervention targeted the gap of knowledge regarding clinical guidelines, medication adherence assessment, and patient education. The QI shows how providing education to the staff will empower them to reinforce patient education and could help develop new clinical pathways that include medication assessment tools, patient education, and patients' follow up.

The findings of the systematic review and results of the QI project will be sent for consideration to be presented in the conference of the American Association of Nurse Practitioners (AANP) in 2021. The Journal for Nurse Practitioner (JNP) is a peer-review publication of the AANP. The abstract will also be sent for consideration to the JNP for publication.

At the clinical setting level, the impact of the QI will continue to be measured through patient adherence. Serum levels of cholesterol, low-density lipoproteins (LDL), and triglycerides (TG) will serve as an indicator of adherence. It is expected that pharmacies and insurance reports regarding patient nonadherence drop in the next six months.

Abstract for publication in The Journal for Nurse Practitioners

Medication adherence has been defined as the process by which patients take the medications on how they are prescribed (Ruppar et al., 2015). Medication nonadherence has become a critical healthcare issue. Several interventions have been tried to increase adherence. Therefore, the objective of this review is to assess if a structured educational program directed to providers and staff could increase medication adherence among patients who are prescribed lipid-lowering medications for primary and secondary prevention of cardiovascular disease. The gathered evidence will lead to the development of a quality improvement project. Three databases were screened to answer the clinical question, and six articles were included in the review. The educational programs ranged from 90 minutes of training up to 2-day educational sessions. The programs included scientific updates, clinical guidelines, feedback, and communication skills. Five out of the six studies found a significant increase in medication adherence after the intervention. Even when different approaches were used, it is feasible to create an educational program targeting providers and their staff to increase lipid-lowering medication adherence. A Quality Improvement (QI) project was implemented in a local Primary Care practice. The project was designed as a pre-post intervention survey. The purpose of the QI was to increase the skills and awareness of the provider's staff to increase the patient's adherence to lipid-lowering medication. After the educational intervention, there was an improvement in staff knowledge, awareness, and skills to assess, educate, and engage patients to promote patients' adherence to lipid-lowering medication. More research is needed to prove the efficacy of different types of intervention targeting providers over medication adherence in other chronic conditions.

Keywords: medication adherence, lipid-lowering medication, providers, educational intervention

Appendix B**PRETEST-POSTTEST****Use of a structured educational program on providers to improve patient's adherence to lipid-lowering medications.****Introduction:**

This questionnaire is an essential part of a quality improvement project aiming to increase patient's adherence to lipid-lowering medication through an educational program targeting providers and staff.

Please, answer to the best of your knowledge. Your response will help to understand gaps in knowledge and rooms for improvement. The questions are structured to assess your understanding regarding cholesterol management, guidelines, assessment of patient's adherence to medication, patient's education, and management.

Demographic:

Gender: Female _____ Male _____

Age: _____

Ethnicity: _____

Position: _____

Questionnaire:**Assessment of guidelines knowledge**

1. Have you received any type of training in cholesterol management for primary and secondary prevention of cardiovascular disease?

_____none _____not sure _____yes

If yes, how many? _____

2. Please respond to the following statements:

Statement	Strongly agree	Agree	Undecided	Disagree	Strongly disagree
I am very familiarized with the latest guidelines for high cholesterol management					
I am knowledgeable about the ASCVD (atherosclerotic cardiovascular disease) risk calculator tools					
I assess for lipid-lowering medication adherence in every encounter					
I usually provide education about cholesterol management and medication adherence					

3. Which of these patients is a good candidate for the use of lipid-lowering medication for primary prevention?

_____ a 25 years old woman with LDL 145 mg/dl

_____ a 45 years old male with LDL 195 mg/dl

_____ an obese patient 35 years old with a family history of HTN

_____ an 80-year-old female with controlled HTN and LDL levels of 105 mg/dl

4. Which of the following individuals with elevated cholesterol are considered high-risk?

Select all that apply

- A patient with clinical ASCVD
- Patient with LDL of 130 mg/dl
- Age 40+ with diabetes mellitus
- 80-year old has had a myocardial infarction

5. In patients with a history of ASCVD, the management should include:

- Use of high-intensity statins
- rest as much as possible
- use of low intensity statins
- take omega 3

6. Which is the target value of LDL in patients at high risk of ASCVD

- 100 mg/dl
- <70 mg /dl
- 70-100 mg/dl
- 120 mg/dl

7. Using the ASCVD risk calculator will help to:

- identify patients at risk
- counsel patients
- assess for adherence to medication
- provide the risk of patients to have a cardiovascular event in the next 10 years

8. Which risk factors, besides the levels of cholesterol, are considered to calculate the risk of ASCVD? *Select all that apply*

- _____diabetes Mellitus
- _____uncontrolled hypertension
- _____Smoking
- _____diet and exercise
- _____weight

Medication adherence knowledge

9. In your opinion, what could be considered medication adherence?

- _____when patients take their medication as prescribed less than 80 % of the times
- _____when patient take the medication as prescribed at least 80 % of the times
- _____When patients forget to take their medication often.
- _____when patients fail to take their medication

10. Do you use any standardized tool to assess medication adherence?

- _____yes _____not sure _____no

11. Do you consider it important to assess medication adherence in every visit?

- _____yes _____not sure _____not at all

12. In your opinion, which would be the best method to assess adherence?

- _____patient self-report _____pill counting(pt. brings bottle to the office)
- _____Pharmacy statements _____serum cholesterol and LDL values

13. In your opinion, why are patient's nonadherence to lipid-lowering medication? *Select all that apply.*

- ___lack of knowledge about unintended consequences
- ___Perceived believe of unnecessary treatment
- ___Memory impairment, forget

Mistrust on providers decision

drug prices, lack insurance

side effects

14. Which of the following is considered a consequence of nonadherence to lipid-lowering medications?

decrease in hospitalizations and healthcare costs

increase in side effect

Harm to patient's health

There is no consequence

Patient education

15. How often do you provide education about cholesterol management and healthcare consequences?

always

frequently

rarely

never

16. How often do you provide education about the need to be adherence to statins?

always

frequently

rarely

never

17. How often do you involve patients in the process of decision making?

always

frequently

rarely

never

18. Please, answer the following statements

Statement	Strongly agree	Agree	Undecided	Disagree	Strongly disagree
Patients should have an active role in creating the treatment plan					
Patients should be included in the decision making					
Patients should be provided with decision-making skills					
Patients should be reminded to be adherence and to follow up					

19. Patient education should include: *Select all that apply*

_____ discussing lifestyle

_____ Medication side effects

_____ follow up and adherence

_____ medication prices

20. Which interventions can help patients to be more adherence? *Select all that apply*

_____ assessing for adherence in every encounter

_____ provide automated reminders (use of technology)

_____ provide interactive educational activities


_____ provide polypharmacy

Appendix C



Office of Research Integrity
Research Compliance, MARC 414

MEMORANDUM

To: Dr. Charles Buscemi
CC: File
From: Maria Melendez-Vargas, MIBA, IRB Coordinator 
Date: March 31, 2020
Protocol Title: "Use of a structured educational program for providers and staff to improve patient's adherence to lipid"

The Florida International University Office of Research Integrity has reviewed your research study for the use of human subjects and deemed it Exempt via the **Exempt Review** process.

IRB Protocol Exemption #: IRB-20-0115 **IRB Exemption Date:** 03/31/20
TOPAZ Reference #: 108826

As a requirement of IRB Exemption you are required to:

- 1) Submit an IRB Exempt Amendment Form for all proposed additions or changes in the procedures involving human subjects. All additions and changes must be reviewed and approved prior to implementation.
- 2) Promptly submit an IRB Exempt Event Report Form for every serious or unusual or unanticipated adverse event, problems with the rights or welfare of the human subjects, and/or deviations from the approved protocol.
- 3) Submit an IRB Exempt Project Completion Report Form when the study is finished or discontinued.

Special Conditions: N/A

For further information, you may visit the IRB website at <http://research.fiu.edu/irb>.

Appendix D

10775 SW 56 ST 1435 W 49 PI
Miami, FL 33165 Hialeah, FL 33012
786-360-4219 305-823-5730



Date: 3/3/2020

Charles P. Buscemi, PhD, APRN, FNP-BC, CWCN

Clinical Associate Professor

Nicole Wertheim College of Nursing & Health Sciences

Florida International University

Dear Dr., Buscemi:

Thank you for inviting De la Calle Medical Center to participate in the DNP Project of Ana L. Balcazar. I understand that this student will be conducting this project as part of the requirements for the Doctor in Nursing Practice program at Florida International University. After reviewing the proposal of the project titled *"Use of a structured educational program on providers and staff to improve patient's adherence to lipid-lowering medications. A quality improvement project."* I have warranted her permission to conduct the project in this company.

We understand that the project will be develop in our setting and will occur in two session in a four-week time frame and will probably be implemented afterward. We are also aware of our staff participation in supporting the student to complete this project, including warrant the student access to our facilities, give consent, deliver the pre-test questionnaire, provide the educational intervention and four weeks after providing the posttest to the recruited participants. We will provide a peaceful environment to safeguard our participant privacy as well as adequate area to conduct the educational activity.

This project intends to evaluate if a structured education targeting providers and staff will could increase patient's adherence to lipid lowering medications. The project will be conducted with the previous consent of potential participants receiving working in our facilities. Prior the implementation of this project, the Florida International University Institutional Review Board will evaluate and approve the procedures to conduct this project. Evidence suggests that a strong patient-provider relationship and providers attitude influence patients' perceptions and adherence to medication. Furthermore, increasing providers and staff awareness of cholesterol management, and medication adherence assessment and management will lead to improvement in our patient's healthcare indicators, reduce healthcare costs, and improve patient's quality of life.

The educational intervention will be classroom format, will last 40-60 minutes and educational materials will be provided to each participant receiving the class. Any data collected by Ana L. Balcazar will be kept confidential and will be stored in a locked filing cabinet at our office.

10775 SW 56 ST 1435 W 49 PI
Miami, FL 33185 Hialeah, FL 33012
786-360-4219 305-823-5730



We expect that Ana L. Balcazar will not interfere with the normal office performance, behaving in a professional manner and following the office standards of care. As Owner of De la Calle Medical Center, I support the participation of our providers and staff in this project and look forward to work with you.

Sincerely,

A handwritten signature in cursive script that reads "Gilda M de la Calle". The signature is written in black ink and has a long, sweeping underline that extends to the right.

Gilda M de la Calle
De la Calle Medical Center