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A Quality Improvement Initiative to Increase Statin Therapy Adherence Among Patients With Diabetes Aged 65 Years and Older

Kelly Nunemaker

University of the Incarnate Word, knunemak@student.uiwtx.edu

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A QUALITY IMPROVEMENT INITIATIVE TO INCREASE STATIN THERAPY
ADHERENCE AMONG PATIENTS WITH DIABETES AGED 65 YEARS AND OLDER

by

Kelly Nunemaker, BSN, RN

APPROVED BY DNP PROJECT ADVISOR / CLINICAL MENTOR:

Dianne Lavin DNP, PsyD, PMHNP-BC, RN

Jesus Yanes MD

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Abstract

The purpose of this project was to improve statin therapy adherence among diabetic patients aged 65 and older treated at a small family practice clinic in western San Antonio. Additionally, the project aimed to decrease low density lipoprotein cholesterol levels in this patient population as recommended to 70 mg/dl or less. Diabetic patients are more likely to die from a cardiac event than patients without diabetes. Statin therapy is an important factor in lowering cholesterol, which reduces the patient's risk for atherosclerosis. Educating patients aged 65 and older about the role of statin therapy in preventing cardiovascular events, stroke, and vascular compromise may increase medication adherence in this population, resulting in appropriate low density lipoprotein levels for prevention of these serious comorbidities. 135 chart reviews took place, from which thirty-three patients were identified for the education intervention. The patients were screened for medication adherence using the Morisky Medication Adherence Scale survey before and after the intervention period to measure adherence to statin therapy. Education about cholesterol and statin therapy was provided during the patient appointment, and a handout was provided for reinforcement of education. Low density lipoprotein levels were drawn by the clinic laboratory before and after the intervention period to measure improvement. Results showed significant medication adherence increase and low density lipoprotein level decrease among project participants after the 10-week implementation, though the target low density lipoprotein level of 70 mg/dl or less was not met.

Keywords: hyperlipidemia, diabetes, T2DM, statin therapy, cardiovascular disease, medication adherence

Diabetes and cardiovascular disease are two of the most common causes of death worldwide, and though there have been many medical advances in treatment of these two diseases, patients 65 years and older with diabetes remain at high risk for death due to cardiovascular disease. The internet has expanded the amount of knowledge and recommendations open to the world; however, this vulnerable population is not one that is familiar with the worldwide web. In many instances, paper education is still a valuable tool that can be utilized to educate patients in this age range.

Many patients 65 years and older are victims of polypharmacy, and this can lead to decreased medication adherence. As a result, these patients are at higher risk of cardiovascular disease not only because they do not know how to use the internet to find educational information, but because they may forget to take their cholesterol medication or they cannot afford it because of all of the other medications they may be taking concurrently.

Statement of the Problem

Type 2 diabetes mellitus (T2DM) is a chronic disease associated with issues such as a sedentary lifestyle and nutritional mismanagement of dietary patterns (Osonoi et al., 2016). T2DM affects anywhere from 341 million to 371 million people in the world (Mohammed, Al-Haj, Phung, Sun & Morisky, 2016), and heart disease is the leading cause of death worldwide (Osonoi et al., 2016). Most patients diagnosed with T2DM are not knowledgeable about the disease and fail to implement a healthy lifestyle. This pertains to adherence to medications that can control the disease and prevent further complications as well. Complications of T2DM include heart disease, stroke, renal failure, peripheral neuropathy and extremity amputation, and diabetic retinopathy which can ultimately cause blindness (Jalilian, Motlagh, Solhi, & Gharibnavaz, 2014). Proper management of T2DM can lead to better quality of life, and

prevention of comorbidities that can increase incidence of morbidity and mortality related to the complications of this disease.

One of the most frequently encountered comorbidities of T2DM, and one of the most fatal, is cardiovascular disease. Cardiovascular disease pertains to disease of the veins, arteries, and the heart, and is mostly due to atherosclerosis. Atherosclerosis is defined by the American Heart Association as a condition that develops when plaque made of cholesterol builds up in the walls of the arteries and makes them narrow and inflexible (American Heart Association, 2016). This makes it extremely difficult for blood to flow, and with less area to pass through, it is easier for a blood clot to form, causing a heart attack, and in the brain, a stroke (American Heart Association, 2016).

Both the American Heart Association and the American Diabetes Association recommend the initiation of statin therapy in the diabetic patient, as these patients are at high risk for cardiovascular disease related to atherosclerosis. However, when patients are given one more medication that is not for something already affecting their overall health, this generally does not persuade them to take said medication. The medications these patients have already been issued to control their T2DM not taken either because they feel fine or they have forgotten. Medication adherence is a major concern, as it is estimated that close to 50% of diabetics are non-compliant with medications of some sort (Mohammed et al., 2016). Non-adherence to medications can lead to hospitalization, emergency interventions, and even death (Mohammed et al., 2016). Some predictors of medication non-adherence are difficulty reading prescription labels, increased intensity of treatment, increased symptom burden, inadequate self-monitoring, and inadequate disease knowledge (DiBonaventura, Wintfield, Huang, & Goren., 2014). The risk for CVD can be decreased by living a healthy lifestyle with proper diet and exercise, and adherence to

medications, including the statins prescribed in order to lower LDL cholesterol and raise HDL cholesterol levels.

Background and Significance

In the United States, cardiovascular disease (CVD) leads to more than 2,000 deaths per day and costs 108.9 billion dollars per year due to health care services, medication costs, and lost productivity of the affected individuals (Moore, Fuller, & Thanavaro, 2015). Dyslipidemia is a leading risk factor for CVD, and more than 32 million Americans 20 years and older have elevated blood cholesterol levels (Moore et al., 2015).

In 2012, more than 29 million Americans had diabetes (9.3% of the U. S. population), and more than 8 million were unaware of the diagnosis (American Diabetes Association, 2016). The death rate due to cardiovascular disease is 1.7 times greater for diabetics than people without a diagnosis of diabetes (American Diabetes Association, 2016). People living with diabetes with high cholesterol levels are at a much greater risk of dying from a cardiovascular complication than people without diabetes.

In Texas, there are approximately 1.8 million people who are currently diagnosed with diabetes, which is 13% of the state's population (University Health System, 2017). More than 400,000 people living with diabetes in Texas are undiagnosed (University Health System, 2017). In Bexar County alone, 11.8% of the population is diagnosed with diabetes, which is more than 130,000 individuals (University Health System, 2017). Control of diabetes in this patient population is especially important, as diabetes is the fourth leading cause of death in Bexar County. Heart disease is the leading cause of death in the United States, in Texas, and in Bexar County as well (San Antonio Metropolitan Health District, 2009).

Control of LDL cholesterol is improving in the diabetic population receiving treatment. Forty-five percent of United States residents treated for hypercholesterolemia were controlled with an LDL level <100 mg/dl between 1999 and 2000, which raised to 63.6% in 2009 and 2010 (Farsaei et al., 2015). However, the improvement of HDL levels does not follow this increase, and remains problematic for those at risk, especially those with T2DM. Statin therapy not only decreases LDL cholesterol, but raises HDL cholesterol as well (American Heart Association, 2016). Diet and exercise are the most effective lifestyle changes that can be made to lower LDL, increase HDL, and decrease risk for CVD (Macias Saint-Gerons et al., 2014). Not every patient will adhere to an appropriate diet and exercise regimen, however, and initiation of statin therapy for patients with increased risk as an adjunct to diet and exercise is appropriate for prevention of CVD in the diabetic patient.

One of the major predictors listed above that may cause a person diagnosed with diabetes to adhere to a medication regimen is lack of disease knowledge. Some studies have shown that education sessions provided to patients with diabetes can improve overall health knowledge and increase medication compliance rates. One study, in particular, conducted in the United Arab Emirates, utilized a 30-minute education session led by a diabetic educator that focused on the importance of adherence in addition to defining the disease process, talking about the medications prescribed and what they do inside the body, and answering any questions the participants had about the specific medications they were taking (Mohammed et al., 2016). The results of the study were significant for improvement of medication compliance in the intervention group (Mohammed et al., 2016). Another study conducted in Iran for diabetic patients used the Health Belief Model to educate patients about their disease in order to improve compliance to medications, and this intervention included six separate education sessions

pertaining to disease knowledge (Jalilian et al., 2014). Results showed that if patients were truly worried about their disease process and the complications, more effort would be taken to improve health outcomes by the patients. The American Diabetes Association estimates the complications and costs of diabetes could be decreased significantly simply by increasing patient awareness and educating to improve prevention of comorbidities (Jalilian et al., 2014). If diabetic patients are non-adherent to diabetic medications, they are likely non-compliant with medications to prevent a disease they do not already have.

Several studies have been conducted in the United States as well, including a large pre-post cohort study conducted at the Cleveland Clinic in which significant regression of coronary atheroma and reduction of cardiovascular events was shown using ultrasound analysis in patients prescribed moderate to high intensity statin therapy (Stegman, Puri, Shao, & Nicholls, 2014). Improvement was shown in all patients, including patients with T2DM. The national guidelines for practice produced by the American Heart Association and the American College of Cardiology strongly recommend initiating statin therapy in patients with T2DM aged 40 years and older, as the evidence shows that statin therapy is effective in decreasing bad cholesterol levels while raising good cholesterol levels in order to prevent cardiovascular disease (Stone et al., 2014).

Assessment

The family practice clinic in which the quality improvement project was implemented is run by a group of 3 physicians, and 11 support staff including 1 practice administrator, 1 office manager, 3 administrative staff members, and 6 medical assistants. One diabetic educator is available 3 days per month for patient classes. Medicare and Medicaid are accepted, as well as

all other commercial insurances. The clinic has several contracts with managed care plans for patients aged 65 years and older for comprehensive disease management and primary care.

Stakeholders are people or groups of people that have a vested interest in clinical decisions and improvements related to evidence supporting clinical decisions (Agency for Healthcare Research and Quality, 2014). The main stakeholders of this family practice clinic are the patients and families of patients, providers and support staff, and payers such as employers and insurance companies. The patients' interests in the clinic stem from a concern for which aspects of the illness are most severe, what treatments are the most effective, and which options are the easiest to implement and maintain (Agency for Healthcare Research and Quality, 2014). Providers are the decision-makers, and they aim existing holes in the data pertaining to best treatment options and most harmful interventions, for the safe and effective management of patients (Agency for Healthcare Research and Quality, 2014). Providers must maintain an appropriate knowledge base to make the best treatment recommendations and must stay current on the most recent evidence-driven guidelines to provide quality care (Agency for Healthcare Research and Quality, 2014). Payers want to ensure that patients are treated with the best evidence-based treatment for expedition of healing, return to normal function, and to prevent complications related to disease processes that could increase direct and indirect costs of medical care (Agency for Healthcare Research and Quality, 2014). All stakeholders involved have a vested interest in the success of medical treatment and should support evidence-based practice and quality improvement measures.

Patients of all ages are seen in the clinic, from pediatrics to geriatrics, with the majority age ranging from 42 to 77 years. There are 848 patients aged 65 years and older seen in this primary care clinic. The current percentage of patients with diabetes mellitus with LDL-C levels

of 70 mg/dl or less is 35.6%. The aim is to increase the percentage of patients with diabetes mellitus with LDL-C levels of 70 mg/dl or less to 70%.

The “2013 ACC/AHA guideline on the treatment of blood cholesterol to reduce atherosclerotic cardiovascular risk in adults: A report of the American College of Cardiology/American Heart Association Task Force on Practice Guideline” states that patients with diabetes mellitus should have lipid panels drawn every 3 to 12 months, and 10 to 12 weeks after the initiation of statin therapy (Stone et al., 2014). Moderate intensity statin therapy should be initiated for patients aged 40 to 75 years with LDL-C levels of 70 mg/dl to 189 mg/dl (Stone et al., 2014). High intensity statin therapy should be initiated for patients aged 40 to 75 years with LDL-C levels of 190 mg/dl or greater (Stone et al., 2014). In order to appropriately manage diabetic patients at risk for cardiovascular disease, evidence indicates that statin therapy should be prescribed when indicated.

Organizational Readiness for Change

The Practice Improvement Capacity Rating Scale is a tool for assessing readiness of an organization for implementation of quality improvement measures that scores a practice overall in colors, with the color red correlating to not ready, yellow to limited capacity for change, and green correlating to ready and capable for implementation of quality improvement measures (Robert Wood Johnson Foundation, 2014). In using this tool, one must first determine who to interview at the practice. The scoring of the tool not only has an overall color of red, yellow, or green, but each criterion is weighted on a scale of 1 to 3, with 1 being lowest importance and 3 being the highest importance (Robert Wood Johnson Foundation, 2014). All criteria with a weight of 3 must be passed by the organization in order to receive a score of green. The clinic received an overall score of 255 by multiplying the scored questions by the weight of the

questions and adding each category to this total score. A score of 255 is considered green according to the scale, which indicates that the clinic ready and capable for QI work immediately (Robert Wood Johnson Foundation, 2014).

Project Focus

The primary objective of this project is to improve the percentage of diabetic patients aged 65 years and older with a LDL-C level of 70 mg/dl or less from 35.6% to 70% and a statin therapy adherence rate increase from 20% to 90% by August 10, 2017. The secondary objective is to increase the percentage of diabetic patients aged 65 and older prescribed statin therapy from 62.6% to 80% by August 10, 2017. In order to accomplish these goals, the LDL-C level was drawn and measured in the blood prior to the quality improvement measure implementation in June 2017 and after the completion of the measure implementation on August 10, 2017. The participants will complete the MMAS-8 survey to assess patient medication adherence prior to the start of the improvement measure in June 2017 and again after the project completion on August 10, 2017.

Summary and Strength of the Evidence

The evidence for this project consists of 8 articles from peer-reviewed journals. Included in these eight articles is one clinical practice guideline, four cohort studies, one correlational study, and two descriptive studies. The findings are consistent for support of education for improving medication adherence in the diabetic patient population. There is also evidence for effectiveness of statin therapy in preventing cardiovascular disease. The overall strength of the articles is acceptable to use as evidence to support this project.

Several studies done in other countries, such as Iran, Spain, Japan, and the United Arab Emirates, support initiation of healthy lifestyle choice including diet and exercise (Osonoi et al.,

2016), and initiation of statin therapy for management of dyslipidemia in patients at risk for CVD (Macias Saint-Gerons et al., 2014). Adherence is not a problem common to patients in the United States with T2DM, but common to many countries. Level 4 evidence in the form of a large cohort study in the United Arab Emirates indicated that adherence could be improved using educational sessions about T2DM, its associated risk factors, and recommended treatment regimens (Mohammed et al., 2016).

A large clinical trial conducted at the Cleveland Clinic in the United States compared rosuvastatin and atorvastatin on regression of coronary atheroma in diabetic and non-diabetic patients. It showed a significant improvement in patients with established atherosclerosis taking one of these medications over the course of 24 months, with intravascular ultrasound measurements taken to visualize regression of plaque in the arteries (Stegman et al., 2014). The evidence in this study, a controlled trial over 2 years, is graded Level 3 for strength of evidence. This study does include the diabetic patient, and is reliable for generalization of statin therapy for the T2DM population.

National guidelines are in place for initiation of statin therapy for cholesterol management of diabetic patients with LDL levels >70 mg/dl. This strength of evidence is Level 1, and the recommendations include statin therapy for T2DM patients with elevated LDL levels to include moderate to intensive statin therapy (Stone et al., 2014).

The evidence is international in support of utilization of statin therapy in the diabetic population in order to control overt CVD and to prevent CVD in those not yet affected by this complication. It is important to control the risk for all complications in T2DM patients, and with heart disease holding fast to its rank as the leading cause of death in the general population, this complication becomes one of ultimate importance for people living with T2DM.

Methods

Project Intervention

In order to accurately measure the improvement of LDL-C cholesterol levels in the diabetic population aged 65 and older in this clinic, a review of electronic medical records took place to retrieve the baseline cholesterol levels from previous laboratory studies taken. During the patient's regularly scheduled appointment, the MMAS-8 was completed by the patient as part of normal patient care routine for the purpose of measuring medication compliance. During the patient appointment, an education handout pertaining to cholesterol control and cardiovascular disease prevention was given to the patient scoring a 6 or less on the MMAS-8 when discussing current statin therapy increase or initiation of statin therapy for prevention of cardiovascular disease.

Patients were scheduled for return appointment at the end of the intervention implementation period for a redraw of blood in laboratory for LDL-C levels and reissued the MMAS-8 to assess for improvement in medication compliance. The scores were assessed and evaluated for significant improvement in LDL-C levels and medication adherence in order to ensure optimal outcomes for this population.

In order to confirm that the project, if successful, can be sustained by the providers and other staff members, a 30-minute staff meeting was held in which the project was explained, including each person's role. The providers will participate in the initial education session during the patient appointments to ensure continuity of care. All staff members were educated on how to find the handouts for education at the American Diabetes Association website.

Organizational Barriers and Facilitators

This clinic possesses many strengths that can facilitate successful completion of this quality improvement measure. The staff utilizes the electronic health record consistently, which makes it easier to track the overall health of the patient population, and to track which areas may need further attention. Parts of the electronic health record are available to patients through the patient portal as well, making it easier for them to read and interpret their own test results and to assist in their own care plan. The clinic has a strong reputation in the community, and there is facilitation of trust between patients, families, and providers. Trust is apparent between members of the health care team in the clinic, which should make it simpler to provide quality overall patient care. Network partnerships exist with managed care plans for the aging population seen in the organization, which makes more resources available to provide a holistic model of care. The office is run efficiently, with short wait times for patients and decreased stress on providers and support staff. All three providers are proficient in the Spanish language. This facilitates trust between patients seen in the clinic who speak English as a second language or not at all. Fluency in Spanish also allows the providers to appropriately educate the entire patient population seen in this organization. The clinic has a number of patients with multiple chronic conditions, such as diabetes, and with the assistance of the diabetic educator the clinic is able to provide quality care from an interdisciplinary approach.

Some weaknesses were also discovered in this organization. There is a lack of written educational materials available in the clinic waiting area or examination rooms. Written education is a supplement for providers that can assist the health care team in ensuring the patient retains education initiated during patient appointments. The continuity of care for some patients who do not come to scheduled appointments is an area of concern, as some patients with

chronic conditions are not attending recommended follow-up appointments to evaluate progress of disease management and medication adherence. Medication cost is an issue identified by some of the staff members in the organization, as they have spoken with patients who are concerned that they will not be able to afford all of the medications required to control their conditions and achieve optimal outcomes. Some procedures a patient may require, such as radiological examinations, have to be done off premises as these resources are not available in this clinic setting, which can be a barrier to appropriate disease management of some patients. The clinic is growing in patient number, however the small space allotted in the building for the clinic makes it difficult to expand the number of patients accepted into the practice. There is limited funding available to expand the clinic to a larger space, which poses another obstacle to providing care to a larger patient population. Lastly, slowed access to referred specialist consultations for patients with chronic disease management can impede the holistic approach to care for these individuals.

The west side of San Antonio is a growing community, with new homes being constructed daily and new businesses opening everywhere. Given this growing community, the patient population is expected to grow. With this clinic's positive reputation, many new patients are expected to choose this clinic as a primary care home for health care needs. A large part of the growing population is in the age range of 65 years and older, and these patients are choosing managed care plans that may have established partnerships with the organization. Urgent care centers, free-standing emergency rooms, and a small community hospital already exist in the area, as well, which could lead to more referrals post-discharge for follow-up care or establishment of primary care.

Some external threats have been established through the SWOT analysis for this family practice care setting. The number of specialty physicians on this side of the city are fewer than

the number needed, and the wait for patient referrals may be extended, leaving the primary care provider with the responsibility of managing multiple chronic conditions in some patients awaiting specialty care. Also, the patients are allowed to choose a primary care provider, and there are many choices for such care on the west side of San Antonio. Patients without insurance due to unemployment or other factors may not be able to seek primary care because of the inability to afford health care costs associated with clinic visits. Insurance companies also reimburse these organizations according to value-based care plans in some instances, and this may lead to decreased income for fee-for-service clinics.

This primary care clinic has the potential to make a difference and to utilize evidence-based measures to improve the quality of health care in the area, and there are many barriers and facilitators to the achievement of this goal, as listed above. Knowledge of the clinic's internal strengths and weaknesses, as well as external opportunities and threats will aid in completion of a successful quality improvement intervention.

Results

A total of 14 males (42.4%) and 19 females (57.6%), aged 65 years and older participated in the project. 16 participants were White (48.5%), 11 Hispanic (33.3%), 4 African American (12.1%), and 2 Asian/Pacific Islander (6.1%). All 33 participants had both an active diagnosis of diabetes mellitus and hyperlipidemia.

Table 1

Demographic Characteristics of Study Participants

Characteristic	Percentage	Mean	<i>SD</i>
Gender		1.58	0.50
Male	42.40		
Female	57.80		
Ethnicity		1.97	1.05
Caucasian	48.50		
Hispanic	33.30		
African American	12.10		
Asian/Pacific Islander	6.10		

Note. *SD* = Standard Deviation

Control of Cholesterol

After the 10-week project implementation period, LDL-C levels of less than 100 mg/dl were controlled 42.4% of the time, a 21.2% increase of the pre-intervention control rate of 21.2%. The LDL-C control for diabetic patients aged 40 and up is recommended to remain at 70 mg/dl or less, and this was found in only 12.1% of the participants. However, this small percentage is an increase of 12.1% since none of the participants were controlled at less than 70 mg/dl. Table 2 represents LDL-C levels before and after implementation.

Table 2

LDL-C Laboratory Values Before and After Education Intervention

Patient Number	Pre-Intervention LDL-C	Post-Intervention LDL-C
1	127	98
2	95	64
3	87	64
4	135	102
5	121	94
6	140	148
7	111	114
8	119	96
9	106	108
10	183	166
11	81	64
12	158	122
13	137	116
14	130	88
15	99	98
16	109	74
17	77	78
18	108	92
19	281	177
20	132	133
21	98	64
22	153	115
23	206	127
24	120	119
25	97	84
26	163	104
27	103	112
28	135	128
29	140	101
30	132	120
31	188	118
32	118	78
33	140	102
Mean	131.18	105.09
<i>SD</i>	25.56	

Note. *SD* = Standard Deviation

Adherence to Statin Therapy Regimen

Medication adherence improved among the group of participants from 0% to 34.46%. This percentage increase was calculated using the formula $(y_2 - y_1) / y_1 \times 100$. For statistical analysis of the MMAS-8 scores, a paired t-test was utilized to determine significance of the difference in scores pre- and post-implementation of the project among participants. The results were consistent with the desired outcome, in that post-intervention adherence scores ($M = 5.36$, $SD = 0.82$) were higher than the pre-intervention adherence scores ($M = 7.21$, $SD = 0.22$). The difference between pre- and post-implementation scores was statistically significant ($M = -1.85$, $SD = 1.35$, $t(32) = -7.87$, $p < .05$). Table 3 displays the paired t-test statistical analysis for medication adherence scores before and after the intervention.

Table 3

Medication Adherence Paired T-Test Results

	Mean	SD	SEM	95% CI for Mean Difference		t	df
				Lower	Upper		
Participants' MMAS-8 score pre- and post-intervention	-1.85	1.35	0.24	-2.33	-1.37	-7.87	32

Note. SD = Standard Deviation, CI = confidence interval, SEM = Standard Error of the Mean.
 $*p < .05$.

Although the target LDL-C level recommended by the American College of Cardiology and the American Heart Association of 70 mg/dl or less was not met, this project's duration was limited at only 10 weeks. Given more time, if adherence is maintained, this population could very well meet the target LDL-C level.

Discussion

The MMAS-8 medication adherence scale was consistently given to patients that entered the office over the age of 65 with a diagnosis of diabetes and hyperlipidemia over the first 2 weeks of project implementation. This was necessary because the implementation of education handout and information session during scheduled appointments could not proceed without an adherence scale in which to score the patient's baseline. The intake period of 2 weeks was necessary in order to have enough time to follow up in the same 10-week period and re-score the patients using the MMAS-8 scale.

Of these 35 patients selected, 35 received education handouts and materials based on the MMAS-8 score of 7 or less. At the end of the 10-week implementation period, these patients were rescreened with MMAS-8 during the follow-up appointment. The percentage increase of 34.46% indicates that many of these patients did make adjustments to his or her daily routine based on the education handout and session provided. The LDL-C levels, for the most part, showed this change in lifestyle with the correlation of decreased laboratory values, though the goal value of 70 mg/dl was not met.

Improvement of patient knowledge is a basic plan for controlling diabetes and complications from the disease (Jalilian et al., 2014). Verbal discussion about risks for cardiovascular disease and what that means for the patient, as well as a printed handout from the American Diabetes Association about cholesterol did show reduction in laboratory values and improved adherence over the 10-week implementation period.

Statin therapy has been proven to reduce the risk of cardiovascular events (Stegman et al., 2014). If the medication is only taken every other day, the patient does not receive the full benefit of the drug. Poor adherence at the beginning of this study, with scores of 7 or less on the

MMAS-8, did correlate with LDL-C levels above the recommended target LDL-C of 70 mg/dl.

With improved adherence, the LDL-C levels did decrease as hoped, and did meet the in 4 participants of the original 35 patients selected (11.43%).

Limitations

The sample size of this project was small with only 35 participants, due to the time limit of 10 weeks for implementation. No earlier implementation could have taken place, as there was time allotted to educate and train staff members about the project and what each person's role would be. Patients who were initially screened and did not follow up were not included in the final number of participants, because there was no way to measure adherence for these individuals. The short time allotted for implementation of the project is also considered a limitation. A longer time period for implementation may result differently.

Recommendations

Out of 52 patients screened with MMAS-8, 35 scored at or 7 or below in a 2-week time period, and hence received an education session and a paper handout about cholesterol and cardiovascular disease prevention. Diabetic patients need education about the risk for cardiac events related to diabetes, and if only 2 weeks yielded 35 patients from an age group of 65 and older who were not adhering to his or her medication regimen, a longer study may produce more patients with the same issue. This education should hence be provided as standard of care for the patients seen in clinic with a diagnosis of diabetes and/or hyperlipidemia.

Implications for Practice

None of the 52 patients diagnosed with diabetes and hyperlipidemia were screened for medication adherence prior to implementation of this quality improvement project. Of the patients screened during the project implementation, 100% of patients were initially scored as

non-adherent with a score of 7 or less on the MMAS-8. After implementation, the 0% adherence rate increased to 45.71% after project completion, with 16/35 patients scoring at 8 or above on the MMAS-8. This finding indicates that patients should be assessed for adherence regularly, either by scale or by asking the patient and/or family members about medication regimens. Reinforcement of education at follow-up appointments by discussing aspects of the patient's individualized treatment plan can assist in reminding patients about goals of treatment.

Knowledge empowers patients to participate in self-care activities, and with this education about cholesterol, patients are empowered to monitor levels with the physician to monitor improvement of the disease process. If diabetic patients track blood glucose levels and pay attention to the glycosylated hemoglobin levels in the physician's office, the LDL-C level should be added to that list for the patient to track with the provider. They will remain informed in this manner, and able to participate in the treatment plan, thus optimizing patient outcomes.

In order for this project to be sustained as a standard of care in the clinic, there must be a method of supervision in place for implementation to continue. The Advanced Practice Registered Nurse can offer supervision in this instance. Implementation and continuance of the American College of Cardiology/American Heart Association guidelines in order to ensure diabetic patients are placed either on moderate or high-intensity statin therapy and maintain LDL-C levels of 70 mg/dl or less has the capacity to impact the diabetic patient population significantly. The Advanced Practice Registered Nurse is able to screen patients for diabetes and high cholesterol, educate about medication adherence and disease management, and give a detailed explanation of any laboratory results analysis. As a provider, the APRN has the ability to positively affect the diabetic population by making this group less susceptible to cardiovascular disease through statin therapy adherence.

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Appendix A: Practice Improvement Capacity Rating Scale

Question	Weight	Criteria	Scripted Questions	Red (0 points)	Yellow (5 points)	Green (10 points)	Score	Comment
1	3	Commitment: Senior Leadership: QI Champion/ sponsor <i>Senior leadership: person or group that has responsibility for designation of time, finances, and resources</i> (Physician, RN, office manager)	Can you tell me about the commitment that senior leadership (the administration/ the practice) has made to the project? <ul style="list-style-type: none"> Do you have a designated leader? Is there a team that meets regularly? In terms of time, finances, resources? 	No designated leader for quality improvement or if designated, not actively engaged.	Leader designated for quality improvement work—however quality improvement team non-existent, or if exists, not meeting regularly to review project status/data.	Leader designated for quality improvement work and quality improvement team meets regularly to review project status/data and discuss improvement opportunities.		
2	3	Commitment: Financial Resources	IF NOT ANSWERED ABOVE: How do the leader and the QI team fit in QI work with their other responsibilities in the practice? <ul style="list-style-type: none"> Are they paid for working on a QI project or is it volunteer work? 	No time budgeted for QI activities. No specific funding to support QI activities.	Insufficient amount of FTE allocated for QI activities and/or limited/small amount of funding for QI activities.	Sufficient amount of dedicated FTE and funding allocated to QI activities.		
3	3	Level of Physician Leader Support	Do you have a physician leader who supports this effort? (Physician leader is one whom the other clinicians and staff look up to and identify as a leader.) <ul style="list-style-type: none"> What is the relationship between this person and the QI team? 	Physician leader has not been engaged in discussions regarding QI initiatives or has not yet confirmed their formal support.	Physician leader has confirmed their formal support of QI initiatives, but there are no regular meetings or interactions to discuss/review progress.	Physician leader demonstrates behaviors consistent with actively supporting QI efforts—this includes convening regular meetings with QI team leaders to review progress and help address issues/challenges.		
4	3	Level of Practice Administrator Support	Does your practice administrator or office manager support this effort? <ul style="list-style-type: none"> How do they demonstrate this to the staff? (How does the staff know they support it?) Do they meet with the QI team? How do/will they help the QI team with this effort? 	Practice administrator has not been engaged in discussions regarding QI initiatives or has not yet confirmed formal support.	Practice administrator has confirmed formal support of QI initiatives, but there are no regular meetings or interactions to discuss/review progress.	Practice administrator demonstrates behaviors consistent with actively supporting QI efforts—this includes convening regular meetings with QI team leaders to review progress and help address issues/challenges.		

5	3	Competing Priorities	<p>Are there any changes that have occurred/are going to occur that may have an effect on this project?</p> <p>Are there any other projects the practice will be working on while this QI project is going on?</p> <ul style="list-style-type: none"> How do you see them affecting this QI project? Do they overlap in terms of goals or data collection? 	<p>Currently converting to an EMR</p> <p>OR</p> <p>Significant staff turnover/changes</p> <p>OR</p> <p># of QI projects competing for time of staff and resources</p> <p>OR</p> <p>Change in leadership expected or imminent</p> <p>OR</p> <p>Merger or acquisition anticipated in near future.</p>	<p>Modest competing priorities, such as end phase of EMR conversion</p> <p>OR</p> <p>Other QI projects, but winding down soon</p> <p>OR</p> <p>Relatively stable staff and leadership structure.</p>	<p>No significant competing priorities</p> <p>OR</p> <p>Significant issues/challenges impacting execution of QI activities</p> <p>AND</p> <p>Stable staff and leadership structure.</p>
	2	Communication	<ul style="list-style-type: none"> Does the rest of the staff know about this effort? How have you kept the staff up to date with the progress of other projects in the past? How are you communicating the work being done by the QI team to the rest of the practice? 	<p>Project not discussed at regular staff meetings, limited knowledge among practice physicians/staff, no data/information posted or distributed</p>	<p>Some effort devoted to sharing project information and updates with practice physicians/staff</p>	<p>Project information and updates discussed with practice physicians and staff at regular practice meetings, data/information shared, input/feedback recruited. Data posted in visible place.</p>
7	2	<p>Access/Use of QI Infrastructure/</p> <p>Resources Available in the Community</p>	<p>Does your practice participate in any community improvement efforts?</p> <p>Any EMR sponsored or trade industry sponsored improvement efforts?</p>	<p>No practice awareness of QI infrastructure or resources available in the community.</p>	<p>Some awareness of QI infrastructure and resources available, but not yet accessing/using.</p>	<p>Practice is accessing/using QI infrastructure/resources available in the community.</p>

8	2	Prior Experience Executing QI Projects	<p>Tell me about the improvement work your practice has done in the past</p> <ul style="list-style-type: none"> What kind of experience do the members of the QI team bring to the effort? Do you keep a record of what you have tried and how it went? How do you decide if what you try/ change is working? (You are looking for answers that indicate they use data to drive improvement.) 	No identifiable improvement interventions pursued to date.	Improvement interventions pursued; but no formal QI method used (Model For Improvement, Lean, Six Sigma, etc.)	Previous improvement interventions pursued using formal QI method.
9	2	QI team designated with appropriate representation	<p>Who is/will be on your QI team? Why?</p>	<p>No QI team in place</p> <p>OR</p> <p>Several team members identified for QI activities, but there is a lack of balance representing the testing to be done (e.g., no RN included on team for PCMH)</p>	<p>Team members identified for QI activities.</p> <p>Balanced representation of staff based on QI activity.</p> <p>No patient partner on QI team.</p>	<p>Team members identified for QI activities.</p> <p>Balanced representation of staff based on QI activity.</p> <p>Patient/parent part of the team.</p>
10	2	Reliability of data	<p>How reliable do you think your reports are?</p> <ul style="list-style-type: none"> Does the information seem accurate to you? Do you compare your data to other practices or national benchmarks? Is there someone who looks over the reports for accuracy? Does the QI team review the reports? 	No designated point person reviewing data for accuracy.	Point person designated, but no defined process for monitoring accuracy/timeliness of data.	<p>Accuracy/timeliness of data monitored and addressed.</p> <p>Quality leadership person/team discusses data accuracy at regular intervals and identifies/pursues improvement opportunities.</p>

11	2	Reliability of data collection	<p>How reliable do you think your data are?</p> <ul style="list-style-type: none"> Do you think the data you need are reliably entered into the EMR with each encounter? Is there a way to tell if they are? Does everyone follow the same process for getting info/data into the EMR? 	Data collection solely dependent on clinicians at time of encounter.	<p>Redundancy built into data collection process.</p> <p>Point person designated, but no defined process for monitoring accuracy/timeliness of data entry.</p>	<p>Defined process for monitoring accuracy/timeliness of data entry.</p> <p>Quality leadership person/team discusses data collection process at regular intervals and identifies/pursues improvement opportunities.</p>
12	2	External Payment Incentives from Commercial/ Governmental Payors Linked to the QI Project	<p>Is the practice being paid to participate in an improvement effort other than MU?</p> <p>Are you being paid to report on or meet quality measures?</p>	Not currently.	Currently being discussed by commercial/governmental payors, but not yet in place.	Currently in place.
13	1	Meaningful Use	Where is your practice in terms of applying for meaningful use?	Not attested to meaningful use.	Meaningful use in design phase.	Meaningful use implemented and criteria met.
14	1	Source of IT support	<p>What do you do when you need to add fields to collect data or run reports?</p> <ul style="list-style-type: none"> Do you do this in office? Do you need to contact someone outside the office? Does this arrangement meet your needs/the needs for the QI project and QI team? 	No internal or external IT support available to the practice.	Internal or external IT support available to the practice, but not meeting needs of QI initiatives.	Internal or external IT support to the practice is meeting the needs of QI initiatives.
15	1	Use of EMR/Registry/ Analytic Reporting Tool for Measurement/Data Reporting	<p>What data will you be collecting for this project?</p> <p>How do you plan to collect the data you will need for this project?</p> <ul style="list-style-type: none"> Is the information currently collected in your EMR? Can you get reports based on the data from your EMR easily? 	No EMR.	EMR in place, but data fields linked to key measures not embedded, or related data reporting capabilities (EMR, registry, or <u>other</u> analytic tool) not yet in place.	EMR with data fields linked to key measures embedded, and data reporting capabilities in place.
<p style="text-align: right;">Total Score</p> <p style="text-align: right;">Must-Pass Criteria Met Yes / No</p>						
<p>Final Score—Circle level Red: 0-99 Yellow: 100-249 Green: 250 or greater and <i>all must-pass criteria met</i></p>						

Practice Improvement Capacity Rating Scale

Guide to Scoring for the Practice Improvement Capacity Rating Scale

1. Score each practice based in each of the criteria

- Red = 0 points
- Yellow = 5 points
- Green = 10 points

2. Each criterion is weighted

- 1: lowest importance
- 2: moderate importance
- 3: most important**

***Criteria with a weighting of 3 is a must-pass area. Practices need to be at the green level on all of these criteria to have a final score in the green.*

3. **Scoring**—Multiply the number of points earned for each criterion (0 v. 5 v. 10 points) by the corresponding weight assigned to that criterion, then sum up the individual scores for each criterion into a total score—for example, let's say the model included only the first two criteria listed in the table below:

- 1st criterion: practice is "yellow"—score for this criteria = 5 points x weight of 3 = 15 points
- 2nd criterion: practice is "green"—score for this criteria = 10 points x weight of 3 = 30 points
- Total score (assuming there were only two criteria in model) = 45 points—the total possible score = 60 points if the practice had scored "green" on both: (10 points x weight of 3) + (10 points x weight of 3)

4. Final Scoring

- Red—Practice is not ready for quality improvement (QI) work.
- Yellow—Practice has limited capacity for QI work at this time but might be ready in the future if improvements are made in the must-pass criteria.
- Green—Practice is ready and capable for immediate QI work.

Date: _____ Practice: _____ Interviewee: _____ Position: _____

Appendix B: SWOT Analysis from Family Practice Clinic

Strengths	Weaknesses
<ul style="list-style-type: none"> ▪ Electronic Health Record foundation ▪ Reputation for quality healthcare ▪ Patient Portal present on website ▪ Strong medical staff and strong leadership ▪ Problem-solving ▪ Trust between staff members ▪ Network partnerships (ex. WellMed) ▪ High level of efficiency ▪ Spanish language proficiency of providers ▪ Strong relationships with patients and families ▪ Interdisciplinary approach 	<ul style="list-style-type: none"> ▪ Lack of available written educational resources ▪ Difficulties in continuity of care ▪ Lack of appropriate medication costs ▪ Limited procedural/diagnostic capabilities ▪ Small clinic with some tight spaces ▪ Slowed access to referring physician documentation ▪ Limited budget
Opportunities	Threats
<ul style="list-style-type: none"> ▪ Growing metropolitan community ▪ Increasing aging and managed care population ▪ Expanding community health care programs 	<ul style="list-style-type: none"> ▪ Competition for specialty referring physicians ▪ Patient choice of primary care provider ▪ Lack of insurance related to high unemployment rate ▪ Reduction of government reimbursement

Appendix C: Morisky Medication Adherence Scale (MMAS-8)

Questions

1. Do you sometimes forget to take your medicine?
 2. People sometimes miss taking their medicines for reasons other than forgetting. Thinking over the past 2 weeks, were there any days when you did not take your medicine?
 3. Have you ever cut back or stopped taking your medicine without telling your doctor because you felt worse when you took it?
 4. When you travel or leave home, do you sometimes forget to bring along your medicine?
 5. Did you take all your medicines yesterday?
 6. When you feel like your symptoms are under control, do you sometimes stop taking your medicines?
 7. Do you ever feel hassled about sticking to your treatment plan?
 8. How often do you have difficulty remembering to take all your medicine?
 1. Never
 2. Once in a while
 3. Sometimes
 4. Usually
 5. All the time
-

Appendix D: Education Handouts for Quality Improvement Project

Toolkit No. 6**All About Cholesterol**

Managing your cholesterol and other blood fats (also called blood lipids) can help you prevent health problems.

There are several kinds of fats in your blood.

- **LDL cholesterol** is sometimes called “bad” cholesterol. It can narrow or block your blood vessels. Blocked vessels can lead to a heart attack or a stroke.
- **HDL cholesterol** is sometimes called “good” cholesterol. It helps remove deposits from the insides of your blood vessels and keeps your blood vessels from getting blocked.
- **Triglycerides** are another kind of fat. High triglycerides raise your risk of a heart attack or stroke.

Cholesterol is also affected by blood pressure and blood glucose (sugar). If your blood glucose and blood pressure are high, it's likely that your cholesterol may be off. All of these are risk factors for diabetes, heart attack and stroke. The more risk factors you have, the greater your risk. Talk to your health care provider about whether you may be at higher risk for diabetes and cardiovascular disease.

What treatments are recommended?

Both lifestyle changes and medicines help control blood fats. Treatment differs from one person to the next. Some people can manage their blood lipids with lifestyle changes like healthy eating and physical activity. Most people need lifestyle changes plus medicines. Work with your health care provider to find a treatment that's right for you.

What steps can you take?

Here are some ways to improve your blood fats. Place a check mark next to steps you're willing to try. Ask your health care provider for more information.

- ☐ If you smoke or use e-cigarettes, quit.
- ☐ Lose weight if needed.



Eating healthy, being active, and taking medicine can help manage cholesterol.

- ☐ Exercise most days of the week. Brisk walking for 30 minutes a day, 5 days a week is a good goal.
- ☐ Switch to a diet low in saturated fat, trans fat, and cholesterol.
- ☐ Your health care provider may also prescribe cholesterol-lowering medicine.

Medicines

Statins are a type of medicine to manage blood fats. They help lower LDL cholesterol. They also help lower your risk for a heart attack or stroke.

Adults with diabetes who are less than 40 years old should take a statin if they also have other risks for heart attack or stroke, such as high blood pressure or high LDL cholesterol. Most adults with diabetes who are 40 or older should be taking a statin.

There are also other medicines that improve blood lipids. Talk to your health care provider about whether you should take a statin or other drugs to reduce your risk for heart attack or stroke.



Guía N.º 6 sobre: Todo acerca del colesterol

El control del colesterol y otras grasas del cuerpo (también llamadas lípidos en la sangre) puede ayudarlo a prevenir problemas de salud.

Hay varios tipos de lípidos en la sangre.

- El colesterol de baja densidad (LDL, por sus siglas en inglés) también conocido como colesterol "malo". Puede angostar los vasos sanguíneos y bloquearlos. El bloqueo de los vasos puede causar ataques al corazón o derrames.
- El colesterol de alta densidad (HDL, por sus siglas en inglés) también conocido como colesterol "bueno". Ayuda a eliminar depósitos de grasa dentro de los vasos sanguíneos e impide que se bloqueen.
- Los triglicéridos son otro tipo de grasa. Un alto nivel de triglicéridos aumenta el riesgo de ataque al corazón o derrame.

La presión arterial y el nivel de glucosa en la sangre también tienen un efecto en el colesterol. Si usted tiene la glucosa y presión altas, es probable que su colesterol no esté dentro de los límites indicados. Todos estos son factores de riesgo de diabetes, ataque al corazón y derrame. Cuantos más factores de riesgo tenga, más peligro corre. Pregúntele a su proveedor de servicios médicos si corre más peligro de tener diabetes y enfermedades cardiovasculares.

¿Qué tratamientos se recomiendan?

Tanto los cambios de estilo de vida como los medicamentos ayudan a controlar las grasas en la sangre. Los tratamientos varían según la persona. Algunos pueden controlar los lípidos en la sangre con cambios en el estilo de vida como comer sano y hacer actividad física. La mayoría de las personas deben tomar medicamentos, además de hacer cambios en su estilo de vida. Colabore con su proveedor de servicios médicos para encontrar el medicamento adecuado para usted.

¿Qué medidas debo tomar?

Estas medidas producen mejoras en los lípidos. Marque las que está dispuesto a tomar. Pídale más información a su proveedor de servicios médicos.

- ☐ Si fuma o usa cigarrillos electrónicos, deje de hacerlo.
- ☐ Baje de peso si necesita hacerlo.



Controle regularmente los niveles de lípidos en la sangre para ayudar a prevenir enfermedades cardíacas, ataques del corazón o un derrame cerebral.

Comer sano, hacer actividad física y tomar medicamentos puede ser beneficioso para controlar el colesterol.

- ☐ Haga ejercicio casi todos los días de la semana. Una buena meta es caminar a paso ligero cinco días por semana durante 30 minutos.
- ☐ Adopte una alimentación con poca grasa saturada, grasa trans y colesterol.
- ☐ Su proveedor de servicios médicos también le puede recetar un medicamento para bajarle el colesterol.

Medicamentos

Las estatinas son un tipo de medicamento para controlar la grasa en la sangre. Ayudan a bajarle el colesterol. También pueden reducir su riesgo de un ataque al corazón o derrame.

Los adultos menores de 40 que tienen diabetes deben tomar estatinas si también tienen otros factores de riesgo de ataque al corazón o derrame, como presión alta y un nivel alto de colesterol de baja densidad. La mayoría de los adultos mayores de 39 que tienen diabetes deben tomar estatinas.

También hay otros medicamentos que mejoran los lípidos en la sangre. Pregúntele a su proveedor de servicios médicos si debe tomar estatinas u otros medicamentos para reducir su riesgo de ataque al corazón o derrame.

