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Patient-Centered Implementation of Statin Therapy in Patients With Type 2 Diabetes

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PATIENT-CENTERED IMPLEMENTATION OF STATIN THERAPY IN PATIENTS WITH TYPE 2 DIABETES

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Giovanna P. Favarato

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Abstract

Heart disease is the leading cause of morbidity and mortality in Americans with type 2 diabetes mellitus. The American Diabetes Association recommends statins and lifestyle modifications for all patients with type 2 diabetes mellitus for the prevention of atherosclerotic cardiovascular events. A patient-centered approach to primary prevention is encouraged, yet there are no specific instructions regarding implementation. The Statin Choice Decision Aid is a tool designed to facilitate shared decision-making between the patient and the provider in the clinical setting. The 2018 American College of Cardiology/American Heart Association guidelines for the primary prevention of atherosclerotic cardiovascular disease for patients with type 2 diabetes mellitus were implemented into practice by prescribing statins and patient education for the appropriate patients. The Statin Choice Decision Aid was integrated into the electronic health record and accessed by the provider during the clinical encounter with the patient to help guide the decision to initiate statin therapy. Results yielded an impressive 82% increase in the provider's statin prescribing practice. In addition, more than half (75%) of those patients had their individual atherosclerotic cardiovascular risk score computed and documented in the electronic health record. The Doctor of Nursing Practice quality improvement project helped to achieve optimal and patient-centered approach to successfully adhering to the American College of Cardiology/American Heart Association guidelines.

Keywords: type 2 diabetes mellitus, cardiovascular disease, statins, shared decision-making

Patient-Centered Implementation of Statin Therapy in Patients with Type 2 Diabetes

Type 2 diabetes mellitus (T2DM) affects nearly 30 million Americans with approximately 1.5 million newly diagnosed cases every year (American Diabetes Association [ADA], 2018). The Texas Demographic Center (2018) estimates that 16.8% of the 2.3 million Texans living with diabetes mellitus reside in Laredo, Texas. As the number of cases of T2DM continues to rise, so does the occurrence of atherosclerotic cardiovascular disease (ASCVD). ASCVD is defined by the American Diabetes Association (ADA) as acute coronary syndrome, myocardial infarction, stroke, and peripheral vascular disease (National Library of Medicine, 2018). The combination of T2DM and ASCVD is the leading cause of morbidity and mortality and can reduce the life expectancy of a person by about 12 years (Schmidt, 2019). The cardiovascular-related expenditure associated with diabetes is valued at $37.3 billion per year (ADA, 2019). Evidence-based guidelines created by the American College of Cardiology (ACC) and American Heart Association (AHA) recommend statin therapy for lipid management and healthy lifestyle as first-line ASCVD prevention strategies in at-risk populations (Grundy et al., 2018). In considering the use of statins for the treatment of ASCVD, a yearly assessment of the patient's 10-year ASCVD risk score is important. This score considers the patient's age, gender, race, comorbidities, blood pressure, and cholesterol levels.

Simply prescribing statins to eligible patients is not always suitable or effective. The challenge emanates from the task of utilizing a patient-centered methodology. Ideally, the decision to begin statin therapy should start with a discussion between the patient and healthcare provider to identify and prioritize a patient's values and preferences. This conversation, referred to as shared decision-making, allows the provider to explain the specifics of treatment in terms of benefits, harms, and costs and directly address patient questions (Serrano et al., 2016). Shared

decision-making is the cornerstone of patient-centered care and helps the provider to identify the patient's social and financial attributes. Evidence-based tools have been developed to help clinicians use a shared decision-making approach to care in the form of education, choice, and conversation (Serrano et al., 2016). Mayo Clinic's Statin Choice Decision Aid (SCDA) was specifically created with shared decision-making in mind. Using the patient's data, the SCDA calculates the projected 10-year ASCVD risk score and by how much it can be decreased by initiating statin therapy (Inselman et al., 2016) (see Appendix A). Using the SCDA to make statin prescription decisions in a patient-centered manner can enhance both provider and patient satisfaction (Ye et al., 2018).

Statement of the Problem

Patients with T2DM are at higher risk of suffering an ASCVD event, such as a heart attack or stroke (Grundy et al., 2018). This risk is also increased by other factors, such as hyperlipidemia, hypertension, obesity, sedentary lifestyle and tobacco use (ADA, 2018). The ACC and AHA explicitly mention the importance of patient-centered approach for the management of high cholesterol levels in adults with T2DM and ASCVD risk assessment for better health outcomes. Upon assessment of the microsystem, the clinic was found to be non-compliant with recommendations made by the ACC and AHA.

Background and Significance

In addition to lifestyle changes, the clinical practice guidelines commissioned by the ACC/AHA (2018), recommend a moderate-intensity dose statin for the primary prevention of ASCVD in patients 40 to 75 years of age, with type 2 diabetes mellitus, a 10-year ASCVD risk score of greater than or equal to 7.5%, and a low-density lipoprotein cholesterol (LDL-C) level greater than or equal to 70 mg/dL (Grundy et al., 2018). Statins are a class of drugs that prevent

the production of cholesterol by the liver and help reduce cholesterol levels in the blood. Statin agents widely prescribed include atorvastatin, pravastatin, simvastatin, and rosuvastatin. The decision to prescribe a statin relies on the knowledge and expertise of practitioners. The advisory bodies, in addition to pharmacological treatment, recommend behavioral changes as the foundation of prevention of ASCVD in the diabetic population. These lifestyle behavioral changes include moderate-intensity aerobic exercise for a minimum of 150 min per week, limiting sodium intake, avoiding saturated fats, and increasing consumption of fruits, vegetables, and low-fat dairy products (Fox et al., 2015).

Shared Decision-Making

Shared decision-making allows clinicians to form an individualized care plan that fosters patient autonomy and shows respect. The three main components of shared decision-making are: (a) recognizing a need for treatment, (b) allocating evidence regarding the benefits and drawbacks of treatment, and (c) appraising patient values and inclinations (Ballard et al., 2017). Pokharel et al. (2016) suggest that eliminating barriers and implementing decision support tools has the potential to improve patient outcomes. Decision aids are an effective way for both patients and caregivers to conduct joint decision-making at the point of treatment (Ye et al., 2018).

Statin Choice Decision Aid

The SCDA is designed to determine the patient's 10-year ASCVD risk score and calculate the degree to which a statin will mitigate the risk (Inselman et al., 2016). It also graphically displays the risks and benefits associated with statin therapy. Clinicians are then able to share that information with the patient and provide a clear understanding of their health status. Upon checkout, the patient is given a handout summarizing the information covered during the

appointment (see Appendix B). After consulting with the provider, the patient is able to make an informed decision as to whether or not to start treatment with a statin or postpone their decision to a later time.

Assessment

The clinic is a small family-owned primary care clinic in Laredo, Texas. The office is located in an administrative tower at Laredo Medical Center, the city's largest acute care hospital. The clinic opened its doors in June of 2011. Together, Dr. G., an internal medicine physician, and his sister, a family medicine physician, opened the practice in June of 2011. Hours of operation are from Monday to Friday between the hours of 8 a.m. to 5 p.m. with laboratory service available at 7 a.m. The age range of patients treated are from 16 and 100 years, with the average age being 60. Personnel consists of one office manager, five medical assistants, three medical office assistants, two billers, and one information technology (IT) expert. There are no mid-level providers practicing at this facility. All staff members are fluent in both English and Spanish. There are eight examination rooms equally divided among the physicians. Handicap accessibility is available throughout the facility. In September of 2015, the organization adopted eClinicalWorks, an electronic health charting system, for documentation purposes. Medication reconciliation is completed by the medical assistants during triage and verified by the physician during the clinical encounter. Laboratory studies done at the clinic are automatically populated into the electronic health record (EHR). For studies done elsewhere, results must be requested and manually scanned into the patient's chart. Patient lab results are reviewed together with the physician at each follow-up visit.

A sample of the clinic population done in a review of 100 charts showed that an overwhelming majority of the patients are Hispanic, and their primary language is Spanish.

Seventy-five percent of patients are Medicare and/or Medicaid beneficiaries, 22% are privately insured, and the remaining 3% are self-pay (see Table 1). Provider services focus on preventative care and chronic care management. The most common chronic illnesses treated are T2DM, hypertension, obesity, hyperlipidemia, and cardiovascular disease and patients usually presented with multiple comorbidities. Nonetheless, there are instances when patients would arrive in crisis requiring direct admission to the hospital or referral to the emergency department. In the event that a patient becomes hospitalized, Dr. G. assumes care on behalf of himself and his sister for all admissions. Patients are seen on a scheduled appointment-basis; however, walk-in appointments are also accepted when openings are available. Patients can expect an estimated wait time of 1 hr. On average, the clinic sees 200-300 patients per week, with Dr. G. seeing an estimated 40-50 patients per day. Referrals are normally made to specialists in urology, orthopedics, and nephrology for cases requiring a higher level of care. Education related to medication administration, such as anti-hyperglycemic injectables prescribed for patients with T2DM, is conducted by the medical assistants using a return demonstration approach. The visit summary which lists new or discontinued medications and outlines the plan of care is issued by the receptionist at checkout.

Table 1

Patient Demographics

	Number of Patients *N* = 100
Gender	
Male	50
Female	50
Race/Ethnicity	
Hispanic	75
Non-Hispanic White	15
African American	5
Other	5
Insurance	
Medicare/Medicaid	75
HMO/PPO	22
Self-Pay	3

Organization's Readiness for Change

A pre-intervention chart audit conducted from September 6, 2019, to September 27, 2019, surveyed the medical records of 100 patients with a diagnosis code of E11.9 (type II diabetes mellitus without complications). There was no report for any of the patients concerning a determined 10-year ASCVD risk evaluation. In addition, only 30% of patients had a statin prescription on board.

The results of the chart review were presented to Dr. G. in a face-to-face meeting. The needs assessment of the clinic highlighted a distinct variance between guideline recommendations and clinical practice. Due to the lack of consideration for the uniqueness of each patient's case, the primary provider expressed hesitation in adhering to the evidence-based guidance. The provider preferred treating each patient at an individual level, rather than prescribing statins based solely on guideline recommendations. A quality improvement (QI) initiative was suggested to align provider practice preferences and adherence to statin therapy guidelines using a decision aid tool.

The clinic is enrolled in the Accountable Care Organization (ACO) program for quality improvement. The clinic has yet to meet the quality metrics for statin therapy guidelines, therefore reimbursement has not been attained. As part of the ACO, reimbursement is allocated in the form of a maximum bonus of 2% of earnings at the end of each year. These values are subject to change at any given time. In the event that a quality measure is not being met, clinics are penalized up to 4% of earnings within the same time frame. To be paid for the application of statin treatment, health care professionals must accurately record the applicable diagnosis code, prescribe a statin, and, if any, contraindications that exist. The goal of the QI project was to help the clinic meet the ACO benchmark by satisfying documentation regulations and supplementing clinic revenue.

Project Identification

Purpose

The purpose of this quality-improvement project was to translate the evidence-based 2018 ACC/AHA guidelines for cardiovascular disease prevention with statin therapy in patients with type 2 diabetes mellitus using the SCDA to support a patient-centered approach.

Objectives

1. By April 27, 2020, the 2018 ACC/AHA guidelines for the primary prevention of cardiovascular disease for patients with T2DM were implemented into practice by prescribing statins for the appropriate patients.
2. By April 27, 2020, the Statin Choice Decision Aid (SCDA) was used during eligible patients' encounters as evidenced by documentation of the patient's ASCVD risk score into the electronic charting system.

Anticipated Aims

1. Within 10 weeks of project implementation, 80% of eligible patients will be prescribed a statin based on the ACC/AHA guidelines.
2. Within 10 weeks of project implementation, the provider will use the SCDA to document the 10-year ASCVD risk score in 90% of patient encounters.

Summary and Strength of the Evidence

A review of the literature supported the foundation of the QI project. Evidence provided insight into gaps that existed between clinical recommendations and a patient-centered approach to practice implementation. The search domains used to find publications were PubMed, CINAHL Complete, MEDLINE ProQuest, and ScienceDirect. Search terms included statins, type 2 diabetes mellitus, cardiovascular disease, shared decision-making, and decision aid. Included in the review of the literature were peer-reviewed articles published between 2015 and 2019, with full-text available, and printed in English.

Statin Therapy

The guidelines for primary prevention of ASCVD specified by the ACC/AHA aligned with the findings in the research studies. Lipid management with moderate-intensity statin

therapy was delineated as one of the superior methods for the reduction of ASCVD in at-risk populations. Despite the well-established evidence regarding the effectiveness of statins for the prevention of ASCVD, there is little evidence to show proof of provider adherence to treatment guidelines. Nineteen clinical trials performed by Chou et al. (2016) included a total of 71,344 participants to compare the effects of statins to placebos. Results validated that statins were associated with a reduced risk of morbidity and mortality related to ASCVD events in adults without a prior history. A similar randomized controlled study by Mortensen et al. (2015) with 37,892 patients corroborated that strict adherence to the appropriate intensity of statin based on risk rating was associated with significantly better patient outcomes. As indicated by the review of literature, most studies related to the efficacy of statins were systematic reviews classified as level one on the Hierarchy of Evidence.

Statin Choice Decision Aid in Practice

There was a minimal number of studies regarding the use of SCDA in practice. There were two articles found that explored the use of the SCDA in clinical practice. However, there was no evidence that the SCDA had ever been used among Hispanics. A descriptive study by Ye et al. (2018) on the opinions of 60 primary care providers suggested that the integration of a point-of-care decision support tool, such as the SCDA, into the EHR increases clinician cognizance and usage related to statins for primary prevention. Results implicated a definitive increase in Statin Choice Decision Aid usage because it was made easily accessible to the user. A comparable randomized controlled study by Perestelo-Pérez et al. (2016) evaluated the perceptions of the SCDA of 168 Spanish patients and 29 clinicians. Findings supported the efficacy of the SCDA as evidenced by increased patient knowledge of statins, risk perception, and satisfaction with the quality of the decision-making process. While decision aid tools are

readily available, the dearth of evidence suggests that they are still being underutilized in primary care.

Shared Decision-Making

A review of the evidence revealed that shared decision-making has not yet been adopted as the norm in clinical practice. A study by Montori et al. (2017) underlined barriers to the implementation of shared decision-making for internists. These included desire, time constraints, and lack of patient comprehension. There remains a need for support from stakeholders and healthcare leaders in order to hold shared decision-making as the standard in clinical practice. Adjusting quality measures to require the use of a decision aid may prompt physicians to adopt this patient-centered practice. On a more positive note, research conducted by Kashaf et al. (2017), elucidated the relationship between shared decision-making and improved patient knowledge, patient risk perception, and decision-making quality. Implications for practice included adopting the shared decision-making paradigm for better health outcomes. The majority of studies related to shared decision-making are descriptive studies categorized as level four on the Hierarchy of Evidence.

Methods

Implementation strategies were intended to be used only for the patients of the physician who served as the Doctor of Nursing Practice (DNP) student's mentor. Interventions were selected to pilot guideline adherence in the clinic. The first step was to conduct an education session for the provider and clinic manager. The second step included generating an EHR alert to signal the provider of the need to perform a risk assessment for patients 40 to 75 years of age with a diagnosis of E11.9 (T2DM without complications). It was the physician's personal preference to solely use the diagnostic code E11.9 to identify patients with a history of T2DM.

Educational Intervention

One 30 min education session was held on the morning of Monday, February 10, 2020, for the provider and clinic manager. The clinic manager was included for the purpose of reinforcement and sustainability after completion of the QI project. The following information was conveyed in the form of a PowerPoint presentation which included: 1) 2018 ACC/AHA guidelines for the primary prevention of CVD for patients with T2DM, 2) statin options, 3) benefits of shared decision-making, and 4) operation of the SCDA. The PowerPoint presentation outline was distributed to the attendees and e-mailed to them for future reference.

EHR Intervention

The student partnered with the information technology systems expert to design an EHR alert used to flag the charts of patients meeting the following criteria:

- 40-75 years of age
- diagnosis of E11.9 (type II diabetes mellitus without complications)
- no history of a statin prescription
- no previously documented ASCVD risk score

The alert was intended to encourage the provider to use the decision aid tool during the clinical encounter. A direct link to the decision aid tool was also made available in eClinicalWorks to enhance accessibility.

Organizational Barriers and Facilitators

Organizational barriers to project implementation included the high volume of patients seen at the clinic on a daily basis. As a result, time constraints were anticipated to hinder the utilization of the SCDA during patient encounters. Another obstacle was the ability of the patient to reject statin therapy perhaps due to taking several drugs, or the aspect of adverse side effects.

Organizational facilitators included the support of the provider and his team for project implementation. This was expected to encourage adherence to the project implementation plan and solicited participation. Moreover, the provider had established long-standing, trusting relationships with his patients. Patients respect and customarily agree with the professional opinion of the provider. In appreciation of their involvement and cooperation, periodic gifts of gratitude (e.g. cookies, fruit, donuts) are provided to the staff.

Ethical Considerations

Ethical considerations for project implementation were the privacy of patients' medical records. No identifiable patient information was used for data collection. Data were recorded on an Excel worksheet and the file was stored on a secure USB drive kept in a locked cabinet located inside the clinic manager's office accessible only to the office manager, physician, and the DNP student. The doctoral student conducting the QI project completed a Health Insurance Portability and Accountability Act and Collaborative Institutional Training Initiative training certification prior to initiation.

Letter of Support

The management at the practice provided a letter of support expressing its approval and support for implementation of the QI project (Appendix C).

Evaluation

A 10-week retrospective review of data obtained from the medical reports was used to evaluate project outcomes. Inclusive criteria for data collection consisted of adults 40 to 75 years of age, with a diagnosis of type 2 diabetes, who have a serum LDL-C of greater than or equal to 70, and who were not on a statin regimen. Corroboration of Clinical summaries were assessed for provider documentation of an ASCVD risk score and evidence that a statin prescription was

sent to pharmacy. This information was located in the "assessment" section of the clinical note. The SCDA Patients had the option of accepting, declining, or deferring statin therapy.

Results

Results were obtained from the charts of all patients ages 40 to 75 years with a diagnosis of type 2 diabetes (E11.9) seen within the 10-week implementation period. A total of 100 patient charts were reviewed between April 28, 2020 and May 5, 2020. Of the 100 patient charts, data showed 42 were female and 58 were male. Atorvastatin, rosuvastatin, and simvastatin were prescribed the most because of cost-effectiveness.

The first aim was that 80% of eligible patients would be prescribed a statin based on the ACC/AHA guidelines. The percentage of statins prescribed increased from 30% to 80%. In spite of the challenges posed by the COVID-19 pandemic, 82% of patients were given a statin, according to the findings (see Table 2). The number of statins prescribed was the lowest during the transition to telemedicine which occurred during week 7 (see Figure 1).

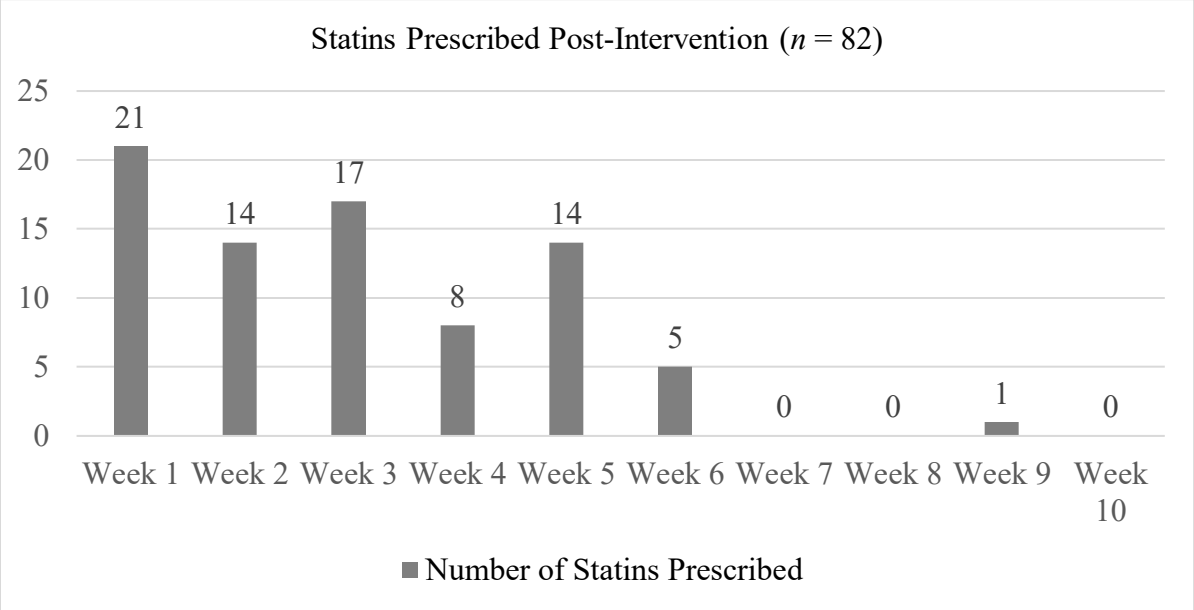
Table 2

Prescription of Statins

	Yes	No	Total
Pre-Intervention	30	70	100
Post-Intervention	82	18	100

Figure 1

Number of Statins Prescribed



The second aim was that the provider would use the SCDA to document the 10-year ASCVD risk score in 90% of patient encounters. Although statins were being prescribed, only 75% of charts displayed evidence of an ASCVD risk score assessment which fell short of the initial goal of 90% (see Table 3). The final 4 weeks of the implementation affected by the COVID-19 pandemic had the least amount of documentation. During this time, only 1 out of the 4 patients had a recorded risk score (see Figure 2).

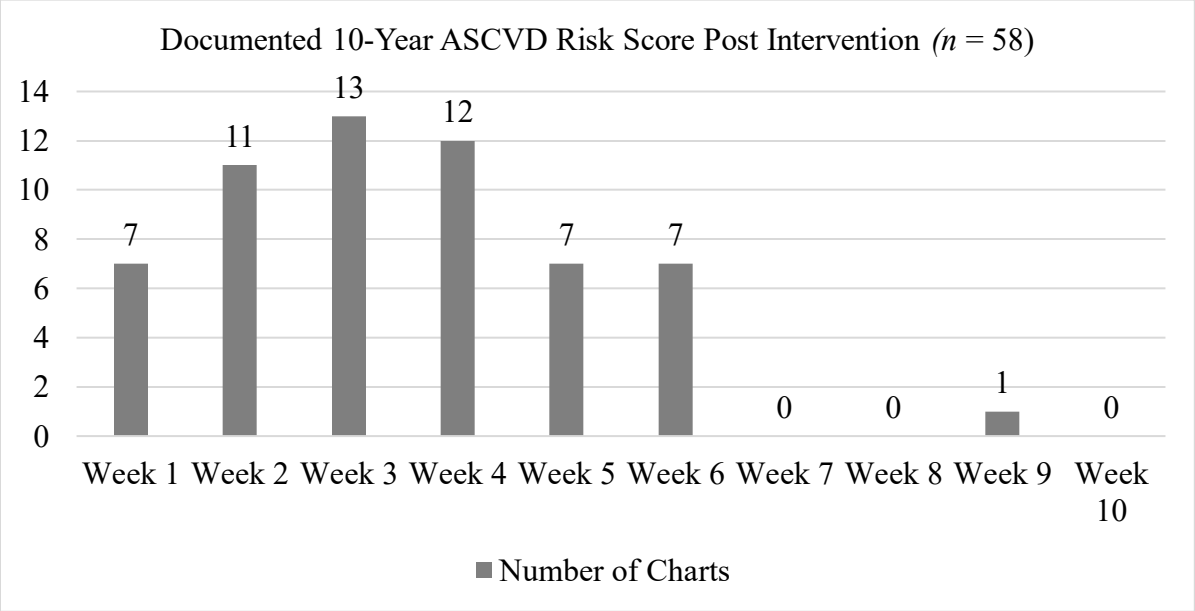
Table 3

10-Year ASCVD Risk Score Documentation

	Yes	No	Total
Pre-Intervention	0	100	100
Post-Intervention	58 (75%)	19 (25%)	77

Figure 2

Documentation of 10-Year ASCVD Risk Score



Discussion

The dramatic rise in the number of statin prescriptions proved to be the biggest achievement of the DNP initiative. Eighty-two out of 100 patients reviewed received a statin prescription which exceeded expectations. Another positive outcome was the overall improvement of cardiovascular risk assessment by the provider. Previously, 10-year ASCVD

risk scores were never documented. Results indicated that the provider's rate of documentation grew from 0% to 75%. Although the goal of 90% was not met, there was a steady increase during the time prior to the pandemic. The strength of this project was that statin prescription practice was affiliated with reimbursement opportunity. One of the objectives of the QI project was to use the SCDA during the clinical encounter to implement clinical guidelines using a patient-centered approach. This finding is aligned by a systematic review of six randomized controlled trials by Serrano and colleagues (2016) which evaluated the impact of shared decision-making in the care of individuals with diabetes. The literature revealed the efficacy of evidence-based decision aids to support shared decision-making as evidenced by an increase in the patient's knowledge, satisfaction, and risk awareness. Although it is beyond the scope of this project, it would be of interest to determine if the level of patient knowledge, satisfaction, and risk awareness was affected by the use of the SCDA.

Limitations

Time constraints limited the use of the SCDA during the clinical encounter as expected. As a result of the pandemic, in-person appointments were replaced by telephone calls which weakened shared decision-making. Research by Neville (2018) suggests that patient relationships are often damaged as a result of telehealth and the lack of human interaction (p. 4). The effectiveness and usage of the decision aid tool was hindered by the lack of face-to-face interaction and provider presence. Likewise, if the patient reported an acute health issue, the provider's attention was sidetracked from assessing the patient's ASCVD risk status to addressing the active problem.

COVID-19

The outbreak of the coronavirus disease 2019, commonly referred to as COVID-19, swept the community in late March. The COVID-19 pandemic produced unforeseen limitations during the latter part of the implementation phase. A shelter-in-place ordinance was enforced by City of Laredo officials on March 31, 2020, and a state of emergency was declared shortly afterward. Times of duress initiated a hurried transition to telemedicine that coincided with the last 4 weeks of the QI project. Consequently, all patient consultations were performed via telephone calls without video conference. Thirty min prior to the scheduled appointment time, the patient was initially contacted by a medical assistant for triage and documentation of the chief complaint. The provider then reviewed the chart and contacted the patient within 30 min. This made instituting a collaborative approach to making treatment decisions difficult because of the absence of the provider's presence. In addition, the patients were not able to jointly view the computer screen which revealed the ASCVD information with the provider, nor could they receive the educational material. The pandemic caused an increase in the number of appointment cancellations and patients became reluctant to have lab work drawn for fear of potential exposure to COVID-19. In addition, there were 19 patients who did not have lab results available for review therefore they were not included in the project sample.

Recommendations for Sustainability

For intervention continuation, the clinic manager was assigned the responsibility of verifying that the EHR alert system is operational on a weekly basis. Issuing a monthly progress report that displays the number of patients prescribed a statin and the amount of potential reimbursement lost may be beneficial. Furthermore, the use of the SCDA to promote statin

therapy can be expanded to include the other provider. Soliciting the support of the medical assistants to promote the project would also be of benefit.

Implications for Practice

Keeping patients healthy and out of the hospital while meeting quality metrics can potentially generate up to $50,000 per year in additional revenue. Increased shared decision-making may improve patient engagement during the clinical encounter and adherence to the medication regimen. Likewise, increased revenue is related to better statin prescription practices. In the future, project permanence will help the provider avoid a penalty for failure to meet the benchmark set by the ACO benchmark, and instead receive financial reward.

Role of the Nurse Practitioner with DNP Degree

The Doctor of Nursing Practice degree provides nurse practitioners with the skills necessary to assume leadership roles and practice at the highest level in order to improve patients' quality of life (Almasy & Champion, 2016). The DNP Essentials are the foundation of practice for doctoral-prepared nurse practitioners. It is the DNP's responsibility to interpret and translate the evidence and apply recommendations for use in practice. The DNP-prepared nurse practitioner must also be knowledgeable in the expert care and management of patients with a variety of conditions. This project was a true application of the DNP Essentials into practice. It fostered interprofessional teamwork and communication for the purpose of improving health outcomes of individuals with T2DM. In addition, the application of telemedicine aligned with DNP Essential IV which is directly related to the use of technology for the transformation of healthcare. Clinical practice was changed by the provider calculating 10-year ASCVD risk scores and prescribing statins to eligible patients in an effort to effectively manage cholesterol

levels. The project also helped to enhance the provider's cognizance of the adverse effects of cardiovascular disease for patients with Type 2 Diabetes.

Patients with type 2 diabetes mellitus remain at high risk for developing cardiovascular disease. It is imperative that healthcare providers take the proper measures supported by quality evidence to aid in the protection of their patients. By assessing the ASCVD risk score and prescribing statin therapy for those at high-risk, further development of comorbidities can be avoided. Moreover, primary care providers must remain current on practice guidelines and best practice standards. When discussing ASCVD prevention, a shared decision-making approach to treatment may help improve the quality of care provided in the primary care setting. During the clinical encounter, clinicians should strive to earn patients' trust in order to attain measurable results. The DNP prepared APRN is equipped with the knowledge and skills to help translate innovative evidence-based guidelines into practice.

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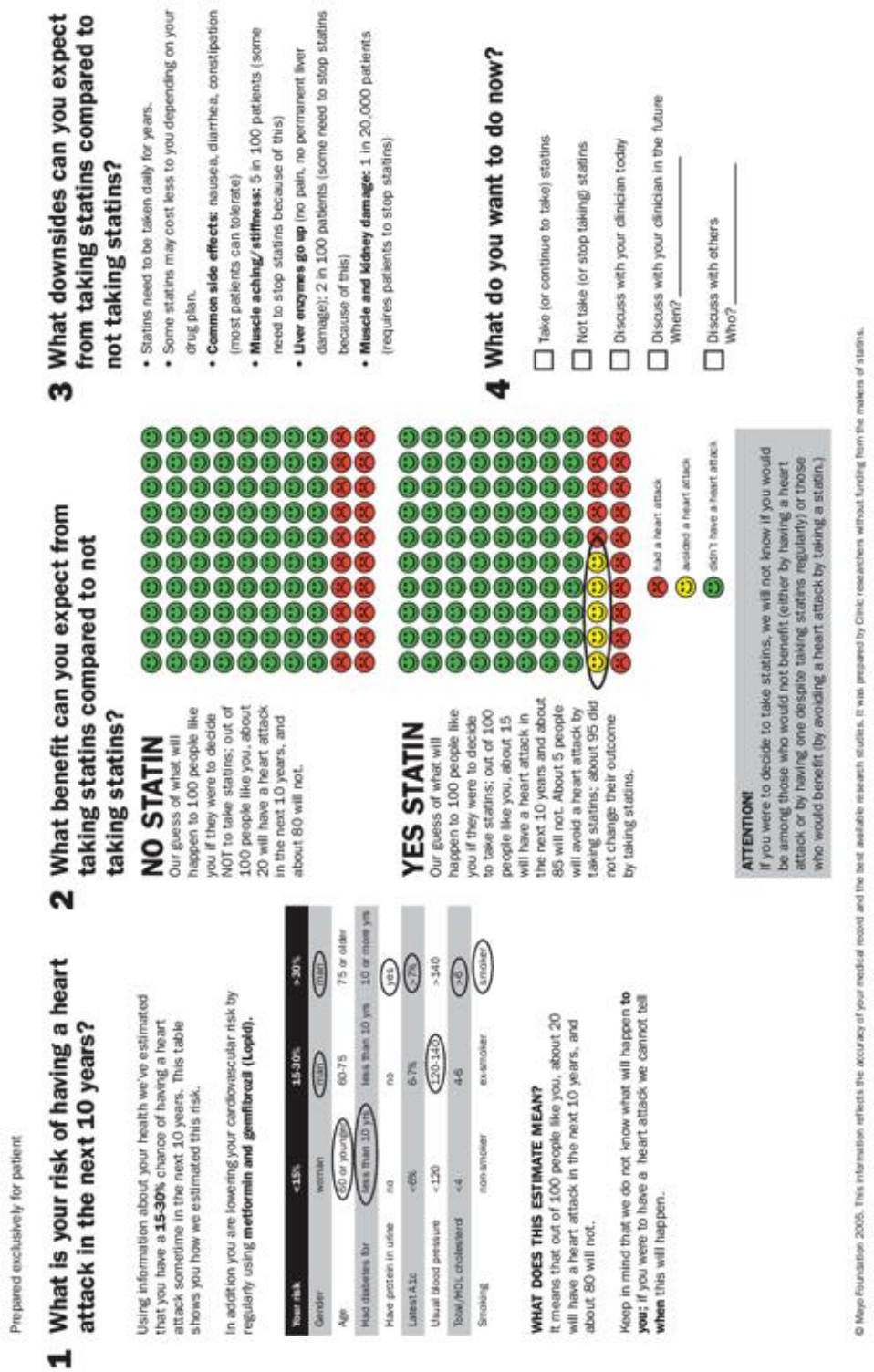
Appendix A

Statin Choice Decision Aid

Appendix B

Patient Handout



Prepared exclusively for patient

1 What is your risk of having a heart attack in the next 10 years?

Using information about your health we've estimated that you have a **15-30%** chance of having a heart attack sometime in the next 10 years. This table shows you how we estimated this risk.

In addition you are lowering your cardiovascular risk by regularly using **metformin and gemfibrozil (Lopid).**

Your risk	<15%	15-30%	>30%
Gender	woman	man	older man
Age	60 or younger	60-75	75 or older
Had diabetes for	less than 10 yrs	less than 10 yrs	10 or more yrs
Have protein in urine	no	no	yes
Latest A1c	<6%	6-7%	>7%
Usual blood pressure	<120	120-140	>140
Total/HDL cholesterol	<4	4-6	>6
Smoking	non-smoker	ex-smoker	smoker

WHAT DOES THIS ESTIMATE MEAN?
It means that out of 100 people like you, about 20 will have a heart attack in the next 10 years, and about 80 will not.

Keep in mind that we do not know what will happen **to you:** if you were to have a heart attack we cannot tell **when** this will happen.

2 What benefit can you expect from taking statins compared to not taking statins?

NO STATIN
Our guess of what will happen to 100 people like you if they were to decide NOT to take statins; out of 100 people like you, about 20 will have a heart attack in the next 10 years, and about 80 will not.

YES STATIN
Our guess of what will happen to 100 people like you if they were to decide to take statins; out of 100 people like you, about 15 will have a heart attack in the next 10 years and about 85 will not. About 5 people will avoid a heart attack by taking statins; about 95 did not change their outcome by taking statins.

had a heart attack
avoided a heart attack
didn't have a heart attack

3 What downsides can you expect from taking statins compared to not taking statins?

- Statins need to be taken daily for years.
- Some statins may cost less to you depending on your drug plan.
- **Common side effects:** nausea, diarrhea, constipation (most patients can tolerate)
- **Muscle aching/stiffness:** 5 in 100 patients (some need to stop statins because of this)
- **Liver enzymes go up** (no pain, no permanent liver damage): 2 in 100 patients (some need to stop statins because of this)
- **Muscle and kidney damage:** 1 in 20,000 patients (requires patients to stop statins)

4 What do you want to do now?

- ☐ Take (or continue to take) statins
- ☐ Not take (or stop taking) statins
- ☐ Discuss with your clinician today
- ☐ Discuss with your clinician in the future
  When? _____
- ☐ Discuss with others
  Who? _____

ATTENTION!
If you were to decide to take statins, we will not know if you would be among those who would not benefit (either by having a heart attack or by having one despite taking statins regularly) or those who would benefit (by avoiding a heart attack by taking a statin.)

Appendix C

Letter of Support

November 4, 2019

Garza Medical Associates

Garza Medical Associates
1700 East Saunders Street Suite A300
Laredo, TX 78041
Phone: 956.728.8120
Fax: 956.728.8615

To Whom It May Concern:

This letter is in support for the proposed Doctor of Nursing practice project conducted by University of the Incarnate Word student, Giovanna P. Favarato. We are excited to collaborate on this important quality improvement initiative are enthusiastic about the student's vision of improving shared decision-making. We will permit access to all the necessary data, as well as administrative support for project implementation. Please consider this information; in case you have any questions or concerns, do not hesitate to contact my office at 956.728.8120.

Sincerely,

Gilberto Garza Lozano, M.D., F.A.C.P.

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