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Implementation of ACE Inhibitor Regimen in Patients With Type 2 Diabetes Mellitus

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IMPLEMENTATION OF ACE INHIBITOR REGIMEN IN PATIENTS WITH
TYPE 2 DIABETES MELLITUS

by

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Rita Ifeanyi Chukwurah

Abstract

The incidence of type 2 diabetes has proliferated and is associated with many problems, including chronic kidney disease. The purpose of this quality improvement project was to implement two evidence-based guidelines that may detect chronic kidney disease and slow its progression in patients with type 2 diabetes by implementing angiotensin-converting enzyme inhibitor or angiotensin receptor blocker therapy according to evidence-based guidelines from the American Diabetes Association. Patients with type diabetes were screened for microalbuminuria and eGFR of $< 60 \text{ mL/min/1.73 m}^2$. Based on lab results, the provider recommended either an angiotensin-converting enzyme inhibitor or angiotensin receptor blocker to patients with as appropriate. The primary aim of this project was to achieve 80% implementation of an angiotensin-converting enzyme inhibitor or angiotensin receptor blocker for patients with type 2 diabetes who met criteria. Second, seventy to 90 percent of early progression to chronic kidney disease among those with type 2 diabetes was to be identified via blood and urine testing. One hundred and sixty-three patients with type 2 diabetes were seen during the implementation phase and screened, and one hundred and thirty-two patients who needed an angiotensin-converting enzyme inhibitor or angiotensin receptor blocker were placed on one or the other. Thirteen patients were on an angiotensin-converting enzyme inhibitor or an angiotensin receptor blocker prior to project implementation. Introducing an angiotensin-converting enzyme inhibitor or angiotensin receptor blocker as recommended for many patients with type 2 diabetes may slow the progression of chronic kidney disease and improve quality of life.

Keywords: type 2 diabetes, chronic kidney disease, diabetic nephropathy, ACE inhibitor, ARB, microalbuminuria, eGFR

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This paper describes a quality improvement project developed, implemented, and evaluated by this Doctor of Nursing Practice (DNP) student in response to a deficit in meeting diabetes guidelines from the American Diabetes Association (ADA, 2018) at a clinic serving a low-income population. Type 2 diabetes (T2D) is one of the most serious chronic diseases in the world in terms of its incidence, prevalence, economic and social impacts, and adverse effects on quality of life (Da Silva et al., 2018). The incidence and prevalence of T2D have increased exponentially in the United States and globally in past decades (Lai, 2016). According to the Centers for Disease Control and Prevention (CDC, 2017a), 30.3 million Americans have diabetes: 29.05 million have type 2 diabetes, and 1.25 million have type 1 diabetes. Among Americans with diabetes, 23 million cases have been diagnosed, and 7.2 million people remain undiagnosed (CDC, 2017a). Additionally, 84.1 million people in the United States have prediabetes, which may lead to T2D within 5 years if not treated (CDC, 2017a). Additionally, diabetes is the seventh leading cause of death among all persons in the United States and the fifth leading cause of death among Hispanics (CDC, 2018).

Statement of the Problem

The DNP student reviewed care of patients with T2D at a primary care clinic serving a low-income population. When reviewing medical records of patients with T2D, the student noted that not all ADA evidence-based guidelines related to diabetes management were being followed. Specifically, individuals diagnosed with T2D were not consistently receiving a urine albumin test and were not being placed on an angiotensin-converting enzyme (ACE) inhibitor or angiotensin-receptor blocker (ARB) as recommended by the ADA (2018).

Background and Significance

Type 2 diabetes is associated with many complications, and diabetic nephropathy and chronic kidney disease (CKD) are among the most devastating complications with respect to

patient survival and quality of life (Lai, 2016). Diabetic nephropathy is a syndrome characterized by the presence of pathological quantities of urine albumin excretion, diabetic glomerular lesions, and loss of glomerular filtration (Lim, 2014). Hyperglycemia associated with T2D is a fundamental cause of vascular complications which may lead to diabetic nephropathy and CKD. Poor glycemic control has also been associated with albuminuria (Lim, 2014). As the population with T2D increases, diabetic nephropathy has become the leading cause of CKD (CDC, 2017b). Approximately 1 in 3 adults with T2D may have CKD (CDC, 2017b). Adults with T2D, high blood pressure, or both have a higher risk of developing CKD than those without these conditions (CDC, 2017b). Other risk factors for CKD include heart disease, obesity, and a family history of CKD (CDC, 2017b).

Diabetic nephropathy involves an increase in proteinuria and a reduction in glomerular filtration rate (eGFR), which often results in kidney damage (Feng-Yi, Fang-Ju, Shih-Hui, & Wang, 2017). Ongoing kidney damage can lead to irreversible renal failure, known as end-stage renal disease (ESRD), which may eventually require dialysis or a kidney transplant (Feng-Yi et al., 2017). Chronic kidney disease among persons with T2D can be detected during a routine periodic health assessment, which should include urine testing for albumin and the albumin-to-creatinine ratio (ACR) and blood tests to assess eGFR (ADA, 2018). The glomerular filtration rate is determined by serum creatinine levels, age, gender, and race and reflects how well the kidneys are functioning. A urine check and ACR test detects the presence of the protein albumin, which establishes preliminary progression of kidney damage (ADA, 2018). A single eGFR value or albuminuria result is insufficient for a diagnosis of CKD. Therefore, these tests must be repeated to confirm a diagnosis that identifies continuous progression of the defining abnormality over a 3-month period (Romagnani et al., 2017).

Diabetic nephropathy may be present at CKD onset and can progress to ESRD (ADA, 2018). Additionally, CKD markedly increases cardiovascular risk. The *2018 Standards of Medical Care in Diabetes* supports prescribing an ACE inhibitor or ARB to normotensive, non-pregnant persons with T2D who have microalbuminuria and an eGFR of <60 mL/min/1.73 m² to slow the progression of CKD (ADA, 2018). An ACE inhibitor or ARB therapy is not recommended for primary prevention of diabetic nephropathy in patients with diabetes who have normal blood pressure, normal creatinine (<30 mg/g Cr), and normal eGFR (ADA, 2018). When the eGFR is <60 mL/min/1.73 m², evaluation and management of potential complications of CKD are required, and patients with an eGFR <30 mL/min/1.73 m² should be referred to a nephrologist for evaluation for renal replacement treatment (ADA, 2018).

According to the National Kidney Foundation (NKF, 2018), CKD has five stages as listed in Table 1. In the first stage of kidney damage, patients present with normal kidney function with an eGFR of > 90 mL/min/1.73m². As kidney function deteriorates, patients with Stage 2 CKD present with a reduction in eGFR ranging between 89 and 60 mL/min/1.73m². In Stage 3a, the eGFR ranges from 59 to 45 mL/min/1.73m² with mild to moderate loss of function; Stage 3b reflects moderate to severe loss of function with eGFR rates fluctuating from 40 to 30 mL/min/1.73m². Stage 4 represents severe loss of kidney function, where the eGFR is between 29 to less than 15 mL/min/1.73m². Stage 5 indicates kidney failure, also known as ESRD, with an eGFR of < 15 mL/min/1.73m² (NKF, 2018).

Table 1

Stages of Chronic Kidney Disease Based on eGFR

| | | GFR | % of kidney function |
|----------|--|--------------|-------------------------|
| Stage 1 | Kidney damage with normal kidney function | 90 or higher | 90–100% |
| Stage 2 | Kidney damage with mild loss of kidney function | 89 to 60 | 89–60% |
| Stage 3a | Mild to moderate loss of kidney function | 59 to 45 | 59–45% |
| Stage 3b | Moderate to severe loss of kidney function | 44 to 30 | 44–30% |
| Stage 4 | Severe loss of kidney function | 29 to 15 | 29–15% |
| Stage 5 | Kidney failure and need for dialysis or transplant | < 15 | < 15% |

Note. Adapted from “Estimated Glomerular Filtration Rate” by National Kidney Foundation (2018).

End-stage renal disease is the fifth and last stage of CKD and requires dialysis or kidney transplantation as life-saving measures (NKF, 2018). Common symptoms include a lowered ability or inability to urinate, confusion, fatigue, malaise, headache, loss of appetite, and dry skin and itching (NKF, 2018). New cases of ESRD in the United States have indicated that 44% of patients also have diabetes, 29% have high blood pressure, 20% of cases can be attributed to some other cause, and 7% of cases occur due to unknown etiology (CDC, 2017b). Table 2 depicts the stages of CKD and the corresponding focus of kidney-related care; Table 3 presents the classification of diabetic nephropathy by albuminuria level.

Table 2

CKD Stages and Corresponding Focus of Kidney-related Care

| CKD stage | | Focus of kidney-related care | | | | |
|-----------------------------|------------------------------------|------------------------------|---------------------------------|---|--------------------------------------|---------------------------------------|
| Stage | eGFR (ml/min/1.73 m ²) | Evidence of kidney damage | Diagnose cause of kidney injury | Evaluate and treat risk factors for CKD progression | Evaluate and treat CKD complications | Prepare for renal replacement therapy |
| No clinical evidence of CKD | | | | | | |
| | ≥ 60 | - | | | | |
| 1 | ≥90 | + | ✓ | ✓ | | |
| 2 | 60–89 | + | ✓ | ✓ | | |
| 3 | 30–59 | +/- | ✓ | ✓ | ✓ | |
| 4 | 15–29 | +/- | | ✓ | ✓ | ✓ |
| 5 | <15 | +/- | | ✓ | ✓ | ✓ |

Note. Adapted from “Standards of Medical Care in Diabetes-2018,” by American Diabetes Association, 2018, *Diabetes Care*, 41 p. s107.

Table 3

Classification of Diabetic Nephropathy by Albuminuria Level

| Urine specimen | Microalbuminuria | Macroalbuminuria |
|--------------------------------|--|------------------|
| Timed overnight collection | 20–199 µg/min | ≥200 µg/min |
| 24-hour collection | 30–299 mg/day | ≥300 mg/day |
| Albumin concentration | 20–300 mg/L | >300 mg/L |
| Albumin–creatinine ratio (ACR) | Men: 2.5–30 mg/mmol Women: 3.5–30 mg/mmol | >30 mg/mmol |

Note. Adapted from “Diabetic Nephropathy: Diagnosis, Screening, and Management,” by R. Bilous, 2013, *Diabetes and Primary Care*, 15, p. 90.

Diabetic nephropathy is the most common cause of CKD worldwide; between 20% and 40% of patients with diabetes develop diabetic nephropathy (Prakash, 2015). Diabetic nephropathy usually worsens over time and increased urinary protein excretion is the initial clinical indicator. Persons who exhibit this complication are at increased risk of cardiovascular disease and, if left untreated, diabetic nephropathy may lead to a rapid decline in renal function, which may result in renal failure and the need for a kidney transplant (Sudhakar, Pasula, & Simpson, 2014). Certain treatments have been shown to slow progression of CKD. Angiotensin converting enzyme inhibitors or ARBs can make a significant difference for patients with diabetes by reducing the risk of progression to CKD in normotensive patients with microalbuminuria (ADA, 2018; Lai, 2016).

The use of an ACE inhibitor or ARB is recommended for non-pregnant individuals with T2D who have a modestly elevated urinary albumin-to-creatinine ratio between 30 and 299 mg/g creatinine. This intervention is strongly endorsed for those with a urine albumin-to-creatinine ratio of 300 mg/g and/or an eGFR of 60 mL/min/1.73 m² (ADA, 2018). Additionally, an assessment of urinary albumin-to-creatinine ratio and eGFR should be performed for all patients with T2D at least once per year (ADA, 2018). Monitoring a patient's glucose level by checking the hemoglobin A1c every three months and recommending appropriate treatment may further reduce the risk or slow the progression of diabetic nephropathy (ADA, 2018). See Table 4 for a list of recommended ACE/ARB medications and comments related to ordering these medications.

Table 4

Angiotensin-converting Enzyme (ACE) Inhibitors and Angiotensin II Receptor Blockers

| Drug Class | Agent of Choice | Comments |
|---------------|---|---|
| ACE Inhibitor | Benazepril, Captopril, Enalapril, Fosinopril, Lisinopril, Moexipril, Perindopril, Quinapril, Ramipril, Trandolapril | <p>Do not use in combination with ARBs or direct renin inhibitor</p> <p>Increased risk of hyperkalemia, especially in patients with CKD or in those on K⁺ supplements or K⁺-sparing drugs</p> <p>May cause acute renal failure in patients with severe bilateral renal artery stenosis</p> <p>Do not use if history of angioedema with ACE inhibitors</p> <p>Avoid in pregnancy</p> |
| ARB | Azilsartan, Candesartan, Eprosartan, Irbesartan, Losartan, Olmesartan, Telmisartan, Valsartan | <p>Do not use in combination with ACE inhibitors or direct renin inhibitor</p> <p>Increased risk of hyperkalemia in CKD or in those on K⁺ supplements or K⁺-sparing drugs</p> <p>May cause acute renal failure in patients with severe bilateral renal artery stenosis</p> <p>Do not use if history of angioedema with ARBs</p> <p>Patients with a history of angioedema with an ACE inhibitor can receive an ARB starting 6 weeks after ACE inhibitor discontinued</p> <p>Avoid in pregnancy</p> |

Note. Adapted from “Hypertension,” by J. Saseen and E. Maclaughlin, 2017, *Pharmacotherapy: A Pathophysiologic Approach*, pp. 57–58.

Studies have shown that ACE inhibitors and ARBs help slow the progression of CKD in patients with T2D (Corbo, Delellis, Hill, Rindfuss, & Nashelsky, 2016; Qin et al., 2014; Sudhakar et al., 2014). One meta-analysis included evidence of the effect of ACE/ARB administration on mortality in patients with non-dialysis-dependent CKD (Qin et al., 2014). Findings indicated that among 81,959 patients with this diagnosis, a protective effect was found when ACEs or ARBs were used; this effect was associated with a reduced risk of all-cause mortality compared with ACE or ARB non-use (Qin et al., 2014). Sudhakar et al. (2014) demonstrated the value of reducing microalbuminuria related to diabetic nephropathy by implementing ACE or ARB therapy in a double-blind controlled trial of 100 patients with T2D. Findings revealed a reduction in 24-hour urine microalbuminuria after 3 months of treatment with ACE or ARB therapy (Sudhakar et al., 2014). Another meta-analysis of randomized controlled trials with disease-oriented outcomes reported that ACE inhibitors and ARBs reduced the risk of progression to CKD in normotensive patients with microalbuminuria and T2D (Corbo et al., 2016).

A systematic review of randomized controlled trials with a T2D population was undertaken to review studies examining normoalbuminuric persons to assess the efficacy of using ACE inhibitors or ARBs to slow the progression of CKD by comparing these interventions to a placebo (Persson, Lindhardt, Rossing, & Parving, 2016). Only studies with 50 or more participants in each arm were included for review. Ultimately, six trials encompassing 16,921 normoalbuminuric patients with T2D were included. After one year of follow-up evaluation of the effect on the development of micro- or macroalbuminuria, results indicated a 16% relative risk reduction for development of microalbuminuria in the ACE/ARB treatment group compared to the placebo groups (Persson et al., 2016).

Assessment

This project was conducted at a small, independently owned family practice clinic with two sites, Clinic A and Clinic B. The clinic sites are in an urban area of the southwestern United States, and both provide care to underserved populations. However, patients at the Clinic B tend to be above poverty level. No appointment is needed at either site. The clinics are headed and owned by a seasoned Doctor of Osteopathic Medicine with experience in emergency medicine and family medicine. The clinics are open Monday through Friday from 9:00 a.m. to 6:00 p.m. and 9:00 a.m. to 2:30 p.m. on Saturdays. Medicare is not accepted at the clinic, but private insurance, Medicaid, and cash are accepted. The mission of this clinic is to provide quality health services and improve the health of every patient who visits through a commitment to excellence. The staff's goal is to provide convenient, cost-effective care to the people they serve.

The clinic staff consists of one medical doctor, three nurse practitioners (NPs), eight medical assistants (MAs), and two secretaries. All clinic staff are bilingual except for the owner. The clinic manager works under the direction of the owner and is in charge of MAs and staff scheduling. The clinic manager and owner communicate verbally or via e-mail to manage changes in day-to-day operations.

The first clinic, Clinic A, is a 3000-square-foot facility with a waiting area, main desk with a medical record room, six triage rooms, two procedure rooms, one physician room, one manager's office, and one laboratory. This clinic is on a bus line route that serves a densely populated, low-income area with high rates of homelessness and recreational drug seeking. The second clinic site, Clinic B, is 1500 square feet and has five triage rooms, two physician offices, one laboratory, a manager's office, and a waiting area for patients. Clinic B is in a blended low-income and low-middle-class neighborhood with some homeless individuals in the area. It is also

on a bus line route.

Clinic A sees approximately 10 to 20 patients per day, 30 to 80 per week, and 200 to 245 per month; Clinic B sees between 15 to 35 patients each day, 45 to 100 per week, and 250 to 345 per month. The total number of new patients seen at both clinics ranges from 75 to 130 per month. Both clinic sites provide preventive medicine, primary care, and management of chronic diseases. Some of the medical conditions treated include hypertension; diabetes; urinary tract infections; and ear, nose, and throat problems. Other medical ailments such as asthma, sexually transmitted infections, cough, sore throat, bronchitis, allergic rhinitis, hyperlipidemia, gastrointestinal problems, pancreatitis, anemia, arthritis, back pain, and chest pain are common diagnoses at both clinics. Minor surgical procedures such as stitches for lacerations, incisions and abscess drainage, and ingrown toenail extraction are performed at the clinics.

Patients who visit the clinics range from 1 to 72 years old and older. Sixty-five percent of the patients who visited the clinic sites at the time of this project were Hispanic/Latino, 10% were Caucasian, 7% were Black or African American, 15% were Asian, and 3% were of another race. Among patients who were Hispanic/Latino, most spoke more Spanish than English. Patients' educational backgrounds ranged from no formal education to a high school diploma or college degree.

As part of the needs survey, the DNP student conducted an oral survey regarding patient satisfaction. For patients who spoke Spanish only, the MAs served as interpreters while the student asked questions. Fifty T2D patients were surveyed in English or Spanish over a two-month period prior to identification of the project purpose and plan. Patients with T2D were asked to indicate their responses on a 5-point Likert-type scale, with 1 being the worst and 5 being excellent. Questions regarding patient satisfaction included the amount of time patients

waited to get an appointment, convenience of the office location, length of time waiting at the office, time spent with the provider, provider's explanation of what was done, provider's sensitivity to patient's special needs or concerns, patient's satisfaction with getting the help needed, and feelings about overall quality of the visit. No identifying information (e.g., patient name, record number, or date of birth) was collected during this survey.

Most of the clients indicated dissatisfaction in some areas of care as evidenced by their scores and commentary. Questions with the lowest scores concerned time spent with the provider, explanation of what was done, and the provider's sensitivity to the patient's special needs or concerns. The mean scores on these three questions ranged between 2.48 and 2.7; see Table 5 for complete results of the patient satisfaction survey.

Table 5

Patient Satisfaction Survey Results

| Questions | 1 = Worst | 2 = Fair | 3 = Good | 4 = Very Good | 5 = Excellent | <i>M</i> |
|--|--------------|-------------|-------------|------------------|------------------|----------|
| Time it takes to receive appointment | | | 1216 | 13 | 9 | 3.38 |
| Convenience of clinic location | | | 30 | 15 | 5 | 3.5 |
| Time waited before seeing the provider | | | 1520 | 10 | 5 | 3.1 |
| Time spent with provider | 6 | | 2410 | 10 | | 2.48 |
| Provider explanation of disease and solution | 10 | | 2015 | 5 | | 2.3 |
| Provider sensitivity to patients' special needs or concern | | 5 | 1520 | 10 | | 2.7 |
| Satisfaction with care received | 10 | | 3010 | | | 2 |
| Overall quality of visit | | | 2515 | 10 | | 2.7 |

Note. *N* = 50 patients with T2D.

The DNP student was granted access by the physician to review the medical history of patients with T2D. With the assistance of the clinic manager, the number of patients seen at least once between October 1, 2017 and September 30, 2018 was determined to be 947. Out of these, 255 (27%) had a pre-existing diagnosis of T2D. The aforementioned figures were determined using the electronic medical record.

Next, 60 records of patients with a T2D diagnosis were chosen randomly and reviewed by the DNP student for demographic information including each patient's age, sex, race/ethnicity, and education level. Information about patients' past medical history, medication history, allergy history, and the most recent results of urine screening (ACR) and eGFR, if completed, were collected for baseline reference. The number of T2D patients with and without medical insurance was noted. Twenty-five percent of the 60 reviewed records had a completed ACR while approximately 60% of records had an eGFR lab result on record. Based on the DNP student's random evaluation of these records, only 25% of patients were on an ACE inhibitor or ARB.

The DNP student provided the physician and NPs with electronic copies of the *Standards of Medical Care in Diabetes Guidelines-2018*. The DNP student then met with providers and the manager simultaneously to discuss a proposal for a quality improvement project. Based on findings from the patient record review, the DNP student suggested a provider-level practice change to order urine albumin and eGFR screening on all patients with T2D and to add an ACE inhibitor/ARB as indicated by ADA evidence-based guidelines (2018). The DNP student explained that implementation of this initiative could improve or slow the progression of CKD. Specifically, the student discussed that the ADA (2018) standards recommended that an ACE inhibitor or ARB be prescribed to non-pregnant individuals with T2D who exhibited "modestly

elevated urinary albumin-to-creatinine ratio between 30–299 mg/g creatinine and strongly recommended [it] for those with a urine albumin-to-creatinine ratio of 300 mg/g creatinine and/or eGFR of 60 mL/min/1.73 m²” (ADA, 2018, p. S105). The physician and NPs recognized the need for a change in practice and were willing to implement the project.

The DNP student met with the clinic manager and the MAs on a subsequent day with the physician’s permission. During that meeting, the DNP student explained the initiative and clarified that the project was not intended to blame anyone, but to improve the quality of services rendered to T2D patients. With the student’s encouragement, all clinic staff agreed to support the project.

Readiness for Change and Stakeholder Engagement

This clinic provided a supportive environment, and staff and providers were observed working together as a team. Providers shared shift reports about daily events, which promoted continuity of care. Initially, staff readiness to incorporate change was challenging. The owner, a key stakeholder, is a medical doctor with excellent leadership skills but was not initially convinced of the need for change. After the DNP student reviewed and discussed the ADA (2018) evidence-based recommendations for patients who may have diabetic kidney disease and the potential cost–benefit ratio, the owner became supportive of the project and asked the NPs, manager, and MAs to commit to the quality improvement initiative. In addition to the physician, the NPs, clinic manager, and MAs were stakeholders invested in their patients’ care and the well-being of the clinic. After the DNP student provided a full explanation of the project to all staff, they became ready to institute a change in their clinical procedures and practices. Based on findings from the patient satisfaction survey, patients also recognized a need for improvement in quality of care and represented another major stakeholder.

Project Identification

Purpose

The purpose of this quality improvement project was to implement the ADA 2018 evidence-based standards of care among patients with T2D related to annual urinary albumin screening, eGFR, screening, and the use of ACE inhibitor or ARB therapy in non-pregnant patients with T2D who demonstrated kidney disease.

Objectives and Anticipated Outcomes

1. Increase provider's adherence to ADA (2018) guidelines for urine albumin screening (ACR) and blood test for eGFR screening among patients with T2D.

Anticipated outcome: 80% of patients with T2D will receive a urine albumin screening (ACR) and blood test for eGFR at least annually.

2. Increase provider initiation of ACE/ARB therapy for T2D patients who meet evidence-based criteria for an abnormal ACR or eGFR.

Anticipated outcome: Prescribed ACE or ARB therapy as indicated for patients with T2D will increase from 25% to 80% by April 30, 2019.

3. Develop and distribute a patient educational pamphlet (Spanish and English) related to the risks of kidney disease associated with T2D and the purpose of ACE inhibitor or ARB therapy.

Anticipated outcome: Provider will approve the developed educational pamphlet, and MAs will distribute it to patients with T2D when patients are placed in an exam room.

Summary and Strength of the Evidence

Healthy People 2020 has instituted objectives regarding diabetes outcomes, including an objective to increase the proportion of persons with diabetes who receive an annual urinary

microalbumin screening (U.S. Department of Health and Human Services [U.S. DHHS], 2019). Additionally, Healthy People 2020 has set an objective to increase the proportion of people with diagnosed diabetes and CKD who receive recommended treatment with ACE inhibitors or ARBs (U.S. DHHS, 2019). These national objectives reflect the need for improvement in these standards of care related to diabetes.

Members of the ADA Professional Practice Committee include physicians, advanced practice registered nurses, pharmacists, and registered dietitians. These professionals have developed a peer-reviewed process to establish goals, guidelines, and components of diabetes care for the professional healthcare community. The practice recommendations are graded based on level of evidence and are updated at least annually and published each year.

Recommendations are graded from highest to lowest as follows: A – evidence from random controlled trials or meta-analysis is available and substantiates the recommendation(s); B – evidence from strong cohort or case-control studies is available and supports the recommendation(s); C – evidence from “poorly controlled” or uncontrolled studies is available; and E – the recommendation is supported by “expert consensus or clinical experience” (ADA, 2018, p. S2). Please refer to Table 6 for project- related recommendations and grades of evidence.

Method

Project Intervention

The providers and MAs were educated on the aim and scope of the project as well as the steps to follow when patients with T2D visit the clinic. First, when a patient came in for an appointment, the MA would check them in, identify whether the patient had T2D, and take a medication history. Then, the MA would place a list of ACE inhibitors/ARBs in the record along

Table 6

Standards of Medical Care in Diabetes

| Standard | Grade of Evidence |
|--|-------------------|
| At least once a year, assess urinary albumin (e.g., spot urinary albumin-to-creatinine ratio) and estimated glomerular filtration rate in patients with type 1 diabetes with duration of ≥ 5 years, in all patients with type 2 diabetes, and in all patients with comorbid hypertension. | B |
| In non-pregnant patients with diabetes and hypertension, either an ACE inhibitor or an angiotensin receptor blocker is recommended for those with modestly elevated urinary albumin-to-creatinine ratio (30–299 mg/g creatinine) B and is strongly recommended for those with urinary albumin-to-creatinine ratio ≥ 300 mg/g creatinine and/or estimated glomerular filtration rate < 60 mL/min/1.73 m ² . | A |
| An ACE inhibitor or an angiotensin receptor blocker is not recommended for the primary prevention of diabetic kidney disease in patients with diabetes who have normal blood pressure, normal urinary albumin-to-creatinine ratio (< 30 mg/g creatinine), and normal estimated glomerular filtration rate. | B |

Note. Adapted from “American Diabetes Association standards of medical care in diabetes-2018,” *Diabetes Care*, 41 S, S105–S106.

with a star sticker on the chart, which indicated to the provider that the patient was diabetic. The providers, namely the medical doctor and NPs, would assess each patient’s medication list to see if he/she was already taking an ACE or ARB. If no eGFR or urine ACR had been obtained for baseline within the past 6 months, then urine was collected to check for ACR and blood was drawn for eGFR to assess for albuminuria and proteinuria. If there was evidence of albuminuria or proteinuria, an ACE inhibitor or ARB was to be ordered for the patient based on ADA recommendations (2018). These tests could be obtained at the clinic, and results were available within one to two hours.

For patients who met criteria to start an ACE inhibitor or ARB, the doctor, provider, or DNP student educated patients on the benefits and side effects of these interventions. Most of the

clinic's MAs spoke Spanish, which afforded the DNP student and providers easy access to an interpreter if a patient did not understand or speak English. Each patient was to be provided brochures developed by the DNP student explaining the benefits and side effects of ACE inhibitors and ARBs in either Spanish or English as appropriate; see Figure 1 for intervention steps.

The provider was to place the patient on a renal dose of an ACE inhibitor/ARB if the patient was not on a regimen already and met the ADA (2018) criteria. After a day, the MA was to contact the patient to ensure that medication had been procured and taken as indicated. The call was included as part of the clinic's protocol of calling patients to make sure their medication was filled and taken as prescribed. Each patient was asked to return to the clinic in 4–6 weeks with his or her medication for re-evaluation.

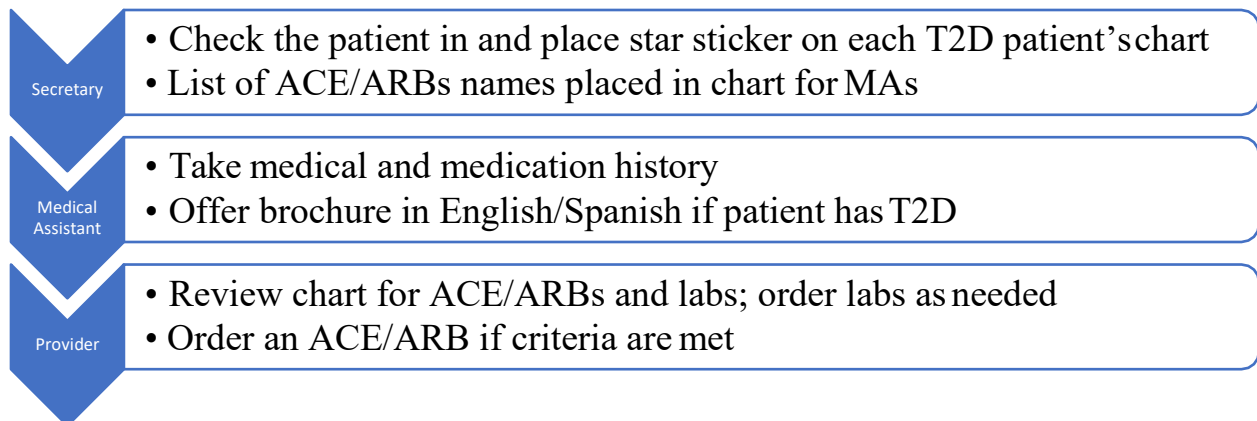


Figure 1. Steps for intervention.

Organizational Barriers

Language was a primary barrier in this project. Eighty percent of the clinic population was Hispanic, and most spoke little or no English; thus, they required a Spanish-speaking MA to interpret during appointments and bridge this gap. The clinic's charting system is 90% on paper, which slowed the chart review process. Financial barriers could have presented obstacles for

patients who were uninsured and paid cash for their visits. Another potential barrier involved the subset of patients who do not earn a steady income and depend on stipends for survival. Lastly, the cost of a new medication could be challenging for some patients to afford.

Facilitators

All clinic providers and staff verbalized their willingness to support and carry out all project objectives by collecting a urine and blood sample to determine ACR and eGFR, including implementing an ACE inhibitor or ARB regimen with T2D patients according to the *2018 Standards of Medical Care Guideline for Diabetes* (ADA, 2018). Staff ensured that the clinics stocked sufficient blood vacutainers, urine cups, needles, dipsticks, and in-house lab equipment to conduct ACR and eGFR tests.

Ethical Considerations

All project information, including relevant diagnostic criteria, was submitted to the Ethics Committee and Institutional Review Board (IRB) of the University of the Incarnate Word, and this study was deemed non-regulated research. The project was reviewed and found not to meet the federal regulatory requirements for human subjects' research; hence, IRB approval was not required. The owner of the clinic agreed to allow the DNP student to implement and evaluate outcomes of this project and furnished a letter of support stating this; see Appendix B for a copy of the letter.

Because many patients seen at the clinic were uninsured, the clinic owner decided to allow free one-time lab (ACR and eGFR) work and 3 months of medication to interested low-income T2D patients who could not afford to pay for lab work or procure their medication. Most patients could afford these steps, and those who could not were given free samples of an ACE inhibitor/ARB for 3 months.

Results

The results of this quality improvement initiative are listed below according to the corresponding project objective.

1. Increase provider's adherence to ADA (2018) guidelines for urine albumin (ACR) and blood test for eGFR screening among patients with T2D.

The anticipated outcome for this objective was set at 80%. During the implementation period, 163 patients with T2D were screened for albuminuria and eGFR by obtaining urine for ACR and eGFR from blood samples. Nineteen patients were not screened because they were already on ACE/ARBs. Out of the remaining 144 patients, 132 tested positive for albuminuria and 12 tested negative; thus, 100% of patients seen with T2D who were not already taking an ACE/ARB were screened for albuminuria. In total, 91.6% exhibited symptoms indicative of present or future CKD. The DNP student reviewed every T2D patient's record weekly to evaluate adherence to this objective and assess for any issues or barriers to implementation. This objective was met and exceeded the goal. Table 7 outlines the weekly data collection used to evaluate project outcomes.

2. Increase provider initiation of ACE/ARB therapy for T2D patients who meet evidence- based criteria for an elevated ACR or eGFR.

The anticipated outcome for this objective was set at 80%. As stated previously, 19 patients were already receiving ACE/ARB therapy and did not meet inclusion criteria for this objective; therefore, 144 patients could have received ACE/ARB therapy equals 144 patient. Of those, 132 patients met the evidence-based criteria for albuminuria and were placed on an ACE/ARB. Twelve patients were ineligible for ACE/ARB treatment as they did not have albuminuria or eGFR of < 60. See Table 8 for related data.

Table 9 presents a demographic overview of T2D patients seen at the clinic. About one-quarter (27%) of patients reported having less than a high school education. Most patients were of Hispanic descent followed by Asian descent. Patients age 66 and above had Medicare. Those who were too young to have Medicare had private insurance; others paid for their visits in cash.

3. Develop and distribute patient educational pamphlet (Spanish and English) related to the risks of kidney disease associated with T2D and the purpose of ACE inhibitor or ARB therapy.

Two hundred brochures were developed in English and Spanish explaining the purpose and benefits of ACE inhibitors/ARBs, and 163 brochures were given to all T2D patients seen; see Appendix A for the sample brochure.

Discussion

The most notable success of this quality improvement project was the providers' adherence to screening patients according to the ADA guideline: 163 T2D patients were screened, and 132 received a prescription for an ACE inhibitor/ARB. Another success was to see patients requesting to be screened based on the brochure provided during a prior visit. These patients wanted to ensure they did not have albuminuria and that their eGFR was not < 60. Major practice changes included the clinic automatically ordering labs for individuals with T2D who had not received labs within the past 3 to 6 months and then placing those who met criteria on an ACE inhibitor/ARB. The strength of this project was that the providers followed the guideline recommendation of providing ACE inhibitors/ARBs to patients with T2D. A potential challenge in this project was the language barrier, which the bilingual MAs helped to resolve. Another potential obstacle concerned finances, which the owner of the clinic mitigated by offering one-time free labs to eligible patients experiencing financial difficulties.

Table 7

Weekly Assessment Data Spreadsheet

| Week | Diabetic Patients Already on (<i>N</i> = 163) | ACE/ARB (<i>n</i> = 19) | Not on ACE/ARB (<i>n</i> = 144) | Placed on ACE/ARB (<i>n</i> = 132) | Not eligible (<i>n</i> = 12) |
|--------|---|-----------------------------|--|---|----------------------------------|
| Wk. 1 | 8 | 0 | 8 | 8 | 0 |
| Wk. 2 | 12 | 1 | 11 | 11 | 0 |
| Wk. 3 | 13 | 1 | 12 | 12 | 0 |
| Wk. 4 | 15 | 0 | 15 | 11 | 4 |
| Wk. 5 | 13 | 3 | 10 | 9 | 1 |
| Wk. 6 | 12 | 2 | 10 | 10 | 0 |
| Wk. 7 | 11 | 0 | 11 | 9 | 2 |
| Wk. 8 | 4 | 0 | 4 | 4 | 0 |
| Wk. 9 | 14 | 1 | 13 | 10 | 3 |
| Wk. 10 | 15 | 2 | 13 | 13 | 0 |
| Wk. 11 | 19 | 2 | 17 | 16 | 1 |
| Wk. 12 | 16 | 1 | 15 | 14 | 1 |
| Wk. 13 | 4 | 1 | 3 | 3 | 0 |
| Wk. 14 | 0 | 0 | 0 | 0 | 0 |
| Wk. 15 | 5 | 3 | 2 | 2 | 0 |
| Wk. 16 | 2 | 2 | 0 | 0 | 0 |

Table 8

Patient Data Analysis for 16 Weeks

| Patient Characteristics | Total (<i>N</i> = 144) | Percentage (%) |
|------------------------------------|-------------------------|----------------|
| Eligible for and placed on ACE/ARB | 132 | 91.6 |
| Not eligible for ACE/ARB | 12 | 8.3 |
| Contraindication to ACE/ARB | 0 | 0 |

Table 9

Demographics of T2D Patients Seen at the Clinic

| Characteristics | Number of Patients (N = 163) | Percentage (%) (N = 163) |
|------------------------|---------------------------------|-----------------------------|
| Age | | |
| 25–35 | 29 | 18 |
| 36–45 | 74 | 45 |
| 46–55 | 23 | 14 |
| 56–65 | 22 | 13 |
| 66–75 | 15 | 9 |
| Gender | | |
| Male | 74 | 45 |
| Female | 89 | 54 |
| Ethnicity | | |
| Hispanic/Latino | 95 | 58 |
| Caucasian | 25 | 15 |
| Black/African American | 11 | 7 |
| Asian | 32 | 20 |
| Education | | |
| No education | 44 | 27 |
| Less than high school | 23 | 14 |
| High school/GED | 45 | 28 |
| Some college | 25 | 15 |
| College degree | 18 | 11 |
| Master's degree | 8 | 5 |
| Insurance | | |
| Insured | 72 | 44 |
| Uninsured | 91 | 56 |

The purpose of this quality improvement initiative was to implement ACE inhibitor or ARB therapy in patients with T2D who met certain criteria; this intervention was intended to enact an evidence-based guideline related to slowing the progression of CKD as a vital part of chronic care of patients with T2D to promote prevention of complications (e.g., diabetic nephropathy) (ADA, 2018).

Cooperation among the providers and other clinic staff contributed to the success of this project. The staff followed the provided education and necessary steps (including in the absence of the DNP student); they also expressed a good understanding of the process. The English and Spanish brochure offered an overview of the advantages and side effects of ACE inhibitors/ARBs, and patients understood the pamphlet well based on their feedback. Some patients were initially reluctant to participate because they did not want to add more pills to their regimen. However, after learning about the benefits of ACE inhibitors/ARBs, they agreed to take part.

Limitations

Due to time constraints, this quality improvement project could not identify and track every patient to verify if they had purchased or were taking the ACE/ARB medication as prescribed. Even if the clinic staff were informed (e.g., via phone) that medication was procured and that patients were taking it, a verbal report is not equivalent to providers seeing and counting the pills remaining. Additionally, patients were not followed and seen at least 3 or 6 months after to monitor for abnormal ACR or eGFR due to the time limits of this project.

Recommendations

To improve the scope of the project, the time frame could be extended to one year or more and include a follow-up appointment. A longer intervention would permit more effective

application of the evidence-based guideline to properly monitor patients' kidney function by screening T2D patients' urine for albuminuria and blood sample for eGFR. Furthermore, a tracking system should be put in place to track all patients and verify if medication was procured and taken as prescribed. A follow-up plan for at least 3 to 6 months should be instituted to monitor patients for side effects, answer their questions about the medication, and monitor kidney function so patients can be referred to a nephrologist upon signs of progressive kidney damage.

Implications for Practice

The American Association of Colleges of Nursing (AACN) has emphasized that a DNP must recognize the scope of practice management along with theoretical and practical strategies to balance productivity with quality of care. Doctorally prepared nurse practitioners are expected to evaluate the impacts of practice policies and procedures on meeting the health requirements of the patient populations they serve. Also, a DNP must be knowledgeable in quality improvement strategies and in developing and sustaining change at the organizational and policy levels (AACN, 2006). There is increased demand on primary care providers in the United States because of changes in healthcare policy and an increase in a diverse and aging population; these issues require active coordination and management of care for patients with chronic diseases (Owens, 2018). The healthcare system is under pressure to provide cost-effective, high-quality primary care due to rising patient expectations, shifting government regulations, and insurance reimbursement (Owens, 2018). NPs, who comprise the most rapidly expanding segment of the primary care workforce and play major roles on interprofessional healthcare teams, must therefore assess patients appropriately. Responsibilities include ordering diagnostic tests and making diagnoses; initiating, coordinating, and evaluating treatment plans; and prescribing

medications (Owens, 2018).

Diabetic nephropathy is a serious complication of diabetes and is linked to significant mortality and comorbidity. Nevertheless, there is a solid evidence base for therapies that can prevent and slow the progression of CKD (Bilous, 2013). Regardless of clear screening and adherence to recommended guidelines, diabetic nephropathy remains considerably underdiagnosed (Kowalski, Krikorian, & Lerma, 2014). Current recommendations for early detection of progression to CKD and yearly albumin-to-creatinine ratio and eGFR checks should be uniformly implemented for all patients with T2D (Kowalski et al., 2014).

This quality improvement project focused on integrating an evidence-based practice guideline into care being offered at the selected clinic. The project aligned with the DNP essentials, which emphasize executive leadership, quality, service, process assessment, and improvement to transform the healthcare field (Sherrod & Goda, 2016). The American Association of Colleges of Nursing stresses that a DNP should possess the knowledge required to effect quality patient outcomes (AACN, 2006, p. 9). The organizational and systems leadership background that a DNP student obtains may improve patient and healthcare outcomes while promoting patient safety and excellence in practice (AACN, 2006, p. 10). The DNP-prepared leader should integrate nursing theory and scientific principles from the social sciences to recognize and address poor outcomes or lack of adherence to evidence-based guidelines that affect patient care. Doctorally prepared nurse practitioners should also be able to skillfully educate and develop a systematic process that guides system change and conduct projects in collaboration with other providers and healthcare staff to achieve high-quality patient outcomes.

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Appendix A: Patient Educational Brochure

English Brochure

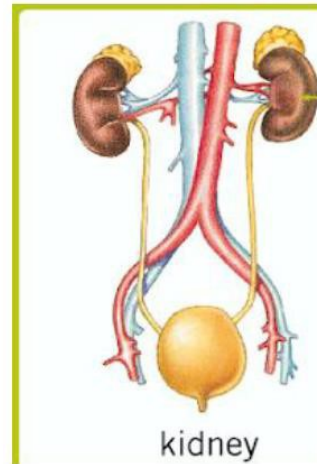


SLOW DOWN THE PROGRESSION OF CHRONIC KIDNEY DISEASE! TALK TO YOUR DOCTOR ABOUT YOUR KIDNEY IF YOU HAVE TYPE 2 DIABETES.

According to American Diabetes Association Standard of Medical Care in Diabetes 2018, ACE inhibitor or an ARB is recommended for non-pregnant T2D individual with modestly elevated urinary albumin-to-creatinine ratio between 30–299 mg/g creatinine and is strongly endorsed for those with urinary albumin-to-creatinine ratio of 300 mg/g creatinine and or eGFR of 60 mL/min/1.73 m² (ADA, 2018).

DOES YOUR LAB WORK SHOW ELEVATED ALBUMIN, PROTEIN OR eGFR less than 60%?

Talk to your Doctor about ACEI or ARBS



kidney

A QUALITY IMPROVEMENT INITIATIVE TO INCREASE USE OF ACE INHIBITOR THERAPY IN PERSONS WITH TYPE 2 DIABETES

Rita Chukwurah BSN, RN

Example of Angioedema



ACE INHIBITORS BRAND NAMES

Benazepril, Captopril, Enalapril, Fosinopril, Lisinopril, Moexipril, Perindopril, Quinapril, Ramipril, Trandolapril

SIDE EFFECT

- Do not use in combination with ARBs or direct renin inhibitor
- Increased risk of hyperkalemia, especially in patients with CKD or in those on potassium supplements or potassium sparing drugs
- May cause acute renal failure in patients with severe bilateral renal artery stenosis
- Do not use if history of angioedema with ACE
- Avoid in Pregnancy

ARBs BRAND NAMES

Azilsartan, Candesartan, Eprosartan, Irbesartan, Losartan, Olmesartan, Telmisartan, Valsartan

ARBs SIDE EFFECT

- Do not use in combination with ACE inhibitors or direct renin inhibitor
- Increased risk of hyperkalemia in CKD or in those on K+ supplements or K+-sparing drugs
- May cause acute renal failure in patients with severe bilateral renal artery stenosis
- Do not use if history of angioedema with ARBs. Patients with a history of angioedema with an ACEI can receive an ARB beginning 6 weeks after ACEI discontinued.
- Avoid in pregnancy

“We Value Your Health”



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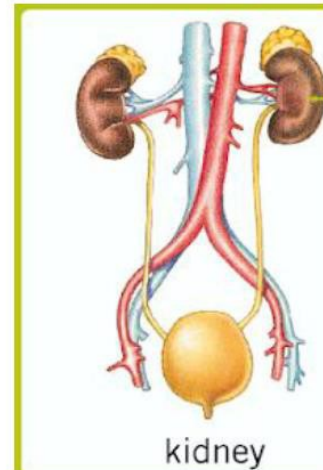
Spanish Brochure

¡BAJA LA PROGRESIÓN DE LA ENFERMEDAD DE KIDNEY CRÓNICA! HABLE CON SU MÉDICO SOBRE SU RIÑÓN SI TIENE DIABETES TIPO 2.

Según el Estándar de Atención Médica de la Asociación Americana de Diabetes en Diabetes 2018, se recomienda un inhibidor de la ACE o un ARB para pacientes con T2D no embarazadas con un índice moderadamente elevado de albúmina a creatinina entre 30–299 mg/g de creatinina y está fuertemente respaldado por aquellos con una relación de albúmina a creatinina en orina de 300 mg/g de creatinina y / o eGFR de 60 ml/min / 1.73 m² (ADA, 2018).

¿SU LABORATORIO DE TRABAJO MUESTRA ALBUMIN ELEVADO, PROTEÍNA O eGFR menos del 60%?

Hable con su médico sobre ACEI o ARBS



UNA INICIATIVA DE MEJORA DE LA CALIDAD PARA AUMENTAR EL USO DE LA TERAPIA DEL INHIBIDOR DE ACE EN PERSONAS CON DIABETES TIPO 2

Rita Chukwurah BSN, RN

EJEMPLO DE ANGIOEDEMA**NOMBRES DE LA MARCA DEL INHIBIDOR DE ACE**

Benazepril, Captopril, Enalapril, Fosinopril, Lisinopril, Moexipril, Perindopril, Quinapril, Ramipril, Trandolapril

EFECTO SECUNDARIO

- No usar en combinación con ARBs o inhibidor directo de la renina.
- Mayor riesgo de hiperpotasemia, especialmente en pacientes con CKD o en aquellos que toman suplementos de potasio o medicamentos ahorradores de potasio
- Puede causar insuficiencia renal aguda en pacientes con estenosis bilateral severa de la arteria renal
- No usar si la historia de angioedema con ACE
- Evitar en el embarazo

NOMBRES DE LA MARCA**ARBs**

Azilsartan, Candesartan, Eprosartan, Irbesartan, Losartan, Olmesartan, Telmisartan, Valsartan

EFECTO LATERAL ARBS

- No usar en combinación con inhibidores de la ACE o inhibidores directos de la renina.
- Aumento del riesgo de hiperpotasemia en la CKD o en aquellos con suplementos de K⁺ o medicamentos de K⁺
- Puede causar insuficiencia renal aguda en pacientes con estenosis bilateral severa de la arteria renal
- No usar si el historial de angioedema con ARBs. Los pacientes con antecedentes de angioedema con un ACEI pueden recibir un ARB a partir de las 6 semanas posteriores a la discontinuación del ACEI.
- Evitar en el embarazo

“Valoramos tu salud”

**Referencias**

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Appendix B: Letter of Support

January 23, 2019

Institutional Review Board
University of the Incarnate Word
4301 Broadway Street
San Antonio, Texas 78209

To whom it may concern:

I, Uriel Torres-Zuñiga NP-C, am aware of the Doctor of Nursing Practice project that will be conducted by Mrs. Rita Chukwurah RN at Cameron Medical and Health Clinic and Town North Medical and Health Clinic. I am aware the quality improvement project *A Quality Improvement Initiative to Improve Use of ACE Inhibitor Therapy in Persons with Type 2 Diabetes*, will be conducted over the year of 2019 and Mrs. Chukwurah will be overseeing the project on sites. I approve, and with the permission of my supervising physician, support the implementation of this DNP project.

Sincerely,

A handwritten signature in black ink that reads "Uriel Torres-Zuñiga". The signature is written in a cursive style with a large, stylized initial "U".

Uriel Torres-Zuñiga NP-C