

IMPROVING THE MANAGEMENT OF PATIENTS
WITH TYPE-2 DIABETES IN A RURAL CLINIC

by

Gregory Lynn Brooks

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In a poem from the 17th Century, John Donne wrote “No man is an island.” He writes how a person grows as a result of those around him. I can confidently say that I am who I am today because of the love and dedication of some very special people around me. I would be remiss if I did not acknowledge those individuals who made this fantastic journey a success.

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DEDICATION

To the countless number of nurse practitioners across the nation who chose to establish their practice in the rural communities of their state. Your service and commitment to providing care to an underserved population is an inspiration to those providers wanting to make a difference in this world. Your willingness to step out and make a difference in other people's lives is an encouragement to those who look up to you and follow in your footsteps.

To the underserved population across the United States with limited access and resources in your community. It is with you in mind that this project was established and carried out; that through continual reflection and constant vigilance, rural healthcare clinics will strive to provide the best possible care for you in all phases of your life. May the growing epidemic of type 2 diabetes in our country be managed with increased vigilance and through the unified effort of patient and provider.

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ABSTRACT

Background and Rationale: The increasing prevalence of type 2 diabetes, particularly in rural communities, is a major problem facing our nation. Many patients are in poor compliance with ADA guidelines for diabetes management. In addition, patients with diabetes in rural communities often face challenges that can impede management initiatives by health care providers (Utz, 2008). Quality care must be achieved to reduce the likelihood of costly, life-altering, and potentially fatal complications (American Diabetes Association, 2008). To manage chronic diseases effectively and prevent secondary complications, an organized quality review process within the practice setting should be in place to address quality indicators in an ordered and timely manner.

Purpose and Aims: The purpose of this project was to develop a quality improvement initiative (electronic diabetes education flow sheet - DEFS) associated with managing type 2 diabetes in a rural, nurse practitioner-managed clinic. The specific objectives were 1) to evaluate the extent to which select type 2 diabetes quality indicators are met; 2) to develop, implement, and evaluate a diabetes education process for a rural, nurse practitioner-managed clinic; and 3) to implement a QI framework clinic personnel can use for future QI initiatives.

Methods: The Plan-Do-Study-Act (PDSA) cycle was the framework used to implement the QI initiative. Process and outcome measures were collected for baseline data and the DEFS was developed. Routine evaluation by the QI committee ensured appropriate utilization of the DEFS. Patients receiving initial diabetes education were

interviewed to understand their perspective of the education experience. For eight weeks, process data was reviewed to ensure improvements in diabetes education.

Results: Data analysis of process measures showed inconsistent documentation of selected quality indicators. Outcome measures were controlled 62% to 70% of the time. Clinical staff successfully integrated the DEFS into patient education and expanded its use to ensure compliance. Limited numbers of patient volunteers prohibited analyzing patient feedback on the education process.

Significance: This project demonstrated how QI initiatives can bring about positive changes in patient management. Based on this demonstration of how the PDSA cycle can be used to address clinical concerns, other rural nurse-managed clinics might use a similar method to implement QI initiatives to ensure quality healthcare.

CHAPTER ONE: INTRODUCTION

Project Problem

Over the past three decades, considerable financial investment has been made in clinical research, which has led to a significant increase in medical knowledge. Yet these advances are inconsistently implemented in the practice setting (Institute of Medicine, 2001). There is a 15- to 20-year delay between the time an efficacious treatment is discovered and its incorporation into clinical practice and patient care (Balas & Boren, 2000). Evidence-based treatment guidelines have been issued by many professional and national organizations in the hopes of improving the management of chronic diseases (IOM, 2001). Even with the development of clinical guidelines, adherence and utilization by health care providers remains uneven throughout clinical practices. Thus most patients seen in primary health care clinics are not able to fully benefit from these research investments and subsequent discoveries.

Passive dissemination of practice guidelines for health problems has not been an effective method for improving patient care (Cabana et al., 1999; IOM, 2001). More active dissemination and effective clinical infrastructures within health care systems are necessary to apply appropriate healthcare.

The Institute of Medicine released a report in 2001, *Crossing the Quality Chasm: A New Health System for the 21st Century*, which called for every component of healthcare to address this widely recognized gap between research knowledge and application to practice (Coffey, Matthews & McDermot, 2004). Two key documents, the *National Healthcare Quality Report* and *The National Healthcare Disparities Report*,

which addressed health care quality, outcomes and efficiency, found considerable treatment variation across the United States. Healthcare providers were inconsistent in the management of health conditions. For example, in some states, only 17% of patients with type 2 diabetes received the recommended flu vaccine, while in other states the rates were as high as 64%. These reports also displayed gaps in what are considered essential elements in quality health care versus the care patients actually received (Coffey et al., 2004). Though research has established and supported clinical guidelines that include essential elements of quality healthcare, these guidelines are implemented inconsistently, and patients often do not receive the necessary care to reduce or prevent complications.

One of the problems facing our nation today is the increasing prevalence of type 2 diabetes. Over the past two decades, primary care providers have seen a dramatic increase in the numbers of patients with type 2 diabetes (Keilers, 2003; Resnick, Foster, Bardsley & Ratner, 2006). Evidence-based guidelines specific to the treatment of type 2 diabetes have been established based on many years of research (American Diabetes Association, 2009) and are valuable references for those clinicians managing diabetes in the family practice setting. Multiple studies have shown that adherence to a comprehensive care plan for diabetes resulted in a reduction in chronic disease complications (Coffey, Mathews & McDermot, 2004). However, many patients seen in family practice settings are in poor compliance with the recommended ADA guidelines for diabetes management (Resnick, et al., 2006). Effective disease management must be achieved in order to reduce the likelihood of costly, life-altering, and potentially fatal complications (American Diabetes Association, 2008).

For patients in rural counties, the problems of increased prevalence of type 2 diabetes is compounded by difficulties in accessing care. The prevalence of diabetes is almost 17% higher among rural Americans than those who live in urban areas (Utz, 2008). Rural regions in the southeast and southwest United States have an especially high prevalence of type 2 diabetes (Gamm, Hutchison, Bellamy & Dabney, 2002; Utz, 2008). The higher diabetes prevalence is thought to be associated with the increased number of people living in a lower socioeconomic status, an older population, and a greater proportion of patients of racial or ethnic minorities (Gamm et al., 2002; O'Brien & Denham, 2008). Rural populations are often less likely to engage in regular physical activity than urban populations and have higher rates of obesity, both of which are major risk factors of type 2 diabetes (Gamm et al., 2002). People with diabetes living in rural communities face additional barriers to health care that can complicate care management. Issues such as distance and transportation, costs of care and the availability of health care providers provide additional challenges to the complex management of diabetes faced by rural health care providers (Utz, 2008). In light of these challenges, clinicians in rural settings must be vigilant and learn to manage diabetes more effectively. Because the majority of people with type 2 diabetes in rural areas are treated in primary care clinics (Gamm et al., 2002), providers in these clinics must become more effective in utilizing the latest research to effectively manage diabetes and prevent an avoidable escalation of chronic problems associated with this disease process.

Background and Significance

There is a great need to close the well-documented gap between the evidence-based care and the care patients actually receive (Glasgow et al., 2004). Barriers to effective care must be recognized and addressed. Underlying reasons for inadequate care delivery are based upon the growing complexity of science and technology and the underutilization of information technology (IOM, 2001). Quality care problems can develop in a disorganized delivery system. Our current health care system often lacks the supportive environment, the necessary processes to ensure comprehensive care, and the effective operating infrastructure necessary to ensure quality health care. An increase in competing demands coupled with a decrease in effective use of time in the patient-provider visit, have resulted in previous attempts at eliminating the barriers to quality care being ineffective (Glasgow et al., 2004; IOM, 2001). For primary care clinics to manage chronic diseases effectively and prevent secondary problems from developing, there needs to be a system within the practice setting to address quality indicators in an organized and timely manner. Because of the limited availability of specialized providers and the distance traveled by those living in non-urban areas for basic health care, rural practitioners must effectively utilize the time they have with their patients and implement the highest quality of care possible (Gamm et al., 2002). Healthcare providers should utilize a well-defined infrastructure to coordinate and apply research supported interventions (Parchman & Kaissi, 2009). By implementing an organized system that addresses diabetes quality indicators, rural health care providers can reduce future micro- and macro-vascular complications, as well as the associated costs of these complications.

Healthcare providers play a pivotal role in improving the quality of care delivered to rural populations (Cabana et al., 1999). Providers must be open to changing their current practice patterns and align their clinical policies to address current practice needs demonstrated to be effective health care (Cabana et al., 1999; IOM, 2001). In the rural health care practices, where diabetes management has been demonstrated to be more complex, health care delivery systems must be assessed to improve the quality of care delivered.

Scope of the Problem

Diabetes is one of the most prevalent diseases in our nation today. The Center for Disease Control and Prevention (2005) states that almost 21 million people (about 7% of our population) have diabetes. Of these, approximately 17.5 million people in the United States have type 2 diabetes (ADA, 2008). This number is expected to increase by approximately 1 million people *per year* due to our country's rising obesity problem (ADA, 2008; CDC, 2007a; Li, Campbell & Tutor, 2004). It has been estimated that, by the year 2050, 12% of the population will have diabetes (ADA, 2008).

Diabetes is a disease characterized by hyperglycemia. While type 1 diabetes results from the body's lost ability to produce insulin, type 2 diabetes is characterized by insufficient insulin production and insulin resistance. In type 2 diabetes, the body does not produce enough insulin to properly metabolize glucose or cannot effectively use the insulin produced, which results in hyperglycemia (Bill-Fleury, 2008; Coffey et al., 2004; ODPCP, 2007). Insulin resistance has a strong link to inactivity and obesity, both of which are on the rise in America and in Oklahoma (Amati et al., 2009; CDC, 2007a;

Oklahoma State Department of Health, Chronic Disease Service, 2002a). Type 2 diabetes accounts for approximately 90-95% of all cases of diabetes and is on the rise in older and younger adults and, alarmingly, in children (Coffey et al., 2004).

In addition to type 2 diabetes, many adults in the United States have pre-diabetes, a condition in which fasting blood glucose levels are greater than the normal maximum value of 100 mg/dl but less than 126 mg/dl, the standard for diagnosing type 2 diabetes (ADA Standards of Care, 2009). Pre-diabetes is estimated to affect between 41-54 million adults over the age of 40 (Fonseca, 2008) and is a major risk factor for developing type 2 diabetes and cardiovascular disease (ADA Standards of Care, 2009).

Diabetes prevalence among adults living in Oklahoma has risen over 40% since 1990 and is considered one of the leading causes of death in Oklahoma (Oklahoma Diabetes Prevention and Control Program, 2007). In 1994, diabetes prevalence for adult Oklahomans was just under 3% (2.9%). By 2004, that number had nearly tripled to 8.5% (CDC, 2005), and by 2006, approximately 10.0% of the state's population had been diagnosed with diabetes (Oklahoma State Department of Health, 2007). This equates to approximately 268,500 people in Oklahoma who have been diagnosed with diabetes. When the number of those diagnosed with diabetes is combined with the number of people who have diabetes but are undiagnosed, the total number of those with diabetes climbs to approximately 419, 600 people in Oklahoma, or 15.6% (OSDH, 2007). In addition, one of every five senior citizens in Oklahoma age 65 and older has been diagnosed with diabetes (OSDH, 2007). In 2004, Oklahoma was ranked sixth in the nation in diabetes mortality (OSDH, 2007). These numbers don't include those over 20 years

old who are considered to have pre-diabetes and will be at higher risk of developing diabetes in the future (NDEP, 2007).

Diabetes is associated with many serious and long term complications, such as cardiovascular disease, kidney disease, eye disease, amputations and flu/pneumonia related deaths (Shojania, McDonald, Wachter & Owens, 2004). Other potential complications include digestive problems, increased susceptibility to infection, dental disease, sexual dysfunction, coma, and even death (Coffey et al., 2004). Many of these complications are preventable or have a degree of controllability (ODCCP, 2007).

People with uncontrolled diabetes have a two- to four-fold increase in the likelihood of experiencing either a stroke or heart attack (CDC, 2007b). Heart disease and strokes account for approximately 65% of all deaths among people who have diabetes (CDC, 2007b). Approximately 40,000 new cases of renal disease occur each year among people with uncontrolled diabetes, with over 100,000 people currently being treated for this problem (CDC, 2007b; OSDH, 2007). Between 12,000 and 24,000 people will become blind due to poorly controlled diabetes each year, and over 80,000 will have either a leg or a foot amputated., Each of these complications, to a degree, is considered preventable and ends up having a tremendous impact on the costs of having diabetes.

In 2007, the total estimated cost of diabetes spent on United States residents was approximately \$174 billion dollars (American Diabetes Association, 2008). Of that amount, 66.7%, or \$116 billion dollars, was associated with treatment of diabetes. Of the \$116 billion dollars spent on diabetes care, only \$27 billion dollars was allocated to the direct treatment or control of diabetes. Fifty-eight billion dollars was spent to treat

chronic complications associated with diabetes, and \$31 billion dollars was used to pay for excess general health costs. The remainder of the total \$174 billion dollars, \$58 billion, was estimated as the cost of lost productivity. This means that less than 16% of the total cost was for direct patient care (ADA, 2008). More money is lost treating diabetic complications related to poor management than on controlling the disease process itself.

In Oklahoma, the estimated annual cost of diabetes in 2007 was approximately \$1.87 billion dollars, (ODCCP, 2007). The per capita cost of a person with diabetes is approximately \$7,000.00, to the state of Oklahoma. Nationally, approximately 1 out of every 5 dollars spent on health care is for someone who has diabetes (ADA, 2008). Per capita expenditures for diabetes care average \$12,000 annually. This is twice the amount an average person without diabetes would spend on healthcare, (ADA, 2008). Diabetes management can be very costly to families, as well as to taxpayers.

Implementation of Quality Care in the Primary Care Setting

Complications of diabetes can be reduced when hyperglycemia is well controlled (Selby et al., 2009). Unfortunately, many providers do not consistently implement screening and management guidelines that have been demonstrated to improve glycemic control and reduce complications (Li et al., 2004). Routine monitoring of glycemic measures and appraisal of clinical markers associated with chronic complications are essential in evaluating and addressing management of consequential diseases (Li et al.). By improving glycemic control and monitoring lipid levels and blood pressure, we can reduce the mortality of cardiovascular events by 30% and reduce kidney disease by 50%

(ODPCP, 2007). With screening and proper care, 90% of diabetes-related blindness can be prevented and 85% of leg and foot amputations can be prevented (ODPCP, 2007). By reducing the number of strokes, heart attacks, vision problems and amputation problems associated with diabetes, the amount of money spent on diabetes related chronic complications will be reduced. Excess health costs and lost productivity due to diabetes can also be reduced.

Though clinical guidelines for managing type 2 diabetes have been published and updated each year (ADA, 2009), studies show limited adherence to the standard of care, with variable application across the nation (Coffey et al., 2004; Nolan & Berwick, 2006). According to the Agency for Healthcare Research and Quality, only 89% of all patients with type 2 diabetes had a HgA1C test performed, with some states reporting rates as low as 64%. Vaccination rates across the states ranged from 17% to 64%, and retinal exams ranged from 50% to 83% and foot exams ranged from 50% to 87%. Only 37% of adults with type 2 diabetes had HbA1C levels within the optimal range (Coffey et al., 2004). A study conducted by the National Healthcare Quality Report, reported the following rates of compliance with routine performance of process measures: HgA1C = 90%, lipid profiling =93.8%, foot examination = 66.3%, retinal examination = 69.7%, and flu vaccination =56.5%. Only 32% of the patients on whom the data was collected had all five measures performed (Nolan & Berwick, 2006).

When Quality Improvement (QI) initiatives were created to address process enhancement, patients demonstrated improved outcomes over time (Peterson, Bynum & Roe, 2008). When clinics implemented policies focusing on guideline adherence and

improving process measurements, or measurements marking health services received, their patients demonstrated improved clinical outcome measurements (Coffey et al., 2004; Peterson et al., 2008). Long-term studies, such as the Diabetes Control and Complications Trial (DCCT), demonstrated that intensified treatment for patients with diabetes reduced long term complications of eye disease, nerve disease and kidney problems, with an overall reduction in HgA1C levels (Coffey et al., 2004). These intensified treatment steps addressed the quality indicators deemed essential to management of the disease process and were applied to a given population in hopes of improving the clinical outcomes of the disease process (Coffey et al.). After these process measurement initiatives were instituted, the clinic instituted a process evaluation to determine whether the QI initiative had the intended affect on the target recipients (Rossi, Lipsey & Freeman, 2004). Thus, applying quality improvement initiatives in the clinical setting to ensure that critical steps in management are performed can lead to improved patient outcomes in a given disease process.

Project Purpose

As the incidence of type 2 diabetes increases in the future, it will be important for providers to develop an efficient system in which to monitor and deliver the quality care necessary to prevent or reduce disease progression (Resnick et al., 2006). By having a program in place that allows process-of-care measurements to be evaluated, the evaluation of care delivery and quality can be reviewed on a regular basis, allowing for improvements to be made (Bell & Levinson, 2007). Successful QI programs have often been difficult to implement due to limited information technology and an appropriate

organizational infrastructure (Salman, 2005). To improve the quality of care delivered in the clinical setting, strategies must be developed to implement and measure QI initiatives, allowing health care providers opportunity to improve management of chronic diseases.

The purpose of this project was to develop and implement a quality improvement project within a rural, nurse practitioner managed clinic to improve select care processes and patient outcomes for those with type 2 diabetes. The project had three specific aims:

1. Evaluate the extent to which selected type 2 diabetes quality indicators are being met in a rural, nurse practitioner managed clinic.
2. Develop, implement, and evaluate a diabetes quality improvement program for a rural, nurse practitioner managed clinic.
3. Develop a QI process that clinic personnel may use for future quality improvement initiatives.

Definition of Terms

Quality: Quality is defined as the extent in which health care services for an individual or a defined population increases the likelihood of preferred health outcomes that are consistent with contemporary professional guidelines (Schuster, McGlynn, Pham, Spar & Brook, 2001). Good quality health care is providing the right care to patients using appropriate services in a competent manner using appropriate communication skills (AHRQ, 2007; Schuster, et al). Measuring quality is centered on two dominating approaches in literature: appropriateness of care and adherence to professional standards (Schuster, et al).

Quality Improvement (QI): Quality improvement (QI) initiatives are programs designed for the purpose of improving patient health care outcomes (American Psychology Association, 2007). Quality Improvement initiatives involve a systematic collection of information from providers, patients, or other stakeholders within the care setting in order to evaluate the quality of care delivered. Quality improvement activities are then designed to improve provider performance, health management outcomes, or efficiency of treatments. These activities are both prospective and retrospective, continually evaluating implemented changes for unintended outcomes, process and outcome measurements (APA, 2009; Varkey, Reller & Resar, 2007).

Quality Indicators: To assist in evaluating whether care meets or adheres to professional standards, quality indicators are established to help define standards of care for a disease process. Quality indicators are measures of specific tasks or processes of care that should occur for each patient with a given disease process or clinical circumstance and are important to assess in improving the quality of health care delivery. Quality indicators are based upon standards of care determined by research literature, professional health organization statements, or expert panels and are used to compare healthcare provider's current performance against the desired protocol (Schuster, et al, 2001).

Process Measures: Process measures are based on the specific guidelines of care associated with a specific process. These measurements are based on care delivery and are in the control of the health care providers and are also considered performance indicators. Process measures reflect the actions taken to improve the quality of care

delivered by the provider or clinic. They reflect whether a necessary screening was done or referred, or whether a laboratory test was drawn or reviewed. Specific to diabetes, process measures evaluates whether HbA1c tests, Lipid profiles, eye exams, foot exams, flu vaccinations, etc. are performed on a routine basis (Coffey et al., 2004; Schuster et al., 2001).

Process Evaluation: a type of program evaluation used to determine whether a designed program is being implemented as planned toward the target recipients. This is also known as implementation assessment (Rossi, Lipsey, & Freeman, 2004).

Outcome Measures: the improvement of a patient's health as the ultimate objective for any QI initiative. Outcome measures are based upon specific measures of a patient's health status. Outcome measures can focus on test results, such as HbA1c levels, cholesterol levels, blood pressure readings. Or they can focus on avoidable hospitalizations due to uncontrolled diabetes, short term or long term complications or avoidable amputations (Coffey et al., 2004).

CHAPTER TWO: PROJECT LITERATURE REVIEW

Introduction to Quality Care

Health care is designed to help people stay healthy over the course of their lives, to recover from acute illnesses and to live with chronic diseases (United States Department of Health and Human Services, 2009). Quality health care provides these services in a safe, efficient, patient centered and timely manner. Unfortunately, patients do not always receive the appropriate care they need and sometimes will accept care that is harmful. Patients may also receive care that is delivered in an untimely manner or without consideration of their preferences and values (USDHHS, 2009).

To address the issue of quality in the health care system, the Institute of Medicine (IOM) published two landmark reports addressing health care delivery. The first report, *To Err is Human: Building a Safer Health System* (IOM, 2000), reported statistics on the number of patients who were injured or killed each year as a result of errors in medicine. This report spurred healthcare professionals to begin addressing safety, errors, and quality within their organizations. In the follow-up report, *Crossing the Quality Chasm* (IOM, 2001), some of the causes of the quality gap were reviewed. The IOM recommended that health care organizations and professionals adopt the goals of reducing the burdens of illnesses and disabilities and pursue six aims for improving health care (safety, effectiveness, patient-centeredness, timeliness, efficiency and equity). The IOM acknowledged the complexity of health care systems and called for a redesign of the delivery of health care. The goal of redesigning was to reduce or eliminate preventable complications in the management of chronic diseases (IOM, 2001; Coffey et

al., 2004). For health care institutions to make quality improvements in managing diabetes, it will be important to understand which components of health care are important in managing the complex disease process, which QI initiatives have shown the greatest benefit in improving quality management and what incentives are there to help drive changes in the over-burdened nurse-managed clinic.

Underlying Reasons for Inadequate Quality of Care

Several key aspects of the current health delivery system clearly contribute to poor quality of care. First, due to the growing complexity of applied science and available technology, health care today is expanding exponentially (IOM, 2001; Ruiz & Simon, 2004). Skills, knowledge, interventions, healthcare devices, and medications have all advanced at a rapid pace, greater than the ability of skilled healthcare providers to apply them safely, effectively and efficiently (IOM, 2001; Leonard, Frankel & Simmonds, 2004). The Institute of Medicine recognizes that quality problems are not necessarily due to a lack of training or effort on the part of the healthcare provider, but rather to the abundance of research that inundates healthcare providers with increasing amounts of information, newer medications and technologies. Clinicians are simply unable to retain all information necessary to provide sound practice (IOM, 2001). Without a substantial change in healthcare delivery, health care science and technology will only increase in complexity and continue to contribute to increasing variation of chronic care management.

The second issue contributing to the lack of quality care is the increased prevalence of chronic conditions. As health science and technology advance and aid in

keeping people alive longer, there is an increase in both the incidence and prevalence of chronic conditions (IOM, 2001). Effective care for those with chronic disease has become an expensive process and requires greater collaboration with patients because over 40 percent of those with chronic illnesses have more than one chronic disease (IOM, 2001; Coffey et al., 2004; Leonard et al., 2004). Care plan development, goals, strategies, support services, follow-up programs, and other components of collaborative management add another layer of complexity to health care provided to those patients (Coffey et al., 2004; Ruiz & Simon, 2004).

A third area contributing to the lack of quality care is the decentralization of the current health care delivery process. The current model of care is complicated by multiple layers of processes, interventions and referrals. These complicated processes often leave patients and their family members bewildered and leave clinicians frustrated and concerned over wastefulness (IOM, 2001; Ruiz & Simon, 2004). Additionally, layers of care processes and handoffs can slow health care delivery, decrease safety, waste resources, leave gaps in coverage and result in the loss of valuable information needed by clinicians to provide appropriate care for patients (IOM, 2001; Zuckerman, 2009).

Finally, the IOM (2001) acknowledges the inability of health care agencies to utilize information technology to the fullest. The Internet has had a major impact in all areas of society except health care, which has remained on the edge of transformation. Fundamental transformations must take place in how services are organized and delivered and how patients and clinicians interact. As part of the transformation, there are major areas where technology can improve the quality of health care delivered.

Information technology can assist providers in gaining improved access to clinical evidence. Using electronic technologies can assist providers in automated data collection through the use of prompts and help reduce errors by standardizing and automating care and identifying potential errors, such as with drug interactions. Health IT can assist in decision making processes by using guidelines that are routinely updated. Enhanced IT could also help with sharing clinical information among various clinics and between clinicians, as well as improving patient and clinician communications (IOM, 2001; Keyser et al., 2009; Zuckerman, 2009).

Quality Improvement Aims

When clinicians or managers recognize an area of care as not meeting safety or quality standards, and want to improve the quality of the care provided, there are specific goals they can adopt to direct their efforts. The six aims proposed by the IOM (2001) are safety, effectiveness, patient-centeredness, timeliness, efficacy, and equity. Each of these, if addressed and improved upon by clinicians, would lead to improving quality care. These aims can help primary care clinics reduce the burden of injuries and disabilities associated with the management of diabetes, and improve the overall health of patients (IOM, 2001).

To avoid harm to patients from the care they received, *safety* should be reviewed at several organizational levels. Safety is defined as the freedom from any accidental injury (IOM, 2001). While not all health management errors result in an injury, an error can arise due to a prescribed plan of action not being completed as intended, or using a wrong plan to achieve a desired outcome. In the clinical setting, safety errors can arise

from a misdiagnosis, using the wrong drug or the wrong dose to manage a problem, or failure to act when clinical signs warrant additional steps for management. Safety errors can occur when testing results are not monitored for follow-up need or data are not shared among providers. Knowledge of the patient, drug interactions, or a reduction in data entry, either the patient's or the provider's, can reduce the safety of health care (Gamm, Kash & Bolin, 2007; IOM, 2001).

Effectiveness refers to health care based on the systematic use of evidence-based research to determine if an intervention improves health outcomes over alternative interventions or no interventions (IOM, 2001). Interventions can include preventive services, diagnostic tests, or directed therapy. Evidence-based practice necessitates that those who provide care avoid overusing ineffective care or under-using effective care. Most equate “evidence-based practice” to using scientifically based interventions; but evidence may come from research studies, clinical expertise or patient values (Driever, 2002; Gamm et al., 2007). Effective care focuses on the process to achieve improvements in patient outcomes or organizational processes instead of implementing packaged interventions (Driever, 2002). Ensuring effectiveness in the clinical setting could incorporate checking for established chronic care measures, reviewing preventive education, and/or assessing for patient satisfaction and whether their needs are being met. Evaluating effective healthcare would also include checking for support from accessory personnel and utilization of clinical and administrative information systems (Gamm et al., 2007). Ensuring effectiveness would include monitoring results of care provided,

studying outcomes and reviewing for opportunities for improvements (Gamm et al., 2007; IOM, 2001).

Patient-centered care focuses on the patient's perception of the illness, previous health care and systems that best fit individual patient needs. Patient-centeredness encompasses qualities of patient preferences, values, responsiveness to needs, understanding and concern (IOM, 2001). It is well accepted in the health community that patients have the right to make their own health care decisions, but this isn't always implemented well (Beckman & Frankel, 1984; Braddock et al., 1999). Respecting patient values and concerns; coordinating care among providers; and interventions, education, physical comfort and support are vital in providing patient-centered care. Clinical and administrative evaluation focusing on patient-centeredness might assess the use of supportive technology, such as electronic health records (EHR), to help coordinate and integrate the necessary care for chronic diseases; and the utilization of a patient satisfaction survey regarding chronic disease management (Gamm et al., 2007; IOM, 2001). Ensuring that patient education is done in a timely manner with necessary reinforcement would also be important (Gamm et al., 2007).

Timeliness of health care addresses the utilization and coordination of all clinical technologies in all clinical areas in a manner that reduces delays in testing and treatment (Gamm et al., 2007; IOM, 2001). The patient's time is important, and patients can become frustrated when there are long, and often perceived unnecessary, waits in the waiting room, for appointments, for laboratory results, and in determining a diagnosis. Delays in knowledge lead to delays in treatment and can be harmful if a potential

diagnosis is not reached in a timely fashion (IOM, 2001). Primary care clinics seeking to improve the timeliness of care delivered could address quality improvement projects directed toward reducing barriers to access, prevention screening, and early intervention. Timeliness in communication with the patient and decreasing wait time for therapy with other health care professionals will also improve quality overall. Ease of record retrieval and provider access to patient health records can reduce time waiting for charts. Clinics must also reduce the time lag to updating a patient's health record and incorporate systems where data can be entered and reviewed simultaneously (Gamm et al., 2007).

Efficacy may be improved by either reducing utilization of resources with no benefit to the patient or by reducing administration or productivity costs. A highly efficient clinic uses resources to get the best value out of services rendered (IOM, 2001). While many QI initiatives result in lowered resource use, others focus on avoiding overuse to reach a greater efficacy by reducing unnecessary duplication or providing the appropriate level of care. Other areas include accurate charting and coding, ensuring all information is available, utilizing a team approach to care and employing information and communication models of coordination (Gamm et al., 2007). Ensuring that appropriate communication has occurred can improve compliance and reduce unnecessary testing that might occur with patients with uncontrolled chronic conditions.

The final aim identified by the IOM is *equity*. Here, the goal of the health care system is to improve the health and well-being of the population, as well as individuals. At the population level, health care systems should focus on improving the health status of everyone in the clinical setting while reducing disparities observed in subgroups.

Equity implies universal access to all patients (Gamm et al., 2007; IOM, 2001), which is a promise that has yet to be achieved. Lack of health insurance affects the patient's ability to access appropriate services, is associated with increased morbidity and mortality, and is considered a barrier to quality (IOM, 2001). At the individual level, all patients should be treated fairly by health care clinics. Quality of services and the availability of care should be based on the patient's needs and not associated with individual characteristics. Race, gender, age, education, location of residence, and other characteristics should not affect the quality of care provided the individual patient (IOM, 2001).

Generally speaking, these six aims are meant to work in a synergistic and complimentary manner (IOM, 2001). Addressing one aim, such as implementing an EHR to address patient-centered care, would help improve other areas, such as safety and efficacy. But there can be tensions among some of them. Primary care clinics will need to work with other institutions and patients to help balance competing objectives. One example of conflicting aims is effectiveness and patient-centeredness, in which the well-educated patient may object to care deemed by the provider to be useful and appropriate. Trying to address all areas with a single intervention may not be appropriate, depending on the intervention being implemented.

The Chronic Care Model

The Chronic Care Model (Wagner et al., 1996) provides a systematic, comprehensive framework for reshaping current health care delivery. This prevention-focused framework has been shown to improve health care processes and reduce disease

outcomes and complications (Kaissi & Parchman, 2009; Siminerio et al., 2008). In order for health care agencies to shift from an acute problem focus to a chronic-care system, six structural elements should be present in the primary care setting (Jackson & Weinberger, 2009; Kaissi & Parchman, 2009; Siminerio et al., 2008). The first essential element is having organizational support for the philosophy, goals and values of the providers and patients. Leaders must be willing to commit policies, time and resources toward reorganizing practices to assist patients in managing their disease processes (Siminerio et al., 2008; Wagner et al., 1996). Without a dedicated health care organization, meaningful improvements in chronic disease management may not be achieved (Siminerio et al., 2008). Relationships between community resources and the clinic should be evident and supportive of chronic care (Jackson & Weinberger, 2009; Siminerio et al., 2008). Community resources and services should be readily identifiable and utilized by patients and providers. Patients should also have a clinical support system in place that provides education and encourages them to actively participate in the management of their diabetes. When providers are proactive, and supportive with time and resources, patient-clinician interaction is more likely to be productive (Siminerio et al., 2008). Practices may need to be reorganized to assist patients by providing counseling, education, feedback, and support to avoid adverse outcomes (IOM, 2001). Providers should incorporate evidence-based practice guidelines, standards and protocols into their clinical decision making processes (Siminerio et al., 2008). The chronic care model also encourages the use of clinical information systems to support clinical practice and improvement (IOM, 2001; Siminerio et al., 2008; Wagner et al., 1996). These

information systems are valuable for collecting, storing, and sharing data in a timely manner in terms of individual patients or populations. Quality measures can be readily assessed and care can be evaluated to provide clinicians with feedback regarding areas of excellence and improvements. Computerized information systems can utilize tools such as patient registries and care reminders for preventive care, follow-ups and evaluative procedures allowing for greater compliance for the provider and patient (Siminerio et al., 2008; Wagner et al., 1996).

The chronic care model utilizes a team concept in patient care. This planned management concept defines team roles and assigns tasks to provide continuity of care and follow-up in diabetes management. These structures are not only necessary to enhance productive patient interventions, but are critical to directing quality improvement efforts (IOM, 2001; Jackson & Weinberger, 2009).

Health care is designed to help people stay healthy over the course of their lives, to recover from acute illnesses and to live with chronic diseases. Quality health care provides these services in a safe, efficient, patient centered and timely manner. Unfortunately, sometimes patients do not receive appropriate care or accept care that is harmful. They also may receive care that is delivered in an untimely manner or without consideration of patient preferences and values (USDHHS, 2009).

Quality Improvement Incentives

Although some QI initiatives are inspired by a need to improve care delivery (IOM, 2001), motivating factors to improve and maintain an initiative can vary (Wolfson et al., 2009). Incentives can come in the form of receiving additional income for quality

performance or accruing better contracts with health plans based on demonstrated quality performance (Shortell et al., 2009). Although there is a growing interest in using financial incentives to encourage improvements in the quality of care (Christianson, Leatherman, & Sutherland, 2008; Shortell et al., 2009), recent studies show that there are other non-monetary incentives that drive the utilization of QI initiatives (Wolfson et al., 2009). In small office settings, financial reimbursement incentives were not found to be a major motivating factor of QI. Instead, clinicians indicated that QI initiatives and engaging in performance improvements were reinforced by the prospect of having greater practice efficiency, increased patient and staff retention, and improved satisfaction with clinical practice (Wolfson et al., 2009). Although only 40% of the clinics in the study indicated an increase in revenues, none of the businesses lost money. Several practices also indicated that by implementing quality indicators and quality mechanisms, a culture of seeking improved practices had developed, creating a renewed desire to participate in additional QI efforts (Wolfson et al., 2009).

Plan-Do-Study-Act Conceptual Framework

In its recommendations to incorporate quality health care in the clinical setting, the IOM called on clinics to redesign care processes, basing them on best practices (IOM, 2001; Taner, Sezen, & Antony, 2007). The term ‘best practice’ refers to the application of clinical practice guidelines in the management of disease processes and provides a way to target QI interventions to help reach desired patient outcomes, including a reduction in resource consumption (Driever, 2002). Stakeholders need to identify necessary changes, adapt the change to their specific clinical setting and implement new approaches to

address disease management challenges. A systematic approach, including the incorporation of performance and outcome measurements, will facilitate clinician review of current operational processes to determine potential areas of improvement in order to optimize care (IOM, 2001; Yun & Chun, 2008).

One quality improvement tool shown to be effective in the clinical setting is the “Plan-Do-Study-Act” (PDSA) model (Coffey et al., 2004; Langley, Nolan, Nolan, Norman & Provost, 1996). (See Figure 1). The PDSA cycle is a framework for systematically planning and implementing a change process to improve quality outcomes. The PDSA model is part of a rapid cycle “trial-and-learning” approach that allows a clinic to implement a small change on a trial basis and quickly follow it up with a learning period to be used as a time to study and evaluate the change (Langley et al., 1996; Plsek, 1999). It allows for testing a change within a clinical microsystem using a small group of people routinely interacting to provide care to a specific population of patients (Langley et al., 1996; Nolan, 2007). The clinic can implement a specific change, study the effects of the intervention through pre-designated measurements and then act, or react, to begin another cycle of change in an accelerated way (Plsek, 1999). By testing a change within a small subsystem, unintended changes can be evaluated and discussed among those overseeing the QI process (Langley et al., 1996). New cycles begin with the planning of the next desired change and conclude with the action being implemented. The new implementation cycle is based upon knowledge gained from previous PDSA cycles.

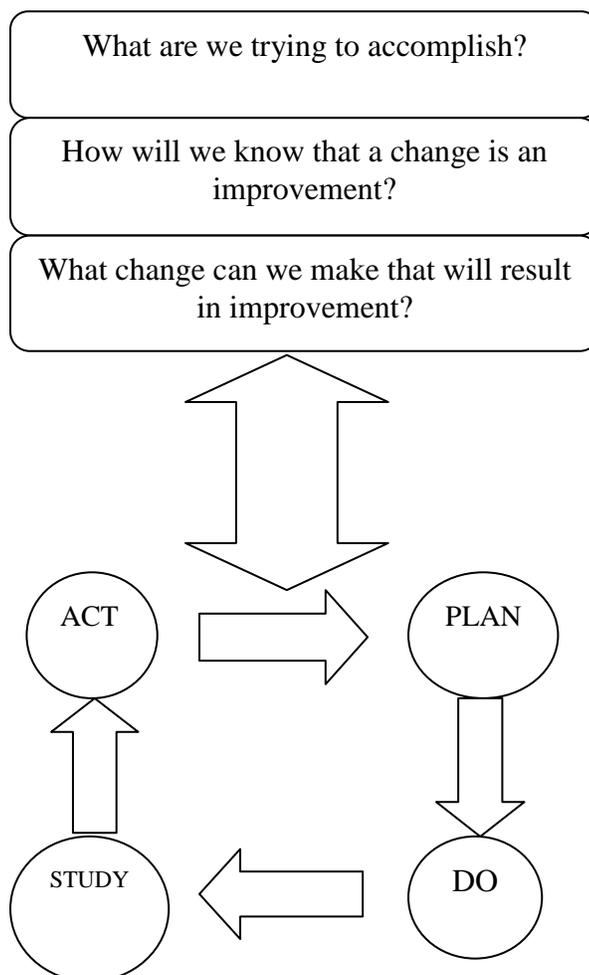


FIGURE 1: The Model of Improvement Using the Plan-Do-Study-Act (PDSA) Cycle (Langley et al, 1996)

The first step in the plan stage is to engage in discussion with strategic stakeholders. These may be healthcare professionals, topic experts, health care planners, clinic owners, and those with a viable interest in the quality improvement process, such as patients (Coffey et al., 2004). In a small rural primary care clinic, strategic stakeholders might include the office manager; health care providers such as the nurse practitioner; medical assistants; and other members of the micro-system such as office

workers or patients who are interested in contributing to the change process or may be identified as providing valuable knowledge toward the desired change. Members outside the clinic who could potentially contribute to the discussion might include professionals to whom the clinic refers to, a pharmacist, or companies assisting with operations within the clinic familiar with the information technologies being used. Widespread staff involvement utilizing expertise from all levels of the clinical operation is important to consider when forming groups as it will allow multiple inputs and views to be expressed. The ability to collaborate and cooperate across traditional boundaries is vital due to the interdependency of each system in the clinic (Plsek, 2007). This group must be large enough to include key participants, including recognized leaders and differing perspectives, yet small enough to be an effective and productive group (Coffey et al., 2004; Plsek, 2007).

The complete model of improvement incorporates three initial questions to be addressed as part of the initial planning phase: What are we trying to accomplish? How will we know if a change is an improvement? What changes can be made that will result in improvement? (Langley et al., 1996). These questions help lay the foundation for the desired improvement and provide the framework for the “trial-and-learning” approach of the PDSA model. Answers to these questions can expedite the learning process and accelerate the building of knowledge (Langley et al., 1996).

Through PDSA question one, “What are we trying to accomplish?” stakeholders identify areas of concern and set aims or goals for a quality improvement initiative. These aims should be measurable and based on a specific length of time. The developed goals

should address a specific population, such as those with type 2 diabetes at a particular clinic in which the QI initiative is directed. Goals should be short and concise (Langley et al., 1996). Quality improvement aims can address a variety of clinical issues ranging from enhancing patient safety by ensuring quality indicators are addressed to reducing waiting times for appointments.

The second PDSA improvement question, “How will we know that a change is an improvement?” addresses the need to establish both measures and a timeline in which the improvement is expected to occur. Measures must be valid, reliable and feasible. Improving patient outcomes may be the ultimate goal, it is also important to include process measures to assess the implementation plan itself. Outcome measures may include pre and post testing to determine if the desired change led to a clinical improvement (Plsek, 1999). For example, an outcome measure of average H_{A1c} levels could be used to determine if a diabetes improvement program was effective in improving glycemic control. A process measure for a diabetes improvement initiative might be the percent of patients with type 2 diabetes who had their hemoglobin A_{1C} levels measured twice during a 12-month time period. If improvements occur, then it can be concluded that the quality improvement initiative was effective. Process and outcome measurement data must be readily available to determine the impact of the initiative and provide direction for the next steps (IOM, 2001; Langley et al., 1996).

The next PDSA question asks, “What changes can we make that will result in an improvement?” This is a pivotal and vital component of the PDSA cycle. Ideas for a proposed change come from many different thought processes, including critical thinking

about a current process, outside observations, creative thinking, literature reviews of scientific journals, or previous experiences of similar situations. Initial ideas for change may be based on logical, scientific, or meritorious foundations that can stimulate additional input from other improvement team members to form an applicable improvement (Plsek, 1999). However, not all ideas for change will lead to actual improvements in care and may impact other clinical functions negatively. Therefore, ideas for improvement initiatives must be carefully considered and evaluated before being implemented.

After these three questions are addressed, the “Plan” phase of the cycle is instigated by defining the identified problem with a precise problem statement. During this time, the appropriate performance measure is selected to evaluate the problem solving effort (Coffey et al., 2004; Langley et al., 1996). The process measurement should be reflective of the small scale trial currently being tested, whether it is the first cycle or a subsequent cycle (Plsek, 1999). Based on the predetermined measurements, a prediction is made regarding how the upcoming initiative will result in improvement (Langely et al., 1996), and the processes changes to carry out the designed initiative in terms of who, what, when, where, etc., are planned.

During the “Do” or implementation phase of the QI initiative, changes are developed and implemented on a small scale. Based on results from the planning phase, process changes are developed and operationalized. The change is then tested and quickly evaluated to determine if it resulted in the desired improvement (Langley, et al., 1996). As with any change in procedure, unexpected problems or unanticipated outcome may

arise during this phase. These types of unexpected occurrences should be documented and analyzed during the next phase by stakeholders, with input from group members affected by the unanticipated outcomes (Coffey et al., 2004).

During the “Study” phase, data resulting from the pilot test are analyzed and compared to the anticipated results identified (Langley, et al., 1996). The analysis includes process evaluation to determine if the pilot study was carried out as planned and what, if any, unanticipated problems occurred. Outcomes data are analyzed, and new knowledge gained as a result of the pilot is assessed (Coffey et al., 2004; Langley, et al., 1996). Once the data are summarized, additional trials or larger scale implementation may be considered. Because costs may be involved and the scope of activities could be broader, the planned action to be expanded will need to be based on solid data and results (Coffey et al., 2004).

During the “Act” phase, the piloted QI initiative that was determined to be effective is refined and disseminated to other parts of the clinic. Quality Improvement committee discussion should identify the changes needed in anticipation of a broader application and training needs for an extensive implementation should be planned. An ongoing monitoring system should be present to look for long term outcomes, both intentional and unintentional. Newer QI initiatives should also be considered to build upon the current success of what has been gained (Coffey et al., 2004; Langley, et al., 1996). Policies should be developed based upon the improvements to ensure a continuation of the QI initiative.

The PDSA model is the improvement framework that will be used in this study because of its easy adaptability to any clinical setting. Possible ideas for improvement can be readily tested in a rapid succession of small trials, trying different variations of ideas and experimenting with what approach would work best in a specific clinical setting (Langely et al., 1996). Each cycle that is implemented properly is informative and provides a foundation for additional improvements to be made. The more cycles that are implemented by a particular system, the more learning can take place and the quicker QI initiatives can be implemented (Coffey et al., 2004; Plsek, 2007). With each cycle of QI performed, clinics can address the aims laid out by the IOM and hopefully obtain a delivery system in close to perfection.

Six-Sigma

Another quality improvement tool is Six-Sigma, which is based on Deming's Plan-Do-Check-Act cycle (Feng & Manuel, 2008). Developed in the 1980's by Motorola, Inc, Six-Sigma is a statistical measuring method designed to decrease costs and process variations while eliminating defects in the end product. Six-Sigma has gradually been implemented in the health care industry in an attempt to decrease medical errors in the health care processes of timeliness, cost, efficiency, quality of care and patient satisfaction (Feng & Manuel, 2008). Using Six-Sigma as a health care QI strategy tool allows clinicians and administrators to identify defects in critical-to-quality measures earlier and motivate managers to take action to correct them. If solutions to problems are recognized and applied early in a given process, errors can be prevented from escalating

into more costly problems later and support an organizations goal of high quality care (Carrigan & Kujawa, 2006; Feng & Manuel, 2008).

One advantage to using Six-Sigma over other methods is in the use of the statistical tools in enabling providers to accurately identify process hindering problems and demonstrate improvements being made in the QI process using objective data (Carrigan & Kujawa, 2006; Feng & Manuel, 2007; Varkey et al., 2007). To determine if health errors have occurred or if costly problems have been eliminated, Six Sigma uses three primary measurements; the sigma level, defects per million opportunities (DPMO), and error-free yield (EFY). The “sigma level” refers to the statistical unit indicating the number of standard deviations a determined process varies from perfection. The higher the sigma level, the lower number of “defects” or care deviating from the standard, and the lower DPMO. An EFY is the percentage of a selected process that is free from any deviation from standard care. A process reaching the six-sigma level has DPMO of 3.4 and is almost virtually error free (99.9996%). Knowing one of the three measurements can help in calculating the other two. These measurements are an alternative way to measure the effectiveness of a given process in reaching quality care (Varkey et al., 2007). Progress observed through statistical calculations can reinforce changes made in the delivery process and lead to additional support by other members of the health care team.

Six-Sigma starts at the leadership level with managers identifying problems and implementing improvements based on the organization’s objectives and goals. A baseline measurement of operational outcomes should be reviewed in relation to the goals and

objectives. This will identify potential areas of improvement, which should be prioritized based on the potential for financial and operational benefits. Like the PDSA model, Six-Sigma incorporates a systematic approach to an identified problem using DMAIC: define, measure, analyze, improve and control. A problem is first defined and goals are established by team members designated to address the problem. The team then identifies and measures key aspects of the current process to report current levels of performance for the targeted improvement. The data are analyzed to seek and validate a causal element. Relationships are explored, and all possible contributing factors are reviewed. Following the data analysis, improvements are piloted in the current process to correct deviations to create a new standard in operational processes. After ensuring accurate measurements in the key process elements and improvements in the targeted results, control systems are set in place to ensure that any deviations from target goals are corrected (Elberfeld, Bennis, Ritzius, & Yhlen, 2007). Similar to the PDSA, the DMAIC incorporates constituents who are familiar with the operations to improve existing processes and explore all potential contributing factors to unmet goals. The DMAIC also incorporates patient input at the very beginning phases to gain input regarding product satisfaction (Feng & Manuel, 2007). DMAIC differs from the PDSA model in its emphasis of statistical presentation to support initiatives and financial gains (Elberfeld et al., 2007). While both models utilize pilot studies to evaluate QI initiatives, completion of a single PDSA cycle can incorporate as little time as a single day, while the DMAIC cycle is more labor intensive and involves a broader analysis of data and can be more costly (Elberfeld et al., 2007; Feng & Manuel, 2007).

Six-Sigma may be difficult to implement in smaller independent primary care clinics. Most reported applications of Six-Sigma have been in large healthcare organizations and hospitals, with employee numbers ranging from 400 to 26,000 (Feng & Manuel, 2007). These organizations incorporate specialists who oversee the application and statistical generation. Due to the expense of hiring these specialists, Six-Sigma may not be appropriate for companies with fewer than 500 employees (Feng & Manuel, 2007). Because of the cost and complexity of the Six-Sigma model, small organizations tend to use the PDSA Quality Improvement model (Feng & Manuel, 2007).

Another reported drawback to Six-Sigma is the time frame that projects take. Unlike the PDSA, which can be performed in days (Plsek, 1999; Varkey et al., 2007), Six-Sigma projects typically average four to seven months to complete (Feng & Manuel, 2007). Reasons for the long delay have been associated with varying problem scopes, and the availability of data and resources, with data availability being the primary factor for the delays (Feng & Manuel, 2007).

Because Six-Sigma originated in a repetitive and automated manufacturing industry, it has had slower acceptance into the health care industry, where health care processes tend to be more complex and variable. Manufacturing processes are viewed as more amenable to a quantitative analysis than varied human interactions (Carrigan & Kujawa, 2006). Because outcomes and interactions vary from patient to patient, the process taken to treat health conditions can be more automated to the point that each provider addresses each situation in the same way, but may react differently based upon patient values or evidence. Therefore, although using Six-Sigma to analyze the patient

care processes in large health care organizations may make sense, it is likely to require too much data and be too time consuming and costly for small health care organizations such as rural clinics.

Quality Care in Diabetes Management

A review of diabetes processes of care over the previous decade (1988-2002) has demonstrated a national improvement in process and outcome measures (Saaddine et al., 2006). In a review of two nationally funded databases from the NHANES and BRFSS studies, nearly 18,000 participant charts were examined. Compared with earlier studies, process measures had improved. Nearly 85% of participants had an annual lipid profile done (increase of 8.3% points, CI 4.0 to 12.7); 67.7% of participants had an annual dilated eye exam (increase of 4.5% points, CI 0.5-8.5); 68.3% had an annual foot examination (increase of 3.8 % points, CI -0.1-7.7); 52.5% had an annual influenza vaccination (increase of 6.8% points, CI 2.9-10.7); and 43% of those with diabetes had received the pneumonia vaccine (increase of 16.5% points, 12.7-20.2). Only 55% of those patients received diabetes education.

In general, outcome measures also improved, but were still far from the goal. Only 20.6% of participants have a hemoglobin A1C >9.0%, and fewer than 70% of participants had a blood pressure less than 140/90. LDL cholesterol was slightly better, with 64.2% of participants having a level <130 mg/dL. These figures demonstrate a modest improvement in process and outcome measurements, but illustrate that improvements can still be made regarding the diabetes measurement indicators (Saaddine et al., 2006).

To provide more efficient and effective healthcare to patients, providers need to incorporate a structured service quality framework and identify critical elements of diabetes care. Clinics that used a practice system within a chronic care framework were more likely to improve the quality of care for those patients with chronic conditions (Solberg, Asche, Pawlson, Scholle & Shih, 2008). In addition to having a system in place to organize thinking and evaluation of QI projects, improvement in patient outcomes was also found to be associated with a leadership commitment to improving diabetes care, participation in diabetes improvement programs, and allocation of resources at the clinic level (Siminerio et al., 2005; Solberg et al., 2008).

In an outpatient endocrine clinic located in an urban setting, the PDSA model was used to enhance patient education and counseling (Varkey et al., 2009). Five cycles of the PDSA tool were used by the clinical staff within a 3-week time span to modify a specific education intervention. A basic patient education tool was formulated during the first cycle and improved upon in subsequent cycles using patient satisfaction surveys and provider input. Ninety-three patients participated in this study; 23 were surveyed prior to the implementation of the QI measures to gain baseline data. Seventy percent were surveyed during all of the post-implementation cycles. The provider team consisted of 10 physicians. This project demonstrates that the PDSA cycle is a feasible tool for creating and initiating system improvements, and that it is beneficial in improving patient education and satisfaction in the care they receive (Varkey et al., 2009).

Quality improvement projects have been shown to be successful in the rural clinical setting. When the Chronic Care Model (CCM) was implemented as part of a QI

initiative in a rural primary care clinic, adherence to the ADA standards of care improved significantly. Elements of the CCM that were applied included delivery system redesign, decision support and self-management education. When improvements were made in an organized manner to the existing system of care delivery and patients received diabetes self-management education (DSME), HgA1Cs and HDL cholesterol levels were significantly reduced. Patient knowledge and empowerment were also improved, important components in the rural community (Siminerio et al., 2005).

Salman (2005) initiated a CQI project in a rural setting to improve the quality of care received by patients with diabetes mellitus and hypertension. HbA1c yearly testing, diabetic control ($HbA1c \leq 7.0$), blood pressure controlled at 130/80 or less, yearly lipid testing, yearly ophthalmology exams, and pneumonia vaccines were the quality of care measures assessed at a clinic in rural Kansas. The clinic, staffed with three providers, served mainly older patients with Medicare and Medicaid insurance, totaling approximately 5,000 patients. An EHR had been introduced three months prior to implementing QI. The QI project involved gathering baseline data, identifying deficiencies in outcome measurements, and developing interventions to address those deficiencies. In re-evaluating the outcome measures, there was significant improvement in the number of patients with controlled HgA1C, as well as improvement in the number of patients receiving a lipid screen, having controlled blood pressure, receiving eye exams and the pneumonia vaccine. Quality of care for patients with type 2 diabetes in the rural setting can be improved using the PDSA model of improvement. This study also shows how the electronic health record (EHR) and its utilization in the clinical setting can

be vital in reviewing and maintaining quality care. The 2003 IOM patient safety report stated that improved handling of health information is a necessary prerequisite to achieving improved patient safety. With EHRs present in the clinical setting, process and outcome measures can be retrieved and evaluated with minimal delays, an important component in the rapid-cycle QI projects.

Seventeen physicians and five nurse practitioners used the PDSA model to implement and develop a diabetes management clinic in an established collaborative practice (Johnson & Raterink, 2009). The clinic was established to assist patients who were newly diagnosed with type 2 diabetes in receiving education toward self-management and other behavior interventions. Using the PDSA model, the clinic was able to implement a care delivery system specifically to address process issues related to diabetes management. The PDSA cycles revealed problems specific to processes within the internal clinic in relation to other providers, such as limited awareness of the program, and the need for additional education materials. Within each cycle, problems were addressed and processes improved upon to improve utilization of the clinic. Though outcome measures were not evaluated in this study, the PDSA cycle was effective in addressing necessary process elements to improve program utilization and implementation (Johnson & Raterink, 2009).

Quality improvement initiatives have been shown to improve patient care delivery and outcomes regardless of size, location, or specialty. By focusing on the aims set forth by the Institute of Medicine, clinicians can address multiple aspects of primary health care that can lead to improved health care. When using the PDSA model of improvement,

clinicians and managers can analyze problem areas, incorporate various perspectives related to the specific processes of concern, and create an environment focused on improving the management of type 2 diabetes. Process and outcome measures can be addressed to reduce the potentially devastating outcomes associated with type 2 diabetes and help patients live longer, healthier lives.

CHAPTER THREE: PROJECT PLANNING AND IMPLEMENTATION

Planning the Project

This quality improvement project used the PDSA model to conduct and evaluate a quality improvement initiative to address the care given to patients with type 2 diabetes at a rural, nurse practitioner managed clinic. Both qualitative and quantitative data were collected and assessed over a two month time period.

Setting

Description of Clinic

The selected clinic for the QI initiative was a small primary health care clinic owned and operated by a family nurse practitioner. Located on a main thoroughfare in a rural town with a population of approximately 5,900 (U.S. Census Bureau, 2009), it was one of two full-time primary health care clinics in town. The clinic was started approximately seven years ago and currently oversees the healthcare of approximately 7,500 individual patients. With two health care providers, there were approximately 900 to 1000 patient visits per month. Most patients seen in the clinic travelled less than 10 miles to be seen. However some patients came in from surrounding rural communities within a 40 mile radius, making the special trips to see particular providers (T. Pendarvis, personal communication, August 14, 2008).

Type of Practice

This clinical practice is a primary care clinic. The clinical providers managed acute illnesses and as well as chronic diseases for patients of all ages. Both health care providers were certified to treat patients throughout the lifespan; however, the physician

did not typically accept new younger or Medicaid patients, focusing instead on adult patients. Compared to the Nurse Practitioner (NP), who sees patients of a variety of ages, from infant to older adult, the physician saw primarily an older patient population. The NP, who was the owner of the clinic, still accepted new patients regardless of age as he continued to build up his clientele (T. Pendarvis, personal communication, August 14, 2008). Both providers managed patients who are newly diagnosed with type 2 diabetes and provided care for those who are at various stages of disease progression.

Clinic Personnel

The staff at the Noble Family Clinic included several assistive personnel. The practice employed three medical assistants (MA), who were responsible for a wide range of clinical tasks. These tasks included checking the patient into the assigned room, documenting from the patient the reason for the visit and relevant information associated with known health conditions. Medical assistants also provided education to those patients who were newly diagnosed with chronic conditions, including type 2 diabetes. They reported laboratory results to the patients and provided additional instructions regarding supplemental diabetes management. Finally, the MAs assisted in setting up patient referrals to specialists for screenings or advanced management, such as for stress testing or cardiology workup for patients with newly diagnosed or advanced diabetes. Some referrals, such as eye exams for people with diabetes, were often left to the responsibility of the patient (T. Pendarvis, personal communication, August 14, 2008). Follow up appointments and scheduling additional appointments were made as the patient left based upon care provider recommendations.

Additional office personnel included the office manager who oversees the operations of the clinic. The office manager was the wife of the NP who owned the clinic and has been involved with clinical operations since the beginning of the practice. She spent most days working with patient accounts and ordering supplies for the office, occasionally performing medical assistant responsibilities during short-staffed days. Other office workers included an insurance collector, who collected money from the insurance companies associated with the clinic and an office temp who worked part time filing charts. An independent laboratory company had a phlebotomist onsite to collect any laboratory tests that were ordered.

Type of Patients

According to the nurse practitioner, the patient population was estimated to be mostly Caucasian-Americans (90%) (T. Pendarvis, personal communication, August 14, 2008). Patients of Hispanic descent comprised approximately 5% of the patient population and African-American patients accounted for approximately 3%. Native Americans comprised roughly 2% of the patient population. Payer mix varied depending on the provider. There was a noticeable difference in the ratio of patients with Medicare and those with private insurance between the providers. Approximately 35-40% of the patients seen by the nurse practitioner had private insurance, 35% had Medicare, 20% had Medicaid, and the remaining 5-10% paid cash (T. Pendarvis, personal communication, August 14, 2008). The physician estimated his percentage of patients with Medicare as 75%, private insurance as 20% and self-pay patients as 5% (K. Faris, personal communication, August 14, 2008).

Of the estimated 7,500 patients the clinic managed, it was projected that 20% of them had type 2 diabetes (T. Pendarvis, personal communication, May 26, 2010). The NP diagnosed approximately one or two new cases of type 2 diabetes per month and estimated seeing approximately 10 patients with type 2 diabetes a week for various other complaints. The estimates of patients who had “uncontrolled” diabetes varied between providers and clinical staff. Approximately 25% of the patients seen by the physician, roughly 6-7 per day, had a diagnosis of type 2 diabetes. Most of the patients were seen for incidental complaints that may or may not have been related to that person’s diabetes. The physician addressed the quality indicators with patients who had diabetes during each visit, regardless of the type of visit. The physician stated he addressed each of the quality indicators close to 100% of the time and felt there were “very few” patients who did not have their diabetes under control (K. Faris, personal communication, August 14, 2008). The NP believed he also addressed the quality indicators appropriately, but was less optimistic about the number of patients who were controlled. He estimated that 25-33% of those patients with type 2 diabetes had A1Cs that were considered “uncontrolled” (M. Pendarvis, personal communication, May 27, 2010). This difference in perception indicated the need to have an objective process in place to allow an aggregate review of patient data for provider knowledge and clinical goal-setting.

Electronic Health Record

The Noble Family Clinic used a computerized software program that allowed medical assistants and clinicians to enter data on an electronic health record. At each clinic visit, medical assistants obtained vital signs and visit data and entered this

information into the EHR. Because the EHR was not fully implemented, they also wrote the same data on a hardcopy health chart. Patients were then taken to an exam room where they waited for their provider. While providers referred to the EHR patient records to gain some initial information, they did not routinely use the hard copy patient record during the patient encounter. Typically the provider reviewed the paper chart and made brief notes regarding patient data and then entered a complete clinical note in the EHR later that day or the following day. Notes written in the EHR were also printed out and saved in the hard copy health record. Laboratory reports and referral letters were scanned into the EHR as a PDF file and also saved in a hard copy form. Occasionally, the computer was used as a reference for educating patients who had been newly diagnosed with type 2 diabetes, but not on a routine basis (T. Pendarvis, personal communication, August 14, 2008).

Individual patient information could be readily viewed on the computer screen and visualized by the health care provider and office staff. Reviewing population data, such as laboratory values or foot and eye exams, was a function the software was reportedly capable of performing, but had not been utilized by the staff to evaluate office procedures, review quality indicators, or monitor clinical statistics (M. Pendarvis, personal communication, May 27, 2010). The EHR was not part of any health care network; and contained only information generated or entered by the practice staff. No outside services accessed or provided information to the individual patient's record. The only quick way a provider had to review laboratory analysis trends on a single patient was to review a hard copy of the ordered tests which were printed with the individual

patient's laboratory trends. While some outcome measures were reviewed by staff on an individual patient, office staff and clinical staff did not use the EHR to review relevant process or outcome measures of the diabetes population as a whole (T. Pendarvis, personal communication, May 27, 2010).

Quality Improvement Approach

This study used the Plan-Do-Study-Act (PDSA) model to implement a quality improvement initiative that includes developing an electronic diabetes education flow sheet.

Planning Phase: Identifying and Designing the Quality Improvement Initiative

Establishing the Project Aim

To begin the QI initiative, a needs assessment was conducted to identify a clinical process that the providers wanted to improve. A needs assessment can provide information about what particular services may be improved upon or initiated (Coffey et al., 2004; Rossi et al., 2004). Potential QI initiatives were reviewed according to potential cost savings, ability to implement a solution, importance to the clinic's objectives, expertise of the clinical staff and the motivation to work on and solve a given problem (Ovretveit, 1999). The needs assessment was done at this clinic by surveying key clinic and office personnel. Questions were asked regarding the overall management of diabetes, clinical processes of concern in addressing specific needs of patients with type 2 diabetes, whether the population is being adequately served, and the operation of the clinical process in managing these patients, including costs and efficiency.

An initial area of concern of the office manager was the inability to identify how well the benchmark standards of diabetes care were being met. While all providers and assistants felt all processes of care were met with each patient, they were not certain to what degree they were being met.

To establish project aims, all staff needed to be clear on the standards of care for people with type 2 diabetes. Therefore, a staff in-service was conducted to review the benchmark standards for type 2 diabetes management. While the staff believed they were managing diabetes appropriately, a graphical representation of current clinical process and outcome measures was used to provide staff with an accurate representation of care provided.

This involved a review of the EHR and a sample of patient charts to explore relevant aspects of diabetes care. Using the EHR, patient demographics were reviewed and the number of patients who currently had type 2 diabetes was obtained. Because of the limited capabilities of the current EHR system, process and outcome measures were reviewed using hardcopy health records. The process measures, related to diabetes care, were reviewed to determine how often the performance indicators were being done for patients with type 2 diabetes. Table 1 lists five process measures recognized by the National Healthcare Quality Report as essential for diabetes care. While many process measures exist for diabetes care, these five were agreed upon by diabetes experts working with the NHQR as the most prevalent and relevant to care and were surveyed to provide a baseline of care to make future comparisons to (Coffey et al., 2004).

TABLE 1. *Initial process measures to be collected for baseline data*

<i>Process Measure</i>	<i>Completion percentage</i>
A1C level	Percent of adults with type 2 diabetes who have a hemoglobin A1c measurement within the last year.
Lipid profile	Percent of adults with type 2 diabetes who have a lipid profile drawn within the last year.
Eye exam	Percent of adults with type 2 diabetes who have a retinal eye examination within the last year
Foot exam	Percent of adults with type 2 diabetes who have a documented foot exam within the last year
Flu vaccination	Percent of adults with type 2 diabetes who received an influenza immunization within the last year

Table 2 includes a partial list of outcome measures that reflected the patients' health status within the clinic. These outcome measures were gathered to provide a general report of the state of care for patients with type 2 diabetes that might identify problems not previously recognized by providers and staff for future QI initiatives (Redick, 1999).

TABLE 2. *Outcome measures to be collected for baseline data*

<i>Outcome measure</i>	<i>Completion percentage</i>
A1c levels	Percent of adults with type 2 diabetes with HbA1c levels <ul style="list-style-type: none"> • >9.0% (poor control) • <9.0% (needing improvement) • <7.0% (optimal control)
LDL-C levels	Percent of adults with type 2 diabetes with LDL-C levels <ul style="list-style-type: none"> • >130 mg/dL (not controlled) • <130 mg/dL (needing improvement) • <100 mg/dL (optimal)
Blood pressure	Percent of adults with type 2 diabetes with most recent blood pressure <140/90 mm/Hg

These measures were extrapolated from a sample of current patient records, representing the entire population of patients age 18 and older with a diagnosis of type 2 diabetes seen at this clinic within the past year. Single patient profiles were not discussed within this PDSA process. Information gathered was stored on a password-protected computer, and paper notes and documentation were shredded.

The office manager and medical assistant familiar with the EHR system were asked to review the process data related to diabetes management. Laboratory records were also reviewed to determine relevant outcome measures associated with diabetes care and controlling long term complications. Specific process data were reviewed and analyzed with the current clinical operations to make comparisons to recognized benchmark standards. Data sources included medical and nursing journals, benchmark criteria from local, state and national reviews and from professional organization standards (Redick, 1999). The collected data were organized and analyzed and presented to the clinical staff for baseline and future use.

A second major area of concern, which was identified by the NP, was the lack of an organized documented approach to patient education for patients diagnosed with type 2 diabetes. Once laboratory work revealed a patient had type 2 diabetes, the patient was asked to return to the clinic for a diabetes education session. During this 30-minute time frame, the NP used a laptop computer in the room to review laboratory work with the patient, as well as to educate the patient on lifestyle management and medications. The NP provided the patient with a dietary information sheet specific to type 2 diabetes and taught the patient how to count dietary carbohydrates. He educated the patient on how to

start exercising and referred them to a fitness center in Noble or in a nearby town for routine exercise. The NP then reviewed eye, foot, skin, kidney, heart, and cholesterol screenings with the patient, possibly referring them to other providers for additional workups. When the NP had completed the education session, the medical assistant demonstrated how to use a glucometer. The patient was also instructed to keep a diet, exercise, and blood glucose diary for a follow-up visit in one month. The NP wanted to have a diabetes education template in place to ensure that all areas of diabetes education were being addressed at the initial point of education (T. Pendarvis, personal communication, May 27, 2010). While the NP believed all of this is important, he sometimes felt rushed and didn't feel all of the education components were documented appropriately. He wanted to ensure that all areas of relevant diabetes education were addressed and that each patient was provided with appropriate handouts generated by his EHR system. The NP also wanted a similar system in place to help manage patients who had uncontrolled diabetes; to ensure essential education was provided and handouts were sent home.

The QI initiative aim was to implement an electronic type 2 diabetes education flow sheet that could be used to guide providers in delivering initial education for those patients newly diagnosed with type 2 diabetes. In addition, the diabetes education flow sheet would be used to provide supplementary education to those patients who had uncontrolled diabetes. The aim of the project was to design a flow sheet that could be utilized by all clinical staff members involved in the education process.

Organizing the Problem and the QI Team

Once the initial stakeholder interviews were completed, a QI committee was organized at the clinic that included me acting as the project coordinator, the nurse practitioner, the physician, the two medical assistants who assist with the education process of patients with type 2 diabetes, and the office manager. These selected clinic members were directly involved with the initial assessment, diagnosis, treatment and education of patients with type 2 diabetes. An essential part of the QI process is to include members from all responsibilities involved in the clinic diabetes education. Team members were chosen based on their knowledge and expertise of critical points of the QI initiative and their involvement in the education process.

During the initial meeting of the committee members, the initial stakeholder interviews were reviewed and compared with the common goals of recommended diabetes education. The committee discussed the proposed QI improvement project and the aims for this clinic. Discussion included the need to develop and utilize an electronic diabetes education flow sheet to ensure patients who are newly diagnosed with type 2 diabetes would receive the appropriate education for self-management. The committee also discussed how the flow sheet could be used to assist patients whose diabetes was not well controlled.

Developing an initial diabetes educational flow sheet.

A prototype of the electronic diabetes education flow sheet was initially developed based on diabetes self-management content currently being provided to patients by the clinic staff (T. Pendarvis, personal communication, May 26, 2010) and compared to the guidelines set by the American Association of Diabetes Educators

(AADE) (Tomky et al., 2008). The AADE task force identified seven self-care behaviors essential for diabetes self-management: healthy eating, activity, monitoring blood glucose levels, medications, problem solving, healthy coping with diabetes, and reducing risks of problems associated with diabetes. Clinical indicators associated with these behavior changes include reviewing A1C, blood pressures, lipid levels, and patient weight. Clinical review of eye exams, foot exams and smoking cessation (if applicable) were also important components included on the flow sheet (Tomky et al., 2008). Appendix B presents the initial education flow sheet developed for this initiative.

The committee members were given a copy of the proposed electronic education template (see Appendix B) for review. The initial plan was to have committee members engage in an on-line, synchronous discussion. Using individual computers in separate office areas, members were to log into an on-line discussion platform to make comments about the template using “collaborative computing.” Collaborative computing uses an electronic meeting platform in which all participants meet in a chat room to discuss various topics using individual computers. Using the ‘collaborative computing’ platform as part of a synchronous discussion, each component of the template could be discussed individually. Each committee member could suggest modifications regarding the education components that may be beneficial for the clinic or process. Committee members would review other member’s comments and make responses, thus creating an “on-line” dialogue.

The purpose of using a collaborative computing platform was two-fold. First, it allowed the clinical members to participate in a discussion about the template without

having to worry about how their opinions might affect their job. Clinical staff could provide feedback and comments in a way that avoided any potential friction in the clinical setting. Second, dialogue between committee members could be saved and reviewed for future analysis and for other potential interventions.

The data collection process was reviewed with all the QI committee members. The developed electronic education flow sheet was to be used during the education process for all patients who were newly diagnosed with type 2 diabetes and for patients whose A1cs were greater than 7.0%. One of the medical assistants was assigned to monitor the diabetes education flow sheet use by keeping a list of patient records in which the education flow sheet was utilized. This list was kept by the medical assistant for a weekly review. Once the educational flow sheet was finalized and developed, the data collection process was initiated and continued for approximately eight weeks.

The anticipated outcome for this QI initiative was the successful implementation of an electronic education flow sheet for patients with type 2 diabetes. By having an electronic education template in place, it was proposed the clinical staff would be able to ensure all essential components of diabetes care would be addressed during the education phase of management. An electronic template would also allow staff to review educational tendencies over a given period of time and make improvements in the future.

Planned implementation.

Once the QI initiative was reviewed by the committee and the contents of the preliminary diabetes educational template had been discussed, the diabetic education flow sheet was ready to be used during the education process in the clinical setting. The

original plan for implementation of the electronic diabetes flow sheet required the developed flow sheet to be transferred to an electronic format and incorporated into the visit reports electronically. The nurse practitioner, physician and the medical assistants who participated in the diabetes education process were to document on the electronic diabetes education template the components of the education process they initiated with the patients. Additional reminders were to include putting tabbed reminders on all charts of patients with laboratory work showing A1Cs to be > than 7.0 or fasting blood sugars greater than 120, to remind them to use the diabetic education flow sheet or posting reminders near workstations. These postings were to remind clinical staff to use the electronic diabetes education flow sheets and to add the names of those patients who it was used on to a master list.

To ensure the electronic flow sheets were being utilized effectively, the QI committee would review the utilization of the education flow sheet each week. Using the collaborative computing platform, the committee would review the number of times the flow sheet was used, the types of patients the education flow sheet was used with, whether they were newly diagnosed patients or those who were considered uncontrolled, and how the practice of using the education process was being used. When reviewing the education process, the committee members would be asked if there were any technological problems using the flow sheet, if there were any parts of the education list needing to be adjusted or reworded to reflect the type of education delivered. Proposed changes would be discussed and implemented on amended education flow sheets.

Patient Interviews

Because the QI initiative was directed toward improving the education process of patients with type 2 diabetes, it was important to gain perspective from those patients being educated as guided by the diabetes education flow sheet. By gaining the patient's perspective, the clinic ensured that the education being delivered was beneficial to the patient in controlling their diabetes. To accomplish this, I contacted volunteer patients who had just received their education from the clinic.

Sample

The sample patient population was males and females, ages 18 and above, who spoke English, and who had been diagnosed with type 2 diabetes within the last year. Most of the clinic population was Caucasian, so the majority of those participating were anticipated to be Caucasian. Because of the specialized education needed for patients who have type 2 diabetes and are pregnant, pregnancy was an exclusion criterion for participating in this QI project. Participants also needed to be cognitively intact. Any patient with a current diagnosis of CVA (stroke), dementia, Alzheimer's or substance abuse was excluded. Also excluded was any patient who was prescribed medications that might impact the cognitive ability of memory, such as anti-anxiety medications (diazepam, alprazolam), antidepressants (amitriptyline and imipramine) or seizure medications (carbamazepine, gabapentin). These conditions were determined by the medical assistant who had access to the patient's chart and could verify the presence of exclusion conditions or medications. Approximately 1-2 patients seen at this clinic were diagnosed with type 2 diabetes each week (T. Pendarvis, personally communication, May

26, 2010). Therefore, it was estimated that 10-20 patients could be enrolled in the project over the 8-week time period.

Patient participants were recruited in the following manner: all patients with an ICD code for type 2 diabetes who had just completed their diabetes education in the clinic were asked by the medical assistant if they would like to participate in a quality improvement project related to diabetes. This was done when the medical assistant was alone with the patient and no other patients or clinicians were around them. The medical assistant told the patient, “Our clinic is taking part in a quality improvement project to address how we educate our patients who have been recently diagnosed with type 2 diabetes. We are asking patients to help us improve our education process by taking part in a phone survey. If you are interested, I have a sheet that will explain the survey and a contact form for you to fill out so our quality improvement team leader can contact you. Are you interested?” Those patients who expressed an interest were given the Patient Participant Disclosure Form (see Appendix C) that explained their participation role in the QI initiative. If they agreed to participate and discuss their most recent visit, they were given the Patient Participant Contact Information Form (see Appendix D) to print their name, sign their name and provide a contact phone number. I then contacted the patient, explained the study, reviewed the disclosure form, and answered any questions. Once this was done, the interview began.

Patient Interviews

Patient interviews were conducted by me over the phone approximately one week following the patient’s visit to the clinic. This allowed the patient to synthesize and

utilize the information given to them. After explaining the project to the patient, I discussed the voluntary nature of participating (See Appendix E). This information was written in the participant disclosure papers they were given (See Appendix C). The healthcare providers were not apprised of who did or did not participate.

To protect the identity of the patients participating in the QI initiative, all phone calls to volunteer participants were conducted at my office, which was distant from the clinic. Patient demographic information was kept on a password protected computer. Each patient participant was given a code name to identify them on notes (Patient001, Patient002, etc). All paper copies of the links between clinic personnel, patient participant demographics and assigned code names were kept in a locked file cabinet. A thumb drive storage of all data collected during this study, including personal identifying information, was kept in the same file cabinet with the paper copies.

Questions were directed toward the patient's thoughts about the education process. Notes taken during the course of the phone call were transcribed to a word document with the assigned code name placed on the top of the document to identify the patient. These notes were combined with comments made by other patients and presented to the clinical staff in aggregate form without any identifying markers. If a person stated they were uncomfortable answering a question, that question was skipped.

Each patient participant received a small book related to diabetes management as a token of appreciation for their participation. They were asked a mailing address so that these booklets could be mailed to them at the end of their interview.

CHAPTER FOUR: IMPLEMENTING THE QI INITIATIVE AND ANALYZING THE DATA

Doing

Preparing the Clinic and Staff

Clinical staff were provided information about the nature of the quality improvement initiative at the beginning of the project in a staff meeting; and flyers announcing the project were placed in the clinic break room, triage area, and in all exam rooms (See Appendix G). Although all staff members were invited to participate in the project, ultimately five participated. Additional staff members were encouraged to be part of the project through my encouragement and additional verbal education about the project.

Patients were also informed of the project with flyers posted in high visibility areas of exam rooms. A number of patients with type 2 diabetes inquired about the project. Approximately 10 inquiries were received from patients by the medical assistants. While these inquiries were mainly from patients who had diabetes for more than a year, two people who were newly diagnosed with type 2 diabetes had initially seen the QI initiative poster and were interested in participating. One patient declined to participate after receiving information about the project. Two other patients who met the inclusion criteria for participating in the patient interviews were recruited by the medical assistant at the end of their diabetes education session, both of whom were interviewed by the project coordinator. Only 3 patients participated in the phone interviews.

Implementing the Project

The project was implemented in several phases. During the first phase, data regarding the patient population was collected from the clinic's EHR. Two other processes occurred simultaneously over the next two weeks. First, the patient charts were reviewed for documentation of selected quality indicators to analyze how process and outcome measures were being addressed. At the same time, the diabetes education flow sheet (DEFS) was developed, based on staff feedback and national guidelines. The initial DEFS were given to the medical assistants for clinical use with patients who were newly diagnosed with diabetes or were not considered controlled by the providers. The QI committee met every other week for a period of two months, to discuss how often the sheet was being used, if there were any unintentional consequences for using the DEFS, and if there were any recommendations. During this time, the committee evaluated if the DEFS was an appropriate intervention for this clinic to adopt as part of their diabetes education protocol. The final phase involved collecting feedback from patients to evaluate the education process from the patient's point of view. This phase occurred simultaneously with the other components of data collection.

The procurement of the selected clinical data did not transpire as anticipated. During the early phase of data retrieval through the EHR, it was discovered that the system did not contain the software necessary to obtain the desired measures. The office manager was not able to readily obtain a list of patients with type 2 diabetes seen within the last year. Rather, she was only able to obtain the total number of patients seen by the clinic within the past year. We discovered that it was impossible to sort by ICD-9 codes.

The clinical staff initially felt they could review electronic patient records for some of the baseline quality indicator data but were uncertain as to how to do this. They felt the physician in the office could perform this task, but he indicated he could not with the current software package. I consulted with the software company who distributed the EHR to determine if other steps could be done to procure the data. Based on the software package the office had purchased, this function was not a possibility. Using the EHR to determine the frequency of quality indicators to electronically review patient charts was not an available option.

Therefore an alternate method for obtaining the baseline data for review was implemented. Using the computer database, the office manager obtained a total number of individual patients seen from between January 1, 2010 and December 15, 2010. During this time period, 12,057 patient visits were managed by this clinic (M. Pendarvis, personal communication, December 15, 2010). Next, the office manager examined the EHR for each month and looked for ICD-9 codes that matched the codes she inputs for patients with type 2 diabetes. Following the visual review of the EHR listing of patients, a total of 298 individual patients with type 2 diabetes had been seen at the clinic in the previous year. Thirty six additional patients had been diagnosed with type 2 diabetes within the last year, bringing the total number of patients with a diagnosis of type 2 diabetes and seen within the last year to 334 (M. Pendarvis, personal communication, December 15, 2010).

The procedure for gathering selected process and outcome measurements was also modified from the original plan. Because of the limitations in the EHR software and

keeping in mind the NP request that this QI initiative not interfere with medical assistants' current job functions, an alternative plan was developed for collecting these data. This plan relied on the medical assistant's task of annually reviewing the medical charts

Because the clinic still documented primarily in hardcopy, they kept the charts of patients seen within the last year in the office area. The medical assistant reviewed the charts one by one to verify if they are current, as evident by having the previous year's sticker on the side of the health chart. If they weren't seen within the previous year, the chart was moved to a different area in the clinic.

During the act of reviewing charts, the medical assistant set aside 40 charts of patients with type 2 diabetes listed on their chart. The medical assistant was given a form that contained the list of process measures and outcome measures that were to be reviewed in each chart (see Appendix A). She then copied the form and used the form to review each chart. To avoid duplicate charting, she copied the chart number at the top of the paper. If the medical assistant was able to locate whether a test was done or documented, she indicated on the form with a "yes." A "no" indicated that the test was either not done or could not be located within the chart. This type of convenience sampling is an appropriate method to provide baseline data for quality improvement projects, future studies or interventions (Hulley, Newman & Cummings, 2001). Table 3 demonstrates the results of the process measures review.

TABLE 3. *Process measures collected for baseline knowledge from charts of patients seen over the past year (2010) (N = 40)*

Test/exam	# of charts in which the management component was found to be performed	Percentage of charts in which management component was found to be performed
A1c level	40/40	100%
Lipid profile	37/40	92.5%
Eye exam	14/40	35%
Foot exam	21/40	52.5%
Flu vaccination	20/40	50%

The selected outcome measurements (Table 4) were collected on the same sheets using the same charts as the process measures. The reviewer either wrote the values or placed a check next to the corresponding result level. If the chart did not have the data, then the area was left unchecked, or a “none” was placed in the area. The results show that most of the outcome measures fall in the optimal values for their individual indicators.

TABLE 4. *Outcome measures collected for baseline knowledge from charts of patients seen during past year (2010)*

Test/exam	Outcome measure values	Percentage of charts with result (number of charts)
A1C level (N = 40)	• >9.0% (poor control)	2.5% (1)
	• 7.0% to 9.0% (needing improvement)	32.5% (13)
	• <7.0% (optimal control)	65% (26)
LDL-C levels (mg/dL) (N = 37)	• >130 (poor control)	16.2% (6)
	• 100 to 130 (needing improvement)	21.6% (8)
	• <100 (optimal control)	62.2% (23)
Blood pressure (N = 37)	• >140/90	29.7% (11)
	• <140/90	70.3% (26)

Implementation of the Diabetes Education Flow Sheet

During the workweek, the office was closed one afternoon to allow staff members unopposed clinic time to complete necessary office tasks. During this time, the Quality Improvement team met to initiate and discuss the QI initiative and evaluate the process by which the diabetes education flow sheet was being used. The QI committee members included me working as the project coordinator, the office manager, the clinicians, and the medical assistants.

Week 1

The first QI initiative meeting was held the first week of January at the clinic. The members present were the nurse practitioner who owned the clinic, the office manager, and two medical assistants. One of the medical assistants had just recently been hired and was encouraged by the other QI members to participate as part of the team. The other MA had been with the clinic since inception and was the assistant for both the NP and physician. The physician and another MA were absent during this meeting.

The QI initiative was reviewed with these four committee members present. The committee members were informed about the development of the QI initiative addressing the education of patients newly diagnosed with type 2 diabetes or those patients who were not under control after a year of diagnosis. The diabetes education flow sheet (DEFS) (see appendix B) was provided to the committee members and they were given instructions on how to log on to the Internet and a password-protected chat room. It was explained to the group that the purpose of the QI initiative was to develop an education flow sheet which could be used by the office to ensure all quality indicators were being

addressed when a patient received his or her initial diabetes education. The DEFS would serve as a guide to provide consistent and comprehensive diabetes self-management education. Committee members were informed that the providers had determined the overall goal was to improve the glycemic control in patients who had A1Cs greater than 7.0. The committee was told that the DEFS would be converted to an electronic format in the clinic's EHR.

The committee members were also told I would be gaining insight from the patient's perspective on how patients were receiving and using the information gained from these visits. Next, each committee member was given a copy of the patient interview questions to review.

The committee members then went to their individual desktop computers to log into the electronic password-protected chat room to begin a synchronous but anonymous discussion of the DEFS. It took approximately 20 minutes for everyone to log into the chat room due to some access issues with the online server. During this time, the office manager reviewed the DEFS with the physician who had since returned to the office. While the physician declined to participate in the online chat regarding potential modifications of the DEFS, he did review the sheet with the office manager and suggested modifications he felt would help with the education process.

During the on-line chat, the office manager and nurse practitioner had to leave for a previously scheduled meeting. The additions the physicians offered for the DEFS were conveyed to me by the office manager. The nurse practitioner also verbally discussed his suggestions with me prior to exiting the clinic. The two remaining members were able to

log on into the password-protected chat room and engaged in an online discussion concerning the DEFS.

Through the chat room discussion, concerns about some material that the clinic did not use in the education process arose. Specifically, the clinic did not routinely provide education material about the glycemic index. This component was left on the DEFS temporarily as the nurse practitioner indicated he wanted this included. Another suggestion was to include education for patients about using blood glucose monitoring logs and bringing them to the clinic each time for evaluation by the provider. This component was added under the “Monitoring Blood Glucose and Goals” section of the DEFS.

A final recommendation proposed by the physician was to include a section for each of the laboratory quality indicators (lipids, A1C, urine proteins, finger stick results, weight and blood pressure). He stated he wanted to have a section in which to document data on subsequent visits. Because documenting data was outside the original scope of the DEFS, the committee discussed the suggestion and reviewed the purpose of the DEFS. The committee decided to include the laboratory documentation area on the DEFS as an education section addressing routine laboratory test results and monitoring of quality indicators.

The initial patient questionnaire (see Appendix F) was reviewed by five members of the clinical staff. All of the committee members stated that the questions were very relevant and appropriate for their clinic. Two additional questions were discussed in the chat room and were added to the original form: These questions were: “Was the patient

taking the medication as directed?” and “Are they able to afford the medications they were prescribed?” Though these questions were not directly associated with the education part of diabetes management, they were included in the patient interview as an additional component of their management information.

At the beginning of the second week of the QI initiative, the DEFS was modified based on the suggestions of the committee members and was copied on to bright yellow paper for easy reference in the chart. The medical assistants were educated on what types of patients to use the DEFS on and how it was going to be used. For each patient brought back to the clinic for diabetes education, the medical assistant was to place a DEFS in the chart for documentation. Additionally, patient who had an A1C greater than 7.0 or who needed additional education on their diabetes was to also have one placed on their chart.

The medical assistant was also instructed on whom to recruit for the patient follow-up interviews. The target patient population for interviews was discussed and those who met the criteria were to be given a patient participation disclosure form and a patient contact information form (see Appendices C and D). A manila envelope with 15 copies of the form was given to the MA to give to potential participants. An empty envelope was provided for the MA to place contact information for those patients who wished to participate in the follow-up interview.

Modifications to the Planned Process

The original plan for this QI initiative was to develop an electronic diabetes education template to be installed on the existing EHR used by the clinic. The clinical staff would use the template to outline their diabetes management discussion. They

would then document the completion of their education on the electronic template. Prior to the start of the first meeting with the QI committee, the office manager informed me that the clinic would be changing the EHR platform in which they documented and kept records. She indicated that this was being done in order to be compliant with Medicaid reimbursement requirements (M. Pendarvis, personal communication, January 6, 2011). The office manager indicated that it would be at least one month before an EHR system would be decided upon. Rather than delay the start of the project, it was decided to complete the QI initiative using a hard copy of the DEFS rather than to transfer it to the current EHR. This would allow the DEFS to still be used and evaluated by the clinical staff, and subsequently modified with less difficulty than on the EHR. Following the completion of the QI initiative, the final hard copy form of the DEFS could then be transferred to the EHR system once the new EHR system was in place.

Originally, the online discussion platform was to be used to discuss modifications to the DEFS and any unintended consequences of the QI initiative. The intent of using the online discussion platform was to ensure anonymous discussion among committee members who may have a sense of discomfort about disagreeing with those who employ or supervise them. After the initial meeting using the online discussion platform, it was decided to discard this method and discuss the DEFS face-to-face in the regular committee meeting. Several factors contributed to this decision. First, as the project manager, I sensed the on-line discussion was more cumbersome to the participants who preferred to discuss issues with everyone at once. When the suggestion was brought up to continue the QI discussion in the online chat room, several staff members stated they

needed to do work instead. However, if the discussion was continued in the group, committee members stayed and provided feedback about the DEFS and the QI process.

While the access problem was corrected, the actual process of recruiting committee members to sit down in front of a computer to discuss the QI initiative appeared more taxing on the clinical staff than actually sitting down and discussing it face-to-face. Clinic members who had other meetings scheduled during the afternoon did not feel they had the time to dedicate to an on-line chat discussion, but instead preferred to discuss it with other members. This was the consensus opinion of all committee members when they were interviewed privately by me. In addition, the interaction among the medical assistants and clinical staff appeared to be collegial in nature. The nurse practitioner and office manager demonstrated to the medical assistants that their opinion was not only welcomed in the communication process, but valued as a part of the committee. The clinical staff not only invited the newly hired MA into the group and encouraged her participation, but asked her how she felt about the recommended changes. They also deferred several questions from the project coordinator to the experienced MA, who felt very at ease in providing feedback. Based on these observations, future QI meetings were held face-to-face in a normal committee setting.

Follow-up QI meetings were originally scheduled weekly at the clinic during times when the clinic was closed. Due to inclement weather and a high incidence of acute illnesses, diabetes education-focused visits were not as prevalent and the DEFS was used only one time during the first two weeks; so the follow-up QI committee meeting met two weeks after the implementation of the DEFS.

Week 3

This was the first meeting following the initial meeting and adjustment to the DEFS. To date, the DEFS was only used one time on a patient who had type 2 diabetes for approximately 13 months. The flow sheet was not actually on the chart at the time of education due to a misunderstanding among the clinical staff as to which patients the DEFS was intended to be applied. However, the nurse practitioner completed the form after the patient had left and placed it in the patient's chart. While the NP did not use the sheet to guide his education, he was able to document what education took place during the session and gained experience in documenting on the sheet.

The committee discussed methods to ensure the DEFS was used, one of which was to insert the DEFS in the charts at the time when the follow-up appointment was made. As project coordinator, I reinforced the purpose of the QI initiative to use the DEFS to help guide diabetes education. Based on this discussion, it was decided by the committee to write the DEFS target population on the outside of the packet holding the DEFS papers to provide guidance. Several patients were scheduled for follow-up visits and clinic staff planned to use the DEFS with these patients. Because the DEFS had only been used one time up to this point, modifications were not discussed during this session of the QI Committee meeting.

Week 5

Due to inclement weather, only three committee members were present for the third QI committee meeting. At this point, the DEFS had been used an additional four times, bringing the total to five times. It was used with two patients who were newly

diagnosed and three with patients whose diabetes was uncontrolled. The committee reviewed the previous meeting's suggested steps of incorporating the DEFS. One MA reported inserting the DEFS on a few charts of patients who had A1Cs greater than 7. The other MA reported how she included the DEFS on a chart of a patient whom she placed in a room. Upon review of the chart, she found this patient did not have appropriate A1Cs and added the DEFS for the provider to review. These additional steps were not considered burdensome by the clinical staff were agreed upon by the committee as appropriate actions to incorporate. The committee members could not identify any negative or unintentional effects of the QI initiative at this time.

The DEFS was reviewed by the committee for applicability and content modification. All committee members spoke positively about incorporating the DEFS in the education process. The nurse practitioner commented how he was able to use the sheet to guide his education based on the listed components. One of the MAs stated she was able to refer to it to ensure all areas were addressed. However, there were several suggestions for modifications made by committee members. First, the nurse practitioner asked to eliminate the glycemic index component from the nutritional management section and replace it with "Calorie Counting." This was the method he employed when he educated his patients. Additionally the "Carbohydrate Counting" section was discussed and it was decided upon to leave it on the DEFS for the time being.

Another suggested modification to the DEFS was to incorporate sections indicating if handouts had been provided. The clinic did have handouts for patient education for various components of diabetes management. The committee decided an

area for documenting what handouts, if any, were provided be added to the DEFS. They recommended a “HANDOUT PROVIDED” section to be added under the following sections: nutritional management, exercise, smoking cessation, foot exams and eye exams. Because a glucose monitoring kit was sometimes provided to the patient, an additional area to indicate this component was done was added under the “Monitoring Blood Glucose and Goals” section.

One final area of discussion in this week addressed using the DEFS as a follow-up guide for patients on return visits. One of the first patients for whom the DEFS was used made a return visit, and the MA who checked the person in was able to refer to the sheet to review some previously discussed components. This question was discussed by the committee members. The MAs agreed that using the DEFS as a review sheet helped to organize follow-up questions on previously educated components. This was seen as a positive unintentional effect of the QI initiative and one the committee was in favor of continuing. They inquired about expanding the DEFS to include a “Follow-up” column in order to document continual education. It was decided to add this in a subsequent QI initiative.

The updated DEFS was delivered to the clinic the next day for immediate utilization. It was copied on bright yellow paper for ease of reference during this study. See Appendix I for the modified diabetes education flow sheet.

Week 7

The QI committee reported using the second edition of the DEFS a total of six additional times since the previous QI committee meeting. It was used with one patient

who was newly diagnosed and five with patients whose diabetes was uncontrolled. Including the project coordinator, a total of five members were present during this meeting. During the review of the DEFS, all of the members reported on the positive aspects it brought to the education process. The nurse practitioner reiterated how it helped recall education components to talk about and provided a guideline for the staff to provide patient education. He concluded that use the DEFS was not an extra burden to his staff, was not cumbersome to use, and added the DEFS was “nothing but beneficial.” The committee discussed ways in which they had started to incorporate the DEFS for those patients who have had diabetes for a while. For example, based on blood test results, the medical assistants and providers offered education toward those quality indicators. Using the DEFS allowed the clinic staff to provide education at varying times. It allowed them to talk about specific areas that may not have been addressed at previous visits. They also reported being able to use the DEFS to review management topics patients may have been educated on several years ago. The opportunity to use the tool on a patient who had previously been educated with the DEFS as a guideline was also discussed. The committee appreciated how the DEFS allowed them to follow-up on the specific education components initiated by the specific provider. There were no recommended changes to the DEFS at this time.

Week 9

The QI committee reported the DEFS had continued to be used on patients who had uncontrolled type 2 diabetes, four within the last two weeks. The DEFS was also used on one patient who was newly diagnosed. Including the project coordinator, four QI

committee members were present at this meeting. The medical assistants reported seeing patients for follow-up exams and using DEFS to help guide review of the process measures. They reported reviewing with the patient if certain management procedures have been done, such as eye exams. Addressing specific process measures was noted by the MA who performed the chart review. She noted being able to see trends in the process measures being collected at the clinic. The MA was especially mindful of areas that she found lacking and used the DEFS to help address those areas. There were no reports of unintentional effects of the QI initiative and there were no modifications suggested at this time.

Patient Participant Phone Interview

Only three of four qualified patients agreed to be interviewed: two females and one male. The goal was between 10 and 20 participants in order to provide feedback to the clinical staff regarding the education they provide. However, clinic staff had overestimated the number of patients newly diagnosed with type 2 diabetes who came to the clinic for care. Therefore, the pool of patients who were newly diagnosed with type 2 diabetes was small. Information provided from only three patients would not provide an accurate representation of the education process in the clinic. This component of the QI process will continue to be an ongoing process.

Studying: Evaluating the Results

When reviewing the QI initiative, it is important to review project outcomes as well as the process by which the initiative was implemented. This QI initiative required several adjustments in order to be carried out, but flexibility should be a key component

of any QI initiative. Any QI initiative must be tailored to the clinic in which it is being implemented, and this one was no different. The outcomes data were reviewed to address unanticipated problems and new knowledge was obtained to construct future initiatives.

Quality Indicators Review

There are several concerns with the method used by the office manager to gather population data. One of the most concerning irregularities is the number of patients seen by the clinic and the number of reported patients with type 2 diabetes. The 334 patients with type 2 diabetes represent 2.8% of the previous year's visits. This number seems disproportionately low compared to the state's projected approximation of 11.0% of Oklahomans with diabetes (OSDH, 2010). The numbers also differ from the projected percentages made prior to the QI implementation. According to the nurse practitioner, the estimated number of patients with type 2 diabetes was approximately 20%, far above the estimated 2.8% of the previous year's visits. The validity of these findings must be questioned. A more accurate review must be initiated in future endeavors using full EHR capabilities.

Several possible explanations may account for the low percentage of patients with type 2 diabetes seen in the clinic last year. First, when the office manager examined the EHR month by month to calculate the number of patients seen with type 2 diabetes, she reviewed by the ICD-9 code for the visit. Some patients may have received a primary ICD-9 code for a problem other than diabetes. For example, a patient with diabetes may have been seen for an upper respiratory infection. The visits would then have been coded for the acute problem and would not necessarily reflect the ICD-9 code for the chronic

problem of diabetes. These patients would not have been counted by the office manager in the list of patients with type 2 diabetes. The second possible explanation for the low percentage of patients with type 2 diabetes is that not all patients who have type 2 diabetes are actually seen on an annual basis. Since both the physician and nurse practitioner projected a higher percentage of patients with type 2 diabetes, the clinic may need to review why they are not seeing as many patients with type 2 diabetes on a regular interval.

The initial review of the process measure findings demonstrated the clinic was inconsistently documenting the recommended management procedures for patients with type 2 diabetes. This was supported by a quote from the medical assistant who pulled the charts for review:

‘Finding the laboratory results was easy. However when I look for documentation for a specific procedure, such as an eye exam or a foot exam, it was difficult trying to go through the notes to see if it was documented. Sometimes we may look at feet as we are reviewing other problems, but it doesn’t get written down that way.’ (MA1, personal communication, February 24, 2011)

While reviewing the charts and gathering process and outcome data, the medical assistant felt she became more aware of documentation and management discrepancies, and stated, “While I was going through the charts and trying to find the data, I was amazed at some of the areas we were lacking in. Things I know we have done, but I just can’t find them.” (MA1, personal communication, February 24, 2011)

The medical assistant stated she had to search for information in order to find it. Some places the data were not readily identifiable, such as the process measures. For example, there was not a place on the chart for the providers to document foot examination performance specifically. The only way she could tell if it was done was by going through the notes and reviewing for documentation that indicated the feet were looked at. She indicated that there wasn't a place to document eyes being examined, regardless of whether it was done or not (MA1, personal communication, February 24, 2011). Other pieces of information were available for her to note the documentation, such as the blood pressures. The blood pressure documentation was a standard part of the routine visit documentation.

Several concerns are reflected in the comments about her search. First, there wasn't a dedicated place on the chart that clinical staff could use to quickly and easily find management data specific to type 2 diabetes, such as routine examinations of eyes and feet, or flu shot administration. This made performing chart reviews for quality improvement difficult and labor intensive. Having a documentation system to organize the management of patients with type 2 diabetes would provide a quicker means to evaluate current management status of select disease processes.

Results of the chart review suggested that the clinic consistently performs A1C levels on their patients with type 2 diabetes and slightly more than 90% had documented lipid profiles in accordance with national guidelines. However, the clinic falls well below the state average in other management areas. Results of chart documentation suggest that only 50% of the patients had received the annual influenza vaccine, compared to the state

average of 62.9% (OSDH, 2010). Chart review results for foot examination were at 52.5%, also below the state average of 65.9% (OSDH, 2010). The percentage of patients with a documented eye exam was nearly half that of results for Oklahoma (35% vs. 65.4%) (OSDH) (see Table 5).

TABLE 5. *Comparison of process measures found in the clinic chart sample and the state average of process measures in the State of Oklahoma*

Process measure	Percent of patients at selected clinic who had procedure documented	Percent of adult Oklahomans who had procedure performed
Eye exam	35%	65.4%
Foot exam	52.5%	65.9%
Flu shot	50%	62.9%

Potential causes for the apparent discrepancy between clinic practice and state levels include lack of inclusion in management and lack of documentation. Lipid profile tests may have been ordered, but the results were not transferred to the chart and were not located by the reviewer. The foot and eye exams may have been done, but may not have been documented or documented in a location unknown to the reviewer; or they simply may not have been done at all. Performing foot exams may not be part of the standard protocol for patients with type 2 diabetes unless they present with a concern. In regards to the dilated eye exams, the physician performs his own eye exams, but the nurse practitioner refers his patients to either their own eye doctor, or to a local ophthalmologist or optometrist (Personal conversation, T. Pendarvis, October 15, 2009). Eye exams that have been referred to another provider (i. e., an ophthalmologist) and the results or documentation of referral may not be documented. Since the clinic did not offer flu shots this past year, there is not a place to document orders for the vaccination to be done in the

clinic or a record of it being done. The flu vaccination results may be skewed due to the clinic staff documenting if they have received one outside the clinic on a consistent basis.

Diabetes Education Flow Sheet Review

The DEFS was used a total of 16 times: four on patients who were newly diagnosed with type 2 diabetes and 12 times on patients who had an A1C greater than 7 and not considered under control. This meets the established goal of using the DEFS 10 to 20 at least 10 utilizations in a two month period.

Early in the QI process, clinic staff viewed using the DEFS as a potential research project, which caused them to take extra steps to ensure the tool was on the chart.

Additional steps reported by the medical assistants included putting the DEFS on patient charts when the MAs scheduled patients for diabetes education and actively reviewing each days charts to determine if any of that day's patients had uncontrolled diabetes.

Eventually, a shift was observed in how the clinical staff reported the utilization of the DEFS. Though the clinical staff initially expressed approval of the planned QI intervention, the staff voiced a greater appreciation for the DEFS in the later weeks of the project. It no longer was seen as an additional task, but rather an integral part of the diabetes education and documentation process. This is evidenced by the staff taking the initiative to apply the DEFS on patients whose diabetic laboratory work comes back with abnormal results.

The implementation of the DEFS has been a positive addition to the diabetes education process. After several modifications from the original flow sheet, the clinical staff state they feel very comfortable in using the template to help guide their diabetes

education. The nurse practitioner reported that when he uses the DEFS, he believes everything is being addressed in an organized manner. He stated he was pleased with the adaptation to the education process and states it was a great addition for patients (T. Pendarvis, personal communication, February 24, 2011).

The MAs have also viewed the addition of the DEFS as a positive step in helping them organize their approach to educating patients and have taken steps to ensure it is a part of their documentation. When a patient presents with an elevated A1C, or is brought in for diabetes education, they routinely place the DEFS in the chart for education purposes. As one medical assistant stated:

“Whenever a patient comes in with type 2 diabetes, we almost automatically reach for the diabetes flow sheet now. It has become a valuable tool in educating and review. It has become an adopted protocol. If I see they have elevated blood sugars, I go and get the sheet and put it on the chart because I know they are going to need it.” (MA1, personal communication, February 24, 2011)

What was once a difficult task to remember is now an automatic response to patient presentation.

Further evidence of adoption of the DEFS in the clinical practice is the additional clinical applications the MAs are instituting with the flow sheet. In addition to using the DEFS in the initial and supplemental education processes, the MAs are expanding the use of the DEFS to ensure patient compliance in return visits. If they identify the DEFS on the patient’s chart on a follow-up visit, the medical assistant will ask questions about the

patient's educated lifestyle changes based on the education the patient received. The medical assistants may also ask about additional process measures that might have been conducted or performed outside of the clinical setting. For example, one medical assistant said:

“I like how we use the flow sheet. I can see what was done at the previous visits, and when I see them again, I can see how things are going. I can see if they kept an appointment or ask specific questions about their exercise.”

(MA2, personal communication, February 24, 2011)

Using the DEFS to guide provider questions toward patient compliance goes beyond the initial education plan of utilization. Referencing the education the patient originally received regarding the established quality indicators gives credence to the original implemented procedure. Not only is the staff implementing the DEFS, but they are trying to apply it to different phases of the patient management process.

Results of Patient Participant Phone Interview

Telephone interviews were conducted with three patients. These interviews generally lasted 20 minutes. This information was collected between week 4 and week 9 of the QI initiative. Based on the number of patients interviewed, it was determined there was not enough feedback to draw a conclusion on the entire education process.

Preliminary data analysis indicated the patients felt the providers were very thorough in their diabetes education. Two patients stated that the providers were very comprehensive in their approach and were unable to recall any areas they felt were not taught very thoroughly. One patient even made the observation in the telephone interview about how

the provider referred to his chart several times during the visit. The patient wasn't sure what the provider was looking at, but did see him refer to the chart for education points several times (patient interview, March 27, 2011).

CHAPTER FIVE: DISCUSSION OF THE NEXT STEPS

Acting: Taking the Next Steps of QI Implementation

The final component of the QI initiative is to refine the change based on what was learned during the project. This includes formalizing new or revising existing clinical policies or procedures, reassigning support staff duties, further educating staff or modifying existing health record templates since the evidence did demonstrate an improvement in the education delivery system. The tested QI initiative can then be applied to other areas of clinical practice. Future cycles will be discussed with the committee to address improvements in other areas of diabetes management, as well as other chronic disease processes.

Implementation Recommendations

The overall response to the diabetes education flow sheet was a positive one. The clinical personnel who used the DEFS stated that they found value in having this education reminder. Because the staff found value in the DEFS and began to use it to guide patient education, policies should be established by the office manager to ensure the continued utilization of the DEFS. When a patient is newly diagnosed, having the DEFS placed in their chart for their next visit could be a standard in the clinical management of these patients. When new patient care employees are hired, they should be trained to use the flow sheet in their diabetes management. This step of using a hardcopy DEFS should be only a temporary bridge in managing patients with type 2 diabetes until the EHR is set up and in use in the clinic.

The clinic should also select and incorporate an EHR platform into their health management system. The clinic is utilizing both hardcopy records and electronic records in their practice. While there currently is an EHR in place within this clinic, the office manager and NP were deliberating on a newer model, one that was more compatible with being able to send data to Medicare for financial reimbursement considerations. This newer model would allow them to also chart on an “i-Pad” type device in the room with the patient (M. Pendarvis, personal conversation. February 10, 2011). The clinic should find an EHR service that they feel comfortable enough to use exclusively to avoid the extra work of double charting.

The lack of ability of the current EHR to be used to retrieve diagnostic and other patient data is a major concern. A company representative for the current EHR system states that the clinic has an option to upgrade to an electronic health record platform that will allow them to perform a population analysis (SOAPware representative, personal conversation, March 22, 2010). This would cost an additional \$500.00 per year based on their current software and platform. This seems to be a reasonable option if the clinic staff decides to continue with the current system. However if they choose not to incorporate this new software, they must find a reliable method for retrieving aggregate patient data in a way that allows clinical staff to analyze process and clinical measures of concern routinely. The new EHR, or upgraded professional package, should have “cross-reference” features to enable review of various patient statistics, i.e., number of patients seen in the past year with diabetes, patients with diabetes who have had their flu shot, etc. When this is implemented, the employees will need to be trained by a representative from

the EHR company on how to retrieve specific statistics. This will allow monitoring on multiple levels. First, the office manager and clinicians will be able to pull data specific to selected patient populations and disease processes on a routine basis. They also will be able to review process and outcome measures in the management and education areas to perform quality assurance checks.

Once the EHR is in place and being used in the clinic, clinical staff will need to configure an electronic copy of the DEFS for the EHR. The EHR template for the DEFS can be developed, incorporating the same components as the final DEFS agreed upon by the clinic staff. The company selling the EHR will need to work with the clinic to ensure the education components are transferred over to the electronic format. Because the clinic is thinking about using i-pads in the clinical setting, the EHR company may work with the clinic on adjusting documentation boxes. When the DEFS is transferred, the clinical staff should implement an additional PDSA cycle to ensure there are no unintentional consequences and the DEFS is still beneficial and helpful.

Because the clinical staff was using the DEFS as a review sheet on follow-up visits, the clinic should consider having the DEFS modified to be used for a review of patient education topics for follow up visits. Results of the QI initiative suggest that the DEFS can be useful, not only in guiding patient education content, but also as a guide for reviewing previously taught content. When the EHR documentation system is in place, the DEFS and return-visit review sheets could be cross-linked electronically to allow clinicians and staff the ability to review quality indicators with patients, assess patient

understanding of previously taught content and address areas of concern, such as necessary laboratory draws or flu vaccinations.

After reviewing the selected process and outcome measures, the clinic should incorporate a documentation system that includes documenting quality indicators associated with the care of patients with diabetes. In the same context as vital signs are documented on all patients for each visit, selected quality indicators associated with diabetes management could be documented on the check-in procedure list. For example, patients who have type 2 diabetes would be instructed to remove their shoes and socks for a foot inspection on each visit. Each fall season, the clinic staff would automatically document when and where the patient received their flu shot in a designated area on the patient care forms. This would allow clinical staff the ability to review the quality indicators specific to type 2 diabetes in a more efficient way. Annual or routine chart reviews can be expedited if staff have a common place to document and review quality indicators. If the EHR is in place and has the ability to calculate and display aggregate data, the process of documentation and data retrieval will be quicker and more complete. Performing routine reviews of process and outcome measures and sharing results with the staff will generate an awareness of the clinical performance goals. This increased awareness of areas of concern may lead to greater staff involvement in quality care delivery.

The office manager and clinicians will need to examine ways to improve type 2 diabetes education based on patient feedback. Once this continuing process is completed, the collected patient data will be organized and printed in a report for the clinic staff to

review. After reviewing the general comments made by all the patients in the follow-up interviews, staff members can discuss ways to continue appropriate education or modify existing steps to improve areas of concern. Once the education modifications are completed, additional follow-up must be instituted to ensure areas of concern are improved upon and there are no unintended consequences. This step will need to be considered once the education feedback from the patient interviews is obtained and reviewed.

Over the long term, it will be important to ensure that the DEFS is current and reflects current evidence. The clinicians will need to review the ADA guidelines for type 2 diabetes management for updates in quality indicators and education needs. Clinical staff should also be aware of any new community resources available that may be of value to their patients. Any changes in the quality indicators, education components or community resources will necessitate modifications in the DEFS to ensure education and QA measures are based on the standards of care.

Additional QI initiatives in other areas of care could assist clinic staff in improving quality of care for other chronic illnesses. Research should be done to address the quality indicators for other chronic diseases, such as hypertension and hyperlipidemia, to determine the standards of care. After reviewing the quality indicators, selected process and outcome measures should be evaluated to determine the quality of care provided. Some quality indicators may overlap other processes, such as education on exercise, or ensuring blood pressure is being treated appropriately. If deficiencies are

found in the chosen quality indicators, a QI initiative may be planned and implemented using the PDSA cycle.

The clinic will receive a follow-up report from the project coordinator which includes these recommendations and a copy of the PDSA flow sheet used to help guide future QI initiatives. By following the PDSA guidelines, they will be able to address perceived and actual deficits in the care they provide their patients. They can address several different areas of patient management with a single PDSA cycle.

Strengths and Limitations of Project

Because of the nature of PDSA model, the direct application of this specific QI initiative is limited. The PDSA model of improvement requires clinicians and managers to analyze problems specific to their clinic and their organization's processes. When considering the aims of quality care, each clinic will have differing areas of concern that need to be addressed. Although the PDSA cycle was used to improve baseline education to a select population in a rural clinic, it has an obvious application to any clinic where providers wish to improve health care delivery. Based on the perceived ease in which this project was carried out, the selected clinic has plans to use the PDSA cycle again for additional QI initiatives to address other populations and other areas of concern discovered during the current initiative.

A perceived limitation of this study is the size of the committee that met on a regular basis. When utilizing the PDSA model in a quality improvement initiative, it is important to have the support and commitment from all levels of operation.

Administrative support is an essential component in a successful QI initiative (Nakayama

et al., 2010). Only four staff members of the six staff members identified at the beginning of the project met routinely. Therefore it is possible that some ideas were not identified during the QI process. However, this is likely typical of the situations faced by small rural clinics. The QI committee for this project contained the essential participants of the owner, manager, the clinician and several support personnel and the experience each one of them brought to the project.

This study demonstrated how the implementation of one idea spurred the development of additional initiatives. Because the committee members were able to discuss areas of concern and areas where documentation was lacking, they were able to discuss additional solutions to these perceived problems. Once the DEFS was incorporated, several of the QI committee members were already utilizing and building upon the education guidance sheet to expand further initiatives on their own. The strength of this study is guided by how well the small team worked together and supported each other's ideas and comments. So while independent rural clinics may differ in the approach they take to improve patient care and safety, this study demonstrates how the PDSA model can be used to address not only a single perceived problem, but a newly recognized problem based on the communication and study that is pertinent to the QI initiative.

Implications for Clinical Practice

From the development and implementation of this single QI initiative, it has been demonstrated that by raising the awareness of a clinic's need to improve, the drive to improve practice becomes an inherent property. Previous studies had demonstrated the

effectiveness of the PDSA cycle in larger clinics and with diabetes management (Johnson & Raterink, 2009; Salman, 2005; Varkey et al., 2009). This project demonstrated how the PDSA quality improvement cycle can be utilized in the smaller, rural setting to implement a change in the patient education of type 2 diabetes. Developing an education tool to ensure education is delivered in an organized manner is one of the first steps this clinic can take in delivering quality healthcare that is safe, efficient and patient centered, as recommended by the United States Department of Health and Human Services (2009).

In addition to the implementation of this PDSA initiative, several areas of concern were discovered by the clinical staff after reviewing charts of patients with type 2 diabetes. Several process and outcome measures were found to be below the anticipated levels of operation and documentation. This result stimulated the staff to explore ways to improve the management of the targeted population through additional QI initiatives. Several phenomena were noted in the clinical use of the DEFS. First, after several process measures were found to be below standard, the clinic staff began to expand the use of the DEFS as a visit follow-up check list. Second, after observing the initial success of the DEFS, several workers began to incorporate the use of the flow sheet in their diabetes management. This second observation is in line with the theoretical model of change acceptance by others discussed by Rogers (2003). A simple awareness of a need and the observation of a successful innovation were instrumental in not only the acceptance of this QI initiative, but also in the drive to improve overall care of patients with type 2 diabetes.

This QI initiative implemented in this rural clinical setting sparked additional desires among the staff to redesign its healthcare delivery and address areas not up to standard. This clinic's aim to provide safe, effective patient-centered care is in alignment with the aims identified by the Institute of Medicine (2001). The programs they are implementing and the clinical reviews they have initiated will provide a solid foundation for improved health care delivery.

Conclusion

This project inquiry was conducted with the intent of improving how a rural, nurse practitioner owned clinic managed patients with type 2 diabetes. The first aim was to determine how well the clinic was addressing selected quality indicators for type 2 diabetes. This was achieved by reviewing charts of patients seen in the clinic within the past year and several areas of improvement were identified. The second aim of this project inquiry was to develop, implement and evaluate a quality improvement initiative specific to this clinic and its providers to help improve the care delivered to patients with type 2 diabetes. This aim was accomplished by using key informant interviews and observations to develop the diabetes education flow sheet, which became a vital component of the education process this clinic utilizes. The final aim was to develop a QI process that the clinic personnel will be able to use for future quality improvement initiatives. This aim was accomplished by utilizing the Plan-Do-Study-Act QI process with the project inquiry and discussing how to incorporate additional PDSA cycles for future initiatives with clinic leaders.

This project inquiry revealed the importance of reviewing one's practice. Rural, nurse practitioner managed clinics should invest the time and effort to ensure the care they provide is of the highest quality. By ensuring that process and outcome measures are meeting or exceeding the standards of care, nurse practitioners can demonstrate to the community they work in that they are delivering quality care in their practice. Advanced practice nurses must constantly seek ways to improve the way chronic diseases, such as type 2 diabetes, if we are to impact our communities around us. It is essential that nurse practitioners embrace the responsibility of providing the highest quality of care to make a change not only in the rural settings but in clinics nationwide.

APPENDIX A:
SAMPLE COLLECTION WORKSHEET

Sample of process and outcome measures collection worksheet

Diabetes Quality Improvement data collection form		
Patient ID #: Date collected: _____		
HbA1c test	Measurement within the last year?	
Lipid profile	Profile drawn within the last year?	
Eye exam	Retinal eye exam within the last year?	
Foot exam	Documented foot exam within last year?	
Flu vaccination	Received influenza immunization last year?	
HbA1c levels	HbA1c levels <ul style="list-style-type: none"> • >9.5% (poor control) • 7.0-9.0% (needing improvement) • <7.0% (optimal control) 	
Cholesterol levels	LDL-C levels <ul style="list-style-type: none"> • >130 mg/dL (poor control) • 100-130 mg/dL (needing improvement) • <100 mg/dL (optimal) 	
Blood pressure	Most recent blood pressure <140/90 mm/Hg	

APPENDIX B:
PROTOTYPE FLOW SHEET

Prototype of the Electronic Diabetes Education Flow Sheet

Diabetes education	Initial	Reviewed	N/A
Discussed diabetes disease process and treatment options			
Behavior changes			
Discussed nutritional management			
• Limiting fat intake			
• Glycemic index			
• Carbohydrate counting			
• Alcohol consumption			
Weight loss goals			
Discussed physical activity needs for disease process			
• 150 minutes of moderate activity per week			
• Resistance training 3 times a week			
Medication			
• Side effects, Call ifs,			
Monitoring Blood glucose and Goals			
• Problem solving for elevated or decreased blood glucose, sick days, when to call			
• Demonstration and return demonstration done			
Risk reduction			
• Smoking cessation			
• Pneumonia vaccine			
• Foot exam			
• Eye exam			
• ASA use			
• Pre-pregnancy counseling			
Coping mechanisms to deal with type 2 diabetes			
Routine laboratory work and monitoring (A1C, Lipids, weight, BP)			

APPENDIX C:
HUMAN SUBJECTS PROTECTION

**THE UNIVERSITY OF ARIZONA HUMAN SUBJECTS PROTECTION
PROGRAM**

PARTICIPANT DISCLOSURE FORM

For IRB Office Use Only:

Project Title: Improving the management of patients with type 2 diabetes in a rural clinic

Investigator: Greg Brooks, MS, ARNP, FNP-C

You are being invited to take part in a quality improvement project being conducted by The University of Arizona. This project will be taking place within the clinic in which you are currently being treated. The purpose of this project is to improve the education and management of patients with type 2 diabetes within this clinic. You are being asked to be in this project because you have been diagnosed with type 2 diabetes within the last 12 months. The clinic is using a newly designed electronic template to enhance the education process. Your input will be beneficial in providing feedback toward improving how the clinic conducts its education toward type 2 diabetes.

If you agree to participate, your participation will involve one phone interview about your most recent visit to this clinic. The interview will consist of a single phone call and will last approximately 15-30 minutes in length. You may choose not to answer some or all of the questions. During the interview, written notes will be made in order to help the investigator review what is said. Your name will not appear on these notes.

Any questions you have will be answered and you may withdraw from the project at any time. There are no known risks from your participation and no direct benefit from your participation is expected. However, the information gained from your involvement will potentially improve the management and care of all patients with type 2 diabetes at this clinic. There is no cost to you except for your time. As a token of appreciation for your participation, you will be mailed a small book to help in the management of type 2 diabetes from the project manager.

Information about you taken during the interview will be written on computer files that will be stored in a computer protected with a password known only to the principal investigator. No one from the clinic will have access to these notes and information.

Information about you will be kept confidential to the extent permitted or required by law. People who have access to your information include the Principal Investigator and project inquiry personnel. Representatives of regulatory agencies such as the Office of Human Research Protections (OHRP) or the Food and Drug Administration (FDA) and entities such as the University of Arizona Human Subjects Protection Program may access your records to make sure the study is being run correctly and that information is collected properly. Reports regarding this quality improvement project will not include your name or any personal identifiers.

You can call the Principal Investigator to tell him about a concern or complaint about this quality improvement project. The Principal Investigator is Greg Brooks, MS, ARNP, FNP-C and can be called at (405) 924-0188. You may also contact the Project Manager's advisor, Dr. Deborah Vincent, PhD, APRN, at (520) 626-9969.

For questions about your rights as a project or research subject; or if you have questions, complaints, or concerns about the project and cannot reach the Principal Investigator or want to talk to someone other than the Project Manager, you may call the University of Arizona Human Subjects Protection Program office.

- Local phone number: (520) 626-6721
- Website (this can be anonymous): <http://orcr.vpr.arizona.edu/irb/contact>.

By participating in the interview, you are giving permission for the project manager to use your information for quality improvement purposes.

Thank you.

Greg Brooks, MS, ARNP, FNP-C
Principal Investigator

APPENDIX D:
CONTACT INFORMATION FORM

Patient Participant Contact Information Form

Dear Participant,

Thank you for agreeing to participate in this clinic's quality improvement project. Your input to this initiative will be truly valuable in helping this clinic maintain the highest quality of care it is committed to providing for you and your community.

Please make sure you read the participant disclosure form. It will provide an explanation of what will be asked of you and should answer any questions you may have.

Please provide the following information:

Your name _____

Your phone number _____

Time of day to best reach you _____

I look forward to contacting you. Thank you again for agreeing to participate

Sincerely

Greg Brooks, MS, ARNP
Principal Investigator

APPENDIX E:
PHONE SCRIPT FOR PARTICIPANT INTERVIEW

Phone script to be read prior to patient participant interview

Good morning/afternoon/evening Mr./Ms. _____

My name is Greg Brooks and I am a family nurse practitioner in school at the University of Arizona. Thank you very much for volunteering your time for this clinic project. The purpose of this quality improvement project is to help the clinic build up and expand their education process of diabetes. The information you provide will help the Noble Family Healthcare Clinic evaluate the care they provide to patients with type 2 diabetes in the future.

Just to verify, were you provided a form that discussed the purpose of this project? This may have been labeled as “Participant disclosure”

Let me remind you of a few items before we begin. This quality improvement project is completely voluntary on your part. You may withdraw from this study any time without any recourse or questions. You also have the right not to answer any questions during any part of the interview.

All individual patient names of those participating in this project will be kept from the clinical staff at the Noble Family Healthcare Center. They will not know which patients are providing feedback to their study, nor will they be told. Information I collect from you today will be presented to them in reports that do not identify you as a participant. I will be taking notes from our conversation, so you may hear some typing in the background. The notes I take from you will be kept in my computer in a password protected file and will be identified only by a code that I have given to you. The clinicians will not see the notes or your agreement to participate. Reports that are given to the clinic will include data in a way that reflects ALL participants; no patients will be singled out or identified specifically.

The questions I will be asking you will be based on your previous visit to the clinic in which you received education toward managing your diabetes.

Do you have any questions for me before we begin?

APPENDIX F:
SAMPLE QUESTIONS FOR PARTICIPANT PHONE INTERVIEW

Sample Questions for Patient Participants Phone Interview

1. What is your age range?
 - a. 21-29
 - b. 30-39
 - c. 40-49
 - d. 50-59
 - e. 60-69
 - f. 70-79
 - g. 80 or above
2. What is the highest grade level (GED, H.S. diploma, college degree)
3. Are you currently employed? What type of work do you do?
4. How long have you known you have had type 2 diabetes?
5. Was this recent visit the first time you have received education about how to treat type 2 diabetes?
6. What was your perception of the education process?
7. Did you feel it was too much? Not enough? Too confusing? Too simple?
8. (If applicable) How did it compare to previous education opportunities?
9. What do you remember about the education received at this last visit?
10. What modifications do you plan to incorporate into your lifestyle as a result of the education you received?
11. What suggestions do you have to help this clinic improve how it manages people who have type 2 diabetes?

APPENDIX G:
CLINIC FLYER ANNOUNCEMENT OF QI PROJECT

QUALITY IMPROVEMENT PROJECT

The Noble Family Healthcare Clinic will be starting a quality improvement project to assess the quality of care given to patients with type 2 diabetes. Over the next weeks, this clinic will be using a Diabetes Education Flow Sheet to help document and demonstrate the care provided by the clinical staff for our patients who are newly diagnosed with type 2 diabetes. Greg Brooks, a Family Nurse Practitioner from Oklahoma City and DNP student at the University of Arizona, will be working with our clinic to evaluate our current management trends and to develop a customized diabetes education flow sheet template in our electronic health record specific to our clinical needs. All clinicians who help manage patients with type 2 diabetes will be asked to help in the design and implementation of this new education flow sheet. Please consider how you can be a part of this QI process to show how the Family Noble Healthcare Clinic is a premier provider in diabetes care.

If you are interested in participating, please contact Greg Brooks, Principal Investigator, at (405) 924-0188

APPENDIX H:
WEEKLY REVIEW OF FLOW SHEET

Weekly Review of Electronic Diabetes Education Flow Sheet

How many times this week were you able to use the education flow sheet for initial diabetes education?

How many times was it used to follow up on patients with uncontrolled diabetes flow sheet?

Has it been beneficial in helping you recall information?

Has it been beneficial in helping you document education?

What problems have you encountered while using the flow sheet?

What solutions do you propose?

APPENDIX I:
FINAL TEMPLATE – DIABETES EDUCATION FLOW SHEET

Final Template Adopted by Clinic as the Diabetes Education Flow Sheet

Date: _____ Patient: _____
 Date of Birth: _____
 ID#: _____

Diabetes education	Initial	Reviewed	N/A
Discussed diabetes disease process and treatment options			
Behavior changes			
Discussed nutritional management			
• Limiting fat intake			
• Calorie Counting			
• Carbohydrate counting			
• Alcohol consumption			
○ HANDOUT PROVIDED			
Weight loss goals			
Discussed physical activity needs for disease process			
• 150 minutes of moderate activity per week			
• Resistance training 3 times a week			
○ HANDOUT PROVIDED			
Medication			
• Side effects, Call ifs,			
Monitoring Blood glucose and Goals			
• Problem solving for elevated or decreased blood glucose, sick days, when to call			
• Demonstration and return demonstration done			
• Document in log and bring to every visit			
• KIT GIVEN TO PATIENT with instructions			
Risk reduction			
• Smoking cessation			
○ HANDOUT PROVIDED			
• Pneumonia vaccine			
• Foot exam			
○ HANDOUT PROVIDED			
• Eye exam			
○ HANDOUT PROVIDED			
• ASA use			
• Pre-pregnancy counseling			
Coping mechanisms to deal with type 2 diabetes			
Routine laboratory work and monitoring (A1C, Lipids, weight, BP, Urine Proteins, Finger stick results)			

APPENDIX J:
DATA COLLECTION INSTRUMENT – QI INITIATIVE

Data Collection Instrument Using the PDSA Work Plan for a QI Initiative

PDSA Worksheet

Clinic:

Date:

PDSA Ramp (Change Concept or ideas being tested):

Baseline performance:

PLAN

Project AIM (Problem statement defined):
(What are we trying to accomplish?)

What change can we make that will result in improvement?

Measures of success:

Data Collection method (Who, What, When, Where?):

Subjects:

of Subjects:

Time period of test:

How will the data be sampled?

How will you know that the change is an improvement?

Anticipated outcome: (Prediction of what will happen)

DO

Listing of changes to be carried out: Who, What, When, Where, How?

Carry out the test, collect data. Display data on chart.

STUDY

Results of test:

Discussion of findings with QI committee.

Comparison to predicted outcomes:

Problems with conducting the test:

Unintended consequences:

Was QI initiative implemented as planned?

Additional knowledge gained?

Summary of findings

ACT: Refine and/or broaden QI initiative

What further actions need to be addressed or implemented following the initiative and study?

What is the plan for the next cycle? What incremental changes can be made to refine the initiative?

Is this change ready to be spread? How can it be broadened or spread to other areas?

What systematic changes and education needs to be taken to ensure the QI is fully implemented into clinic policy and protocol?

Next opportunities to improve or necessary to change?

APPENDIX K:

DATA COLLECTION INSTRUMENT – NOBLE FAMILY HEALTH CARE CLINIC

Data Collection Instrument Using the PDSA for a QI initiative at Noble Family Health Care Clinic

PDSA WORK PLAN FOR QI INITIATIVE

PDSA Worksheet

Clinic: **Noble Family Healthcare Clinic**

Date: Spring 2011

PDSA Ramp (Change Concept or ideas being tested): Diabetes Education Flow Sheet

Baseline performance:

PLAN

Project AIM (Problem statement defined):

(What are we trying to accomplish?)

The aim of the project is to develop and implement a documentation system to ensure delivery of a comprehensive diabetes education plan for those patients who are newly diagnosed with type 2 diabetes.

What change can we make that will result in improvement?

It is proposed that the development of an education flow sheet to be used for patients with type 2 diabetes will help organize clinicians with their approach toward the initial education process. The long range goal is to lower the average A1Cs of patients seen in this clinic with type 2 diabetes

Measures of success: Success will be measured when a diabetes education flow sheet (DEFS) has been developed, modified and is continually being used by the clinical staff in the education of their patients with type two diabetes. Early meetings will be held to modify the DEFS to ensure compatibility with the clinic and staff.

Data Collection method (Who, What, When, Where?):

The clinical staff will review the proposed DEFS prior to implementing the QI project. Once approved, the staff will use the sheet each time a patient receives diabetic training from the clinical staff, either for newly diagnosed patients or for patients who are considered uncontrolled. They will use the DEFS to guide their education and to assist in documenting their education. Each time the sheet is used, the MA who places the DEFS in the chart will note the date and patient chart for review. Each week, the clinical staff comprising the QI committee will meet to review the QI initiative and determine if there is any change that can be made or should be made to help accommodate the clinic. Changes will be proposed by the staff and the DEFS will be modified to reflect these changes. The new DEFS will then be used by the clinical staff and evaluated in a week's time.

The MA will ask patients who are newly diagnosed to participate in a phone interview about the education they received at this clinic. The interviewer will ask patients about the components of their diabetes education. The target group will be those who have had diabetes less than one year, are of age 21 years or older, speak English and do not have

any current memory impairments of their recall ability.

Subjects:

of Subjects: Goal is 20 patients in which to use the DEFS on and 10 newly diagnosed patients to interview regarding the education they receive.

Time period of test: 8 weeks

How will the data be sampled? Each person who is newly diagnosed with type two diabetes and those who have had diabetes but are not considered under control and require additional education will be targeted by the staff to use the DEFS in their education.

In addition, those who are recently diagnosed with type 2 diabetes will be asked to participate in a phone interview to review components of the education they received.

How will you know that the change is an improvement? Feedback from clinical staff to inform project coordinator of DEFS implementation and if changes will need to be implemented. The project coordinator will discuss how the flow sheet is being used and offer guidelines to its utilization.

In addition, the project coordinator will interview patients who have recently received diabetes education from the clinic using the DEFS to review their thoughts on the education process.

Anticipated outcome: It is anticipated that the DEFS will become incorporated in the education process and will be reported as beneficial to the clinic staff.

DO

Listing of changes to be carried out: Implementation of the diabetes education flow sheet (DEFS). Note the initial QI project was to involve the development of an electronic diabetes education flow sheet. However, due to the transitioning of the clinic to different Electronic Health Record (EHR) within the clinical setting, it was decided to implement a hard copy diabetes education flow sheet in the patient's chart to pilot the content of the DEFS. When the EHR system is decided upon by the clinical staff, the hardcopy DEFS can be transferred to an electronic version.

Who: When a patient is recognized as having type 2 diabetes and returns for the follow up visit for baseline education, the medical assistant (MA) will place a DEFS on the chart.

What: The DEFS will include baseline diabetes education content that is recommended by the AMA and adjusted for how the clinic educates newly diagnosed patients with type 2 diabetes. The DEFS will act as a guideline for clinical education to ensure appropriate components of diabetes education is included.

When: Starting 2nd week of January and carried out through the first week of March.

Where: Noble Family Health Care clinic

How : DEFS will be placed on patient's chart who has been newly diagnosed with type 2

diabetes, or is a patient who has been diagnosed with type 2 diabetes and has already had education but whose laboratory data demonstrate a A1C of greater than 7.0%

STUDY

Results of test: Overall positive response from Nurse Practitioner, and two medical assistants who have been using the DEFS. No input provided directly by the physician, but MA who works with the physician feels it has been an appropriate guide to help direct patient education. Has been used by MAs who are checking patients in on follow-up visits to evaluate education previously offered and if patient is utilizing education.

Discussion of findings with QI committee. This has been overwhelmingly a positive addition to the hardcopy chart and has been demonstrated to be a helpful reminder for the clinicians in their education. No other updates or modifications have been offered since the previous updates so it is ready to be transferred to the EHR data collection system and modified to allow clinic to review education components on a future basis.

Comparison to predicted outcomes: Clinical staff felt this would be a positive addition to chart and has demonstrated itself to also be beneficial as a review tool to review previously prescribed interventions.

Problems with conducting the test:

Problem #1: It was initially decided to implement an electronic copy in the EHR, but due to the intent to transfer to a new EHR, the electronic version of the DEFS was made a hard copy form.

Problem #2: The research project could have liked to have included more newly diagnosed patients in order to provide input on the education process. This can still be done outside of this QI project.

Unintended consequences: No unintended outcomes were brought up by clinical staff in group meetings and in individual discussion. However, the initial problems encountered electronic discussion platform may have dissuaded some members (physician and potentially another MA) to avoid being a part of the QI project as evaluators.

Was QI initiative implemented as planned? Initially planned to incorporate as part of the EHR, but was made a hard copy instead (see previous discussion)

Additional knowledge gained? DEFS can be used as a review sheet to evaluate previous interventions as well as an education template.

Summary of findings: Overall, the DEFS utilization was viewed as a positive improvement to the education process. Modifications were made from the initial DEFS to accommodate clinical education components and the final sheet has been useful in a variety of ways.

ACT: Refine and/or broaden QI initiative

What further actions need to be addressed or implemented following the initiative and study?

The DEFS can now be transferred to an electronic template once an EHR service is determined by the clinic. Additional patient input is desired to complete the evaluation of the education the clinic provides to patients with type 2 diabetes.

What is the plan for the next cycle? What incremental changes can be made to refine the initiative? Once the DEFS is placed in the EHR, it will need to undergo a similar PDSA cycle to ensure it is still functioning as it is intended. Reviewing from a hard copy health chart will be different than reviewing from an EHR.

This type of education flow sheet can be applied to other chronic disease processes. For example the same type of education process can be applied to those who may be newly diagnosed with hypertension, hyperlipidemia, or other disease processes of concern. As with the DEFS, these new education flow sheets may also be considered for those who have chronic disease problems with modifications.

What systematic changes and education needs to be taken to ensure the QI is fully implemented into clinic policy and protocol? Clinical policy should be adjusted to support the utilization of the DEFS. All clinical personnel involved with educating patients with type 2 diabetes should be instructed to use the DEFS and to ensure it is on the chart when education begins, or started in the EHR when it is transferred to the electronic format.

Next opportunities to improve or necessary to change?

1. Reviews of the health charts revealed several process measures are lacking in documentation: Foot examinations, eye examinations, and Flu vaccinations. Future QI projects can address steps that will assure these are performed and documented
2. The QI initiative was intended to improve the way the patients with type 2 diabetes are educated. Due to the limited number of people who were newly diagnosed with type 2 diabetes, the number of participants who participated in the education review with the project coordinator was also limited. The project coordinator recommends continuing the process of gathering data from newly diagnosed patients who have received education from the clinical staff to identify areas that need strengthening or improvement.
3. Because the DEFS was also being used as a follow-up guide for review purposes, I would recommend having a process in place to assist with this practice once the DEFS is placed on the EHR.

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