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An Evaluation of Providers' Interventions and Patients' Adherence in Diabetes Management

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Final DNP Project Report

An Evaluation of Providers’ Interventions and Patients’ Adherence in Diabetes Management

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Fall 2016

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# Table of Contents

Acknowledgement...........................................................................................................iii

List of Tables..................................................................................................................v

List of Figures..................................................................................................................vi

Abstract..............................................................................................................................1

Final DNP Project Report.................................................................................................2

Conclusion.........................................................................................................................24

References..........................................................................................................................25
List of Tables

Table 1 Study Demographics.................................................................30

Table 2 Patient’s Subjective Evaluation of Adherence Assessed at Each Visit......................31
PROVIDERS' INTERVENTIONS AND PATIENTS' ADHERENCE

List of Figures

Figure 1 Comorbidities ..................................................................................................................32

Figure 2 Documented Interventions.........................................................................................33

Figure 3 A1C Changes (Visit 1 – Visit 2) ..............................................................................34
Providers' Interventions and Patients' Adherence

Abstract

**Background:** Diabetes is one of the leading causes of death and disability in the United States including Kentucky. Despite advances in medicine, the current management of type 2 diabetes mellitus (T2DM) remains challenging. Poor self-management coupled with the increasing complexity of the disease can lead to poor glycemic control.

**Purpose:** The purpose of this project was to examine current practices related to insulin-using patients’ treatment adherence and management of T2DM. In addition, providers’ perceptions on the management of T2DM were also assessed.

**Methods:** A retrospective chart review and semi-structured interviews were conducted. Patients (N = 84) with T2DM, over the age of 18, with hemoglobin A1C > 7.5% and on insulin were included in the review. Providers (N = 5) were recruited for the interviews.

**Results:** Despite a lack of assessment in patient adherence, glycemic control improved significantly at visit 2, demonstrated by a mean A1C reduction of 0.52% (p = 0.001). That change was found to be statistically significant between the group that received medication adjustments along with written education and those who did not receive any changes to their treatment plans. However, though not statistically significant, the most improvement in A1C was found among those who received medication changes along with verbal and written education. An inconsistency in the delivered education was also noted.

**Conclusion:** Overall, the gap in care is in the assessment, documentation and education process at the practice. The findings suggest a great need for improvement in assessment and documentation of patient adherence, and development of a standardized diabetes education delivery model. Information from this project will help build a foundation for future quality initiatives to improve the delivery of diabetes education at primary care practices.
An Evaluation of Providers’ Interventions and Patients’ Adherence in Diabetes Management

**Introduction**

Diabetes is one of the leading causes of death and disability in the United States, and it is especially prevalent in Kentucky (Kentucky Cabinet for Health and Family Services; KCHFS, 2015). From 2000 to 2013, the prevalence of diabetes in Kentucky adults increased from 6.5% to 10.6%, with approximately 95% having type 2 diabetes mellitus (T2DM; KCHFS, 2015). As of 2014, approximately 11% of adults in Louisville had been diagnosed with diabetes (Center for Health Equity, 2014). Despite advances in medicine, the current management of T2DM remains challenging. Poor self-management coupled with the increasing complexity of the disease can lead to poor glycem control. The purpose of this practice inquiry project (PIP) was to examine current practices of providers at a primary care clinic related to patients’ adherence and management of their T2DM. The identification of a potential gap and barriers to diabetes management can lead to the development of evidence-based strategies to help providers and patients effectively manage T2DM.

**Background**

Diabetes, especially when uncontrolled, is associated with a number of complications such as retinopathy, nephropathy, neuropathy, and cardiovascular diseases. Diabetes is the leading cause of adult blindness, end-stage kidney disease, and non-traumatic lower-extremity amputation (KCHFS, 2015). Individuals with diabetes have a two to four-fold increased risk of developing coronary artery disease and stroke compared to non-diabetics (KCHFS, 2015). In a prospective cohort study, glycated hemoglobin (A1C) was found to be associated with mortality in patients who had poor glycemic control (Landman et al., 2010). The authors also found that
cardiovascular mortality risk in patients with an average A1C of equal or greater than 9% was three times higher than in patients with A1C of 6.5 to 7%.

Diabetes not only increases the morbidity and mortality and compromises the quality of life of individuals affected by the disease, it also places a financial burden to the U.S. economy. The estimated total diabetes cost in the United States in 2012 was $245 billion and in Kentucky in 2013, the cost was $3.85 billion (National Center for Chronic Disease Prevention and Health Promotion, 2014). Further, there is a positive correlation between diabetes complications, healthcare cost, and A1C (McBrien et al., 2012).

There are many factors that affect diabetes management. Providers must recognize that the management of diabetes is very complex for most patients. A systematic review by Nam et al. (2011) found that a number of variables influence diabetes self-care behaviors consisting of physical, psychological and social factors. These factors include comorbidities, health beliefs, knowledge, health literacy, culture, financial resources, and social support (Nam et al., 2011).

**Literature Review**

Management of chronic disease and prevention of its complications is one of the main focuses of primary health care. T2DM is a chronic illness that requires continuous medical and self-care. In order to prevent complications and reduce morbidity and mortality, education on both the disease process and self-management is crucial. The ultimate goal of diabetes management is optimal glucose control that leads to reduction of cardiovascular risk and organ damage. Adherence to medication, self-monitoring of blood glucose (SMBG), diet and lifestyle change are associated with lower A1C (Schectman, Schorling, & Voss, 2008). Furthermore, every percentage
drop in A1C can reduce the risk of nephropathy, retinopathy, and neuropathy by 40% (KCHFS, 2015).

Primary care providers must deliver medical interventions and provide education to include physical activity and diet control. Interventions are best delivered when tailored to individual patients’ needs. Studies have demonstrated that diabetes education, such as lifestyle counseling, leads to reduction in A1C, diabetic complications, acute healthcare utilization, and total cost of health care (Martin & Lipman, 2013; Morrison, Shubina, & Turchin, 2012). In a systematic review, a significant association was noted between engagement in self-management education and decrease in A1C (-0.80) (Chrvala, Sherr, & Lipman, 2015).

**Self-Management**

Successful diabetes care requires not only the individualization of interventions but also treatment goals and glycemic targets. The American Diabetes Association (ADA) (2016) guideline recommends an A1C of less than 7% for most non-pregnant adults. However, more stringent A1C goals of less than 6.5% could be selected for certain patients, such as individuals that have no significant cardiovascular disease, have shorter duration of diabetes or lower risks for hypoglycemia (ADA, 2016).

Personalized A1C goals of less than 8% may be appropriate for patients with a history of severe hypoglycemia, limited life expectancy, advanced vascular complications, and extensive comorbid conditions (ADA, 2016). In these patients, particularly older adults and adults at high risk for cardiovascular disease, more stringent A1C goals could lead to harmful adverse effects. An observational study based on four large randomized controlled trials found that for a majority...
of adults over 65 years of age, the harms associated with A1C target lower than 7.5% or higher than 9% outweighed the benefits (Lipska, Krumholz, Soones, & Lee, 2016).

Gerstein et al. (2008) conducted a long-term randomized study with more than 10,000 T2DM patients who were at high risk for cardiovascular disease. Increased mortality rates were found in the intervention group with A1C goals of less than 6% as compared to the group with A1C goals of 7 – 7.9%. Based on these results and recommendations from the ADA, providers should individualize treatment and glycemic goals according to each patient’s needs and characteristics. Strategies for improving persistent poorly-controlled diabetes mellitus includes: being cognizant of patients’ lifestyles, medication regimens and comorbid conditions, and addressing barriers to self-management (Crowley et al., 2014).

Recognition and proper management of co-existing physical and psychological conditions are beneficial in improving diabetes management. Patients with multiple comorbidities have been found to frequently experience barriers to self-management due to competing health and financial demands (Jerant, Friederichs-Fitzwater, & Moore, 2005). Results of a cross-sectional study showed a significant association between multiple comorbidities and lower perceived health status and lower levels of physical functioning in older adults (Bayliss, Ellis, & Steiner, 2007).

Psychological conditions such as depression and other emotional stresses are potential barriers to optimal glycemic control. This is due to the fact that mental health can affect patients’ perceptions about the disease and their self-management behaviors. Depression is also associated with increased morbidity, mortality, functional limitation, and increased health care costs (Chao, Nau, Aikens, & Taylor, 2005). In a systematic review and meta-analysis, depression was found to be associated with a 1.5-fold increased risk of mortality in people with diabetes (Van Dooren et
al., 2013). Lack of awareness from providers regarding patients’ psychological health also affects diabetes management. Yet, Peyrot et al. (2005) reported that providers expressed a lack of confidence in their ability to identify and treat psychological problems in patients with diabetes.

Other factors have been associated with successful self-management. For example, the financial strain placed upon individuals and their families cannot be understated. In a retrospective cohort design, general financial and medication-specific financial strain was found to be significantly associated with medication non-adherence, even after income adjustment (Lyles et al., 2016). In addition, family and social support are closely associated with self-care. Mayberry and Osborn (2012) found that patients with non-supportive family members reported lower adherence to their medication regimens and had poorer glycemic control. This finding suggests that social support should be a valuable factor for providers to assess in addition to financial strain.

Medical Management

Proper management of diabetes should include the evaluation of each patient’s physical, psychological, and social factors as mentioned above. In addition, a study by Schectman et al. (2008) found that adherence to appointments was a strong predictor of glycemic control and that missed appointments should be assessed as a barrier to diabetes self-management. These potential barriers should be identified and minimized.

Understanding the clinical interventions and barriers of diabetes management from a provider’s point of view can lead to quality improvement initiatives. Diabetes management is not only influenced by patients’ self-care behaviors but also providers’ interventions, such as
pharmacotherapy and education. Providers’ attitudes, perceptions, beliefs, and knowledge about diabetes management can have an impact on their strategies. Results of the Diabetes, Attitudes, Wishes, and Needs study revealed that a provider’s prescription practice was associated with his or her perception of patients’ behaviors (Peyrot et al., 2005). These providers reported that they were likely to delay the initiation of insulin therapy if they perceived their patients to be less adherent to medication or appointment regimens (Peyrot et al., 2005).

There are substantial data to support the importance of assessing adherence, comorbidities, management strategies, potential barriers, and providers’ perceptions in patients with diabetes. A systematic approach with interventions that focus on healthy lifestyle change, self-management, prevention of complications, and education can lead to optimal management of diabetes mellitus (ADA, 2016). However, due to the intricacy of the disease, achievement of optimal diabetes self-management and glycemic control often remains an arduous task. Therefore, the process of continuous quality improvement can identify treatment gaps and potential barriers and guide providers to improve the quality of diabetes healthcare services.

**Purposes**

This practice inquiry project (PIP) was conducted at an outpatient primary care practice located in south of Kentucky. The clinic provides services such as disease prevention, health maintenance, diagnosis and treatment of acute illnesses, and management of chronic conditions. The clinic also serves as the community’s access to most health care services. This primary care practice includes four physicians, three nurse practitioners, and one nurse navigator. This practice has a large population of diabetics and there has been no evaluation of the process and outcomes of their current diabetes management.
The two main purposes of this project were to: 1) evaluate current management practices of patients with T2DM who currently have an A1C of greater than 7.5 and are on insulin therapy, and 2) identify treatment gaps between current practice and target goals with input from the clinical providers. The specific objectives were to:

1. Assess patients’ comorbidities and medication regimen.

2. Assess documented patients’ adherence to recommended treatment.

3. Describe diabetes-related interventions implemented by providers.

4. Assess changes in A1C between two subsequent visits.

5. Assess any potential barriers to treatment and self-management documented in providers’ notes.

6. Assess for any missed appointments related to diabetes visits and referrals.


Methods

Study Design

This gap analysis involved a retrospective chart review of patients with T2DM with an A1C greater than 7.5% who were on insulin therapy. Data collected on patient demographics included: gender, age, ethnicity, medical coverage, marital status, body mass index (BMI), and smoking status. Patients’ comorbidities were evaluated. In Appendix A, the survey instrument with a complete list of the variables is provided. For examples, conditions such as hypertension,
hyperlipidemia, and depression were assessed. The medication regimen was also evaluated to include other diabetes medications in addition to insulin.

Patients’ adherence was evaluated based on a diabetes follow-up visit template that was built into EPIC which is an electronic medical records (EMR) system. The template includes assessment of each patient’s subjective evaluation of their self-care management. Variables such as overall adherence to medical plan along with SMBG, current diet, meal planning, and exercise were reviewed.

Types of diabetes-related interventions along with referrals to a Diabetes Self-Management Education (DSME) program, dietician, or nurse navigator were evaluated at visit 1. Interventions such as verbal education, medication adjustments and diabetes written materials (handouts) were targeted. Verbal education is delivered by providers, licensed practical nurses (LPN), or medical assistants (MA). Patients can also receive education through mailed letters or the MyChart service within the EMR. The MyChart program is available to all patients; it gives them immediate access to their charts and allows for communication with providers through emails. Changes in A1C between visit 1 and visit 2 were evaluated and how the interventions and delivery methods impact that change. Data regarding potential barriers and missed appointments documented in providers’ notes were included in the analysis.

In order to evaluate providers’ perspectives regarding optimal management of T2DM, focused interviews were conducted. Five primary care providers practicing at the target facility (two nurse practitioners and three physicians) were asked to respond to questions about the management in patients’ adherence to recommended treatment guidelines. In Appendix B is an outline of the questions.
PROVIDERS' INTERVENTIONS AND PATIENTS' ADHERENCE

Informed Consent Process

This PIP was a retrospective chart review along with a targeted interview with providers. Protection of human subjects was obtained from the University of Kentucky’s Institutional Review Board (IRB). The Healthcare Office of Research Administration associated with the practice also approved the project proposal (see Appendix C for copy of IRB approval letter). Providers were consented prior to the interviews (see Appendix D for a sample of consent form).

Subject Recruitment

The inclusion criteria included: 1) all primary care patients at the clinic; 2) had two diabetes follow-up visits within the year of 2015 with an ICD-9 or ICD-10 diagnosis code for T2DM or uncontrolled T2DM; 3) over the age of 18 and not pregnant; 4) had an A1C of greater than 7.5% and on insulin therapy; and 6) currently not being managed by an endocrinologist. Charts of patients not meeting these criteria were excluded from the study. After evaluating the EMRs of 140 patients, only 84 met the specified inclusion criteria.

Providers were contacted and invited to participate in a face-to-face semi-structured interview that would last approximately 15 minutes. The purpose of the interview was explained to each provider. Participation was strictly voluntary. Interested providers were provided with informed consents explaining what the project was about and what they would be expected to do if they agree to participate. All results were recorded in writing and transferred to an electronic Microsoft Word document.
Study Procedures

Medical records were accessed through EPIC which is an electronic, secure, encrypted, firewall protected EMR. Using the data collection form in Appendix A, chart audits were conducted in a workroom at the Nursing Institute at a medical building. Data were de-identified by assigning each patient a unique patient identifier number. A separate worksheet was used to link the patient EMRs to the correlating unique patient identifier numbers. This worksheet was stored separately from the data in an authenticated secure, firewall protected folder. The worksheet was permanently deleted upon conclusion of the data analysis.

The providers’ interviews were confidential and did not contain any identifying information. Providers’ names and years of experience were not recorded; their roles (e.g., APRNs, MDs) were not linked to patient outcome data. Privacy of the individual interview was ensured thusly: Each interview was conducted in a private room at the office, and only the provider and the interviewer were present during the interview. Providers’ data were collected on handwritten papers during the interview and transcribed into electronic Word documents. All paper records were destroyed after the information was transferred into electronic documents.

All data collected were stored on a password protected, identity authenticated secure, firewall protected research folder. The information services representatives did not access the folder; no technical issues were encountered during the study. All data were permanently deleted upon conclusion of the data analysis.
PROVIDERS' INTERVENTIONS AND PATIENTS' ADHERENCE

Data Analysis

Collected data were recorded into an SPSS spreadsheet. The SPSS software version 22 was used for statistical analysis. The University of Kentucky College of Nursing statistics department was utilized to help analyze data obtained from the study. Descriptive statistics including frequency distribution were utilized to assess the patients’ demographic variables, patients’ adherence and providers’ interventions. The duration of time between two visits was also evaluated using descriptive statistic.

The paired t-test was utilized to compare changes in glycemic control between the first and second visit. Means (M) and standard deviations (SD) were used to describe changes in A1C between the initial and follow-up visit. Spearman correlation coefficient was utilized to assess the relationship between the number of comorbidities and A1C. One-way analysis of variance (ANOVA) with post-hoc analysis was utilized to analyze the impact of interventions and delivery methods on A1C changes. A p-value of less than 0.05 was used to determine significance for all the statistical tests.

Results

Sample Characteristics

Patients’ demographic data including gender, race, medical coverage, marital status, smoking status and medication regimen are reported in Table 1. The entire sample (N = 84) was Caucasian, male (58%), married (60%), non-smoker (88%), with a mean age of 64 years (range 28 - 83) and had Medicare coverage (68%). All patients were insulin-treated T2DM with a majority of them being on dual or triple therapy.
Comorbidities

Physical comorbidities in this sample are represented in Figure 1. The most prevalent comorbidities were hyperlipidemia (87%), hypertension (86%), and obesity (73%). Among the psychological comorbidities, anxiety (27%) and depression (23%) were the most common. Overall, the average number of comorbidities among all patients was five, with a range of one to eleven. There was a weak, positive relationship between the number of comorbidities and A1C ($r = 0.23$, $p = 0.04$).

Adherence

Between the two visits, the two areas most likely to be assessed were SMBG (31% and 32%) and current diet (32% for each visit). Within those completing SMBG (81% and 74%), the majority were testing one to two times per day. For those having a diet evaluation, most reported following a low salt diet (Table 2). For the 15% of patients that were assessed for meal planning at visit 1 and 14% at visit 2, the majority of them did not participate in meal planning. Physical activity was rarely engaged upon by those who were evaluated for this variable. When looking at the same patients that were assessed for the same criteria at both visits, it appears that SMBG (21%) and diet (30%) were the most likely to be discussed.

Glycemic Control

The paired t-test was utilized to compare changes in glycemic control between visit 1 and visit 2. There was a statistically significant decrease in the A1C from the first visit ($M = 9.15$, $SD = 1.26$) to the second visit ($M = 8.63$, $SD = 1.39$; $p = 0.001$). The mean decrease in A1C was 0.52 with a 95% confidence interval ranging from 0.23 to 0.81.
Intervention

Interventions that were implemented for visit 1 were evaluated. These included: medication adjustments, referrals, and education. The types of education encompassed verbal instruction and written information. The verbal instruction was either given at the point of care by the provider or after the visit, delivered through the ancillary office staff (LPN/MA). After evaluating the data, the decision was made to differentiate the education into the generic scripted handout and those that received individualized verbal instruction. This latter group encompassed those that received verbal education at the office visit, those who were mailed results with a personalized message and those who received a message via email (MyChart).

Interventions were found to vary across the sample (see Figure 2). A majority of patients (61%) received the scripted outline of general diabetes self-management (SMBG, diet, physical activity, medication adherence, foot and eye care). Based the chart review, 27% of the sample received the written handout and medication adjustments. Approximately 17% received verbal and written instructions regarding their A1C and 8% received medication adjustments along with verbal and written education. There were five patients who were only told no changes would be made to their medical management.

ANOVA was conducted to explore the impact of interventions on A1C changes from visit 1 to visit 2. Among the eight groups, there was a statistically significant difference in A1C changes between the two groups ($F = 2.36, p = 0.31$). Post-hoc comparisons using the Tukey HSD test found that the mean difference in A1C for the group that were told to continue treatment ($M = +1.06, SD = 1.54$) was significantly different from those that received medication adjustments along with diabetes handout ($M = -0.91, SD = 1.36; p = 0.04$). No significant difference between the other groups was found. Though not reaching statistical
significance, the group that received a combination of medication adjustment, verbal and written instructions was found to have the highest improvement in A1C (M = -1.17; p = 0.40) (Figure 3).

**Delivery mode.** Intervention delivery methods were also assessed. Only 18% of the sample patients had A1C results at the time of their first visit for providers to address face-to-face. The majority of patients (n = 69, 82%) did not have their A1C results at the first visit. Rather the lab test was drawn at the conclusion with results communicated afterward along with treatment recommendations. The results and treatment recommendations were then communicated to patients by either an LPN (19%) or MA (46%). Result letters along with treatment recommendations were mailed to 30% of the patients and 4% received the information from providers through MyChart. ANOVA was conducted to explore the impact of each method of communication on A1C changes from visit 1 to visit 2. There was no statistically significant difference in A1C changes between the groups (p = 1.41).

**Barriers**

A total of 14% of patients have documented barriers to diabetes treatment. These included: physical impairment (limited activity due to the use of wheelchair and cane, and back problem), lack of desire to learn (patient stated that he or she knew what should be done but did not want to do it, patient was minimally interested in committing to lifestyle changes), memory impairment (forgetfulness), depression, and family dynamic (caregiver strain). Furthermore, financial strain was found to be the most prevalent (8%). Documented financial strain included inability to afford diabetes medications and supplies, ophthalmology and podiatry care, and healthy food.
Follow-up Visits

Documentation of any missed appointments was evaluated during the retrospective chart review. A majority of patients did not have documentation of missed appointments, only 5% did not show up to their appointments as scheduled. The average duration between the two visits was 130 days.

Providers’ Interviews

Three physicians and two nurse practitioners participated in the interview. This represents 70% of all full-time primary care providers working at the clinic. The findings of the interview were grouped into four main themes including guideline, education, barriers, and recommendations.

Guideline. More than half of the providers (60%) reported utilizing the ADA guideline when providing care for patients with T2DM. The usual A1C goal for all patients was less than 7%. However, a less stringent A1C goal of less than 8% was reported to be appropriate for some patients that have an extensive history of cardiac disease.

Education. All providers refer patients that were newly diagnosed or not meeting A1C goals to their nurse navigator for self-management and nutritional counseling. Dietician referrals were reported by 40% of the providers but mostly for newly diagnosed patients. One provider reported that he refers less than 10% of his patients for diabetic counseling due to patients not wanting to go. All providers utilize diabetes handouts to provide patients with information such as medications and lifestyle modifications. Most providers (80%) felt that the printed education materials would be helpful if the patients took time to read them. The reading materials should facilitate patients to ask important questions related to their diabetes care at follow-up visits. The providers did not know if patients were utilizing what was being given to them.
Barriers. Some perceived barriers that prevent patients from adhering to their treatment plans were mentioned by the providers. These barriers included: financial strain such as inability to afford healthy foods and medications, lack of insurance coverage, co-existing mental health issues, lack of understanding of disease course, lack of desire to learn, lack of self-motivation (e.g., some patients did not want to follow-up every three months and some patients even requested to be seen every year), and health literacy. In addition, access to a certified diabetes educator (CDE) was limited. Currently, appointments to meet with a CDE were booked out a full year in advance.

Recommendations. Some recommendations were suggested by the providers for improving the current practice of diabetes management. These recommendations included: individualized diabetic education across visits, education on best practices and nutrition counseling, utilization of the nurse navigator for newly diagnosed patients, and having a focus on physical activity and weight control.

Discussion

This PIP, using both quantitative and qualitative methods, aimed to examine the current management of patients with T2DM. Also treatment gaps to achieve optimal glycemic control were evaluated. In this practice, among a group of insulin-using T2DM patients who were not at glycemic goal, there was a reduction in the mean A1C between two visits. A number of issues were noted in the documented records that offer strategies for improvement.

The results revealed a significant decrease in A1C from visit 1 (M = 9.15%) to visit 2 (M = 8.63%). As reported by the providers, the usual A1C goal for most patients is less than 7%. However, for some patients with an extensive history of cardiac disease or multiple comorbid conditions, a goal of less than 8% was selected by some providers. The individualization of
glycemic targets by providers is consistent with recommendations from the ADA (2016) and several other research findings (Gerstein et al., 2008; Lipska et al., 2016).

Even though there was a significant improvement in A1C among the sample, 8.6% is still above the target goal of 7 – 8%. Perhaps this could be due to the comorbidity burden among the patients included in the project. Several studies have identified the negative effects of co-existing chronic conditions on diabetes self-management (Bayliss et al., 2007; Jerant et al., 2005), including frequent barriers to self-care, and lower perceived health status and physical functioning. The average comorbidities per patient were five and more than 70% of patients had hyperlipidemia, hypertension, and obesity. In this sample, high number of comorbidities was found to associate with higher A1C (p = 0.04).

In addition to the physical comorbidity burden found among the study sample, 23% of patients had depression and 27% of patients had anxiety. This result is consistent with a previous study by Bot, Pouwer, Zuijdersma, Van Melle, and De Jonge (2012), which found that the prevalence of depression among patients with diabetes is more than three times higher than the general population, 20 - 25% in comparison to 6.7%. Furthermore, depression can lead to poor glycemic control and worsened health status (Holt et al., 2014). However, these findings are limited in their importance as the current treatment of these conditions was not evaluated.

According to the ADA (2016), assessment of patients’ adherence should be a priority in diabetes management. Assessment of the patient’s adherence to treatment, SMBG, diet, and physical activity is essential at each diabetes visit. The continuous evaluation of patients’ adherence allows providers to identify the causes of hyperglycemia and to modify treatment approaches accordingly. However, based on the results of this project, adherence to treatment
was not consistently assessed or documented by the providers at both visits. Therefore, it was difficult to evaluate for an overall improvement in self-management behaviors.

Patients’ perceptions of adherence to treatment were evaluated in less than 10% of patients at both visits. Interestingly, the changes in adherence, though not significant, were found to correlate with the changes in A1C among these patients. Understanding how patients perceive their own self-management in total allows for a starting conversation about self-management. It can be thought of as similar to a pain scale, wherein self-evaluation can be made.

Only a third of the sample (31%) was questioned regarding SMBG, within this group 81% were completing SMBG at visit 1 and 74% at visit 2. It was difficult to evaluate patients’ adherence to SMBG because the recommended regimen was not documented in the charts. The evaluation of patients’ SMBG at each visit can mitigate the under or overuse of SMBG. This important self-management tool recommended by the ADA (2016) for all insulin-treated diabetics was not fully utilized by all patients.

Providers should ensure that patients incorporate glucose values into their self-management plans. Interventions, such as adjusting insulin dosage, food intake, and exercise to achieve target fasting blood glucose, are the ultimate goal (ADA, 2016). Frequent SMBG can reduce patients’ risk of hypoglycemia and help them identify factors that cause hyperglycemia (Elgart, Gonzalez, Prestes, Rucci, & Gagliardino, 2015). In this retrospective chart review, all the patients were on insulin therapy during the time of evaluation; therefore it is critical that these patients monitor their glucose on a daily basis.

Diet and exercise were not consistently assessed by providers at each visit. Most who were asked reported being on a low salt diet with very few engaged in actual meal planning. Possibly, the high prevalence of co-existing hypertension among the patients accounted for their
report of limiting salt intake. It may also be that diabetic meal planning is far more complicated than focusing on eliminating just salt from the diet. Exercise was also rarely asked by the providers with essentially no one participating in routine exercise.

Physical activity and nutrition are the foundation of T2DM self-management. The ADA strongly recommends that both are routinely discussed with diabetics. A1C levels have been shown to decrease not only with routine exercise but also with the level of intensity (Boule, Haddad, Kenny, Wells, & Sigal, 2001; Boule et al., 2003). Furthermore, the ADA (2016) recommends either carbohydrate counting for patients on insulin or having a fixed amount of daily carbohydrates. Each of these lifestyle modifications requires continual reinforcement for long lasting behavioral change.

Interestingly, the providers in this analysis cited both exercise and diet as being the cornerstone of diabetes management. Yet this was not reflected in the chart review. Though, a nutritionist and the DSME program were available for these patients, very few had been referred for those services. A CDE was also available but those appointments are booked a full year in advance. The A1C in the sample did decrease most when medication changes were made along with verbal and written education. Possibly, education was delivered but not charted and previous referrals were not captured. Unfortunately, patients were not interviewed to assess the amount of education delivered.

One of the most common perceptions frequently expressed by the providers was that they did not feel their patients were interested in attending classes or meeting with the dietician. This may be why so few referrals were made. Even visits with the nurse navigator to provide self-management and nutritional counseling were not utilized. One might surmise that either the
providers lost faith in their patients’ willingness for self-management or they were discussing this with the patients who refused the referral.

Chronic disease management is not easy for either providers or patients. Patients have to make lifestyle changes that are foreign to many of them. Oftentimes, they see the management within the purview of the providers and the solution is medications. This leads to a strained relationship between providers and patients. Providers get frustrated, leading to generalizations about patients, i.e. “nobody will exercise or eat right”, and patients are overwhelmed. Hence, it is it is easier to eliminate dietary salt than staying away from satisfying carbohydrates.

In this analysis, two-thirds of the sample had a medication adjustment based upon their A1C. The ADA (2016) emphasizes the importance of a patient-centered pharmacological therapy along with lifestyle modifications. In this sample, patients who received medication changes along with some type of education had the most improvement in their A1C. This reemphasizes the importance of providing education along with medication adjustments. If only medications were adjusted, the message patients might receive is that medications are more important than lifestyle changes. Unfortunately, the inconsistent charting made it difficult to draw firm conclusions.

There was no consistency in the education that was charted in this gap analysis. A systematic and structured model would ensure that each patient receives the same standard of quality diabetes education consistent with the ADA guideline. The evaluation of clinic’s resources and personnel are imperative in designing an effective standardized model of diabetes education. However, with the lack of access to a CDE, the nurse navigator will probably take on an essential role. There is evidence that a nurse-driven standardized diabetes education process when
embedded in a primary care practice significantly improves patient’s A1C (Mendez et al., 2016; Stellefson, Dipnarine, & Stopka, 2013).

A systematic approach to successful diabetes management requires not only the implementation of patient-centered interventions but the exploration of barriers to adherence. Lyles et al., (2016) emphasize the importance of assessing financial factors in achieving adequate glycemic control. Though only 14% of the sample had documented barriers, financial strain was the most commonly reported. Due to the sample size (n = 12), correlation with A1C and reported barriers was not performed. However the average A1C of patients within this group was higher than the overall average A1C of the entire sample from visit 1 and visit 2 (10.05% and 9.06% compared to 9.15% and 8.63%, respectively). This might be an area the nurse navigator could address and assist patients in finding affordable options, i.e., pharmaceutical patient assistance program.

Effective self-care behaviors entail adherence to treatment, such as medication, diet, physical activity, and follow-up appointments. A study by Schectman et al., (2008) found that adherence to appointments was a strong predictor of glycemic control. In this sample, only 5% of patients missed their scheduled appointments. This sample did comply with recommended follow-up visits and may indicate the emphasis they placed on attending their scheduled appointments. What remains in question is their commitment to lifestyle modifications.

**Limitations**

The design of this PIP as a retrospective chart review from one setting has several limitations. First, the relatively small sample size of the analysis (N = 84) limits the generalizability of the findings. Second, the sample from one setting is not a representative of the general diabetes population at other primary care clinics. There was no diversity in the sample;
therefore, these findings might not be applicable to other ethnic groups due to different cultural backgrounds. The results are subject to confounding risk factors that were not measured but could have an impact on glycemic control, such as hospitalization between visits, steroid therapy, and acute illness.

This project used existing medical records and providers’ interviews to generate information for quality improvement initiatives. A paucity of information regarding patients’ adherence was noted in the study results, which could be due to insufficient assessment or documentation from the providers. However, due to the limited scope of the project, this was not fully explored.

One limitation of the qualitative data is that it was not obtained from the insights of patients with T2DM. In-depth interviews with patients would provide an accurate assessment of their knowledge, self-care behaviors, and barriers to treatment. The triangulation of various sources of data would provide a more thorough analysis of patients’ adherence and factors that affect glycemic control.
Conclusion

Despite the above limitations, the findings from this practice inquiry project contribute to the literature by emphasizing the importance of continuous diabetes management. Optimal diabetes management entails comprehensive assessment and evidence-based individualized interventions. Specifically, a comprehensive assessment that should occur at each follow-up visit needs to include patient’s self-care behaviors, comorbid conditions, barriers to self-management, and treatment strategies. This is especially important for the improvement of glycemic control in patients with persistent poorly-controlled diabetes mellitus.

Overall, the gap in care seems to lie in the assessment, documentation and education process at the practice. Despite poor assessment of patient adherence, there was a significant improvement in A1C. This could indicate that there is an issue with documentation among the providers.

The results of this project have several valuable clinical implications. The findings suggest a great need for improvement in assessment and documentation of patient adherence, and development of a standardized diabetes education delivery model. A future project is needed to explore the utilization and effectiveness of a non-CDE nurse in providing DSME to patients. Information from this project will help build a foundation for future quality initiatives to improve the delivery of diabetes education at primary care practices.
References


PROVIDERS' INTERVENTIONS AND PATIENTS' ADHERENCE


PROVIDERS' INTERVENTIONS AND PATIENTS' ADHERENCE


Table 1

*Study Demographics*

<table>
<thead>
<tr>
<th>Variable</th>
<th>Number/Percent</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Gender</strong></td>
<td></td>
</tr>
<tr>
<td>Males</td>
<td>49 (58.3%)</td>
</tr>
<tr>
<td>Females</td>
<td>35 (41.7%)</td>
</tr>
<tr>
<td><strong>Race</strong></td>
<td></td>
</tr>
<tr>
<td>Caucasian</td>
<td>84 (100%)</td>
</tr>
<tr>
<td><strong>Medical Coverage</strong></td>
<td></td>
</tr>
<tr>
<td>Private</td>
<td>22 (26.2%)</td>
</tr>
<tr>
<td>Passport</td>
<td>5 (6%)</td>
</tr>
<tr>
<td>Medicare</td>
<td>57 (67.9%)</td>
</tr>
<tr>
<td><strong>Marital Status</strong></td>
<td></td>
</tr>
<tr>
<td>Single</td>
<td>8 (9.2%)</td>
</tr>
<tr>
<td>Married</td>
<td>50 (59.5%)</td>
</tr>
<tr>
<td>Divorced</td>
<td>10 (11.9%)</td>
</tr>
<tr>
<td>Widowed</td>
<td>14 (16.7%)</td>
</tr>
<tr>
<td>Unknown</td>
<td>2 (2.4%)</td>
</tr>
<tr>
<td><strong>Smoking status</strong></td>
<td></td>
</tr>
<tr>
<td>Smoker</td>
<td>10 (11.9%)</td>
</tr>
<tr>
<td>Non-smoker</td>
<td>74 (88.1%)</td>
</tr>
<tr>
<td><strong>Medication Regimen</strong></td>
<td></td>
</tr>
<tr>
<td>(including insulin)</td>
<td></td>
</tr>
<tr>
<td>Mono therapy</td>
<td>7 (8.3%)</td>
</tr>
<tr>
<td>Dual therapy</td>
<td>39 (46.4%)</td>
</tr>
<tr>
<td>Triple therapy</td>
<td>33 (39.3%)</td>
</tr>
<tr>
<td>More than three medications</td>
<td>5 (6%)</td>
</tr>
<tr>
<td><strong>TOTAL</strong></td>
<td>84 (100%)</td>
</tr>
</tbody>
</table>
Table 2

*Patient’s Subjective Evaluation of Adherence Assessed at Each Visit*

<table>
<thead>
<tr>
<th>ADHERENCE</th>
<th>PATIENTS (numbers &amp; percentage)</th>
<th>Visit 1</th>
<th>Visit 2</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Compliance with treatment</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>“None of the time”</td>
<td>0 (0%)</td>
<td>0 (0%)</td>
<td></td>
</tr>
<tr>
<td>“Some of the time”</td>
<td>2 (28%)</td>
<td>2 (18%)</td>
<td></td>
</tr>
<tr>
<td>“Most of the time”</td>
<td>3 (43%)</td>
<td>1 (9%)</td>
<td></td>
</tr>
<tr>
<td>“All of the time”</td>
<td>2 (29%)</td>
<td>8 (73%)</td>
<td></td>
</tr>
<tr>
<td><strong>Glucose monitoring</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>None</td>
<td>5 (19%)</td>
<td>7 (26%)</td>
<td></td>
</tr>
<tr>
<td>1 – 2 x / week</td>
<td>1 (4%)</td>
<td>0 (0%)</td>
<td></td>
</tr>
<tr>
<td>3 – 4 x / week</td>
<td>1 (4%)</td>
<td>0 (0%)</td>
<td></td>
</tr>
<tr>
<td>1 – 2 x / day</td>
<td>14 (54%)</td>
<td>14 (52%)</td>
<td></td>
</tr>
<tr>
<td>3 – 4 x / day</td>
<td>5 (19%)</td>
<td>6 (22%)</td>
<td></td>
</tr>
<tr>
<td><strong>Current diet</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Generally healthy diet</td>
<td>6 (19%)</td>
<td>3 (10%)</td>
<td></td>
</tr>
<tr>
<td>Generally unhealthy diet</td>
<td>5 (16%)</td>
<td>7 (22%)</td>
<td></td>
</tr>
<tr>
<td>Low salt diet</td>
<td>20 (65%)</td>
<td>21 (68%)</td>
<td></td>
</tr>
<tr>
<td><strong>Meal planning</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>None</td>
<td>10 (76%)</td>
<td>7 (58%)</td>
<td></td>
</tr>
<tr>
<td>ADA exchange</td>
<td>1 (8%)</td>
<td>0 (0%)</td>
<td></td>
</tr>
<tr>
<td>No concentrated sweets</td>
<td>1 (8%)</td>
<td>3 (25%)</td>
<td></td>
</tr>
<tr>
<td>Dietician visit</td>
<td>1 (8%)</td>
<td>2 (17%)</td>
<td></td>
</tr>
<tr>
<td><strong>Physical Activity</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>None</td>
<td>4 (29%)</td>
<td>3 (23%)</td>
<td></td>
</tr>
<tr>
<td>Rarely</td>
<td>9 (64%)</td>
<td>8 (62%)</td>
<td></td>
</tr>
<tr>
<td>Intermittently</td>
<td>1 (7%)</td>
<td>2 (15%)</td>
<td></td>
</tr>
<tr>
<td><strong>TOTAL</strong></td>
<td><strong>N = 84</strong></td>
<td></td>
<td><strong>N = 84</strong></td>
</tr>
</tbody>
</table>
### Comorbidities

**N = 84**

<table>
<thead>
<tr>
<th>Condition</th>
<th>Count</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hyperlipidemia</td>
<td>73</td>
<td>87%</td>
</tr>
<tr>
<td>Hypertension</td>
<td>72</td>
<td>86%</td>
</tr>
<tr>
<td>Obesity</td>
<td>61</td>
<td>73%</td>
</tr>
<tr>
<td>Neuropathy</td>
<td>39</td>
<td>46%</td>
</tr>
<tr>
<td>CAD</td>
<td>35</td>
<td>42%</td>
</tr>
<tr>
<td>Nephropathy</td>
<td>27</td>
<td>32%</td>
</tr>
<tr>
<td>Anxiety</td>
<td>22</td>
<td>26%</td>
</tr>
<tr>
<td>Depression</td>
<td>19</td>
<td>23%</td>
</tr>
<tr>
<td>COPD</td>
<td>19</td>
<td>23%</td>
</tr>
<tr>
<td>Retinopathy</td>
<td>17</td>
<td>20%</td>
</tr>
<tr>
<td>CVA</td>
<td>8</td>
<td>10%</td>
</tr>
<tr>
<td>Diabetic ulcer</td>
<td>8</td>
<td>10%</td>
</tr>
<tr>
<td>Dementia</td>
<td>3</td>
<td>4%</td>
</tr>
<tr>
<td>PVD</td>
<td>2</td>
<td>2%</td>
</tr>
<tr>
<td>Memory impairment</td>
<td>2</td>
<td>2%</td>
</tr>
</tbody>
</table>

*Figure 1. Comorbidities.*
Figure 2. Documented Interventions (N = 84).
Figure 3. A1C changes (Visit 1 – Visit 2).
Appendix A

Proposed Data Collection Instrument

Patient Identifier: _____ Diagnosis Code: _____ Gender: male/ female/ transgender Age: ____

Race/ethnicity: Caucasian / African-American / Hispanic / Asian / other

Medical coverage: none / private / Passport / Medicaid / Medicare

Marital status: single / married / divorced

Height: ____ Current Weight: _______ Last visit weight: _______ BMI: ______

Visit: 1 or 2 (if 2, how many days apart) ____________ Smoking status: smoker/non-smoker

Medication regimen: Oral
  • Monotherapy _______
  • Dual therapy__________ & ____________
  • Triple therapy ___________ & ____________ & ______________

  Insulin
  • ____________________________________________________________

Co-morbidities: retinopathy / neuropathy / foot ulcer / cardiovascular disease (CAD/PVD/CVA) / chronic obstructive pulmonary disease (COPD) / nephropathy / obesity / hypertension / hyperlipidemia

Level of provider: physician / physician assistant / nurse practitioner

Adherence:

Subjective evaluation of compliance with recommended treatment:
All of the time/ most of the time/ some of the time/ none of the time

Glucose monitoring regimen:
5 + x per day/ 3 – 4 x per day/ 1 – 2 x per day/ 3 – 4 x per week/ 1 – 2 x per week

Current diet: diabetic/ generally healthy/ unhealthy/ high fat & cholesterol/ low fat & cholesterol/ high salt/ low salt/ vegetarian

Meal planning: none/ ADA exchange/ no concentrated sweets/ calorie counting/ carb counting/ dietician visit

Exercise: daily/ every other day/ three times a week/ weekly/ intermittent/ none
Provider’s education:
- diet/physical education ____________________________
- acute complications (hypoglycemia/ hyperglycemia/ sick day)____________________
- chronic complications (daily foot exam/ proper footwear/ annual eye exam/ podiatry visit)____________________
- other diabetes related education (i.e., glucose monitoring)________________________
- referral to Diabetes Self-Management Education ____________________________

Potential barriers documented in notes:
- cultural/religious _________________________________
- emotional (e.g., fear of needles) _________________________________
- lack of desire to learn _________________________________
- depression ____________________________________________
- mental disability ________________________________________
- family dynamic _________________________________________
- physical impairment (speech/visual/hearing)________________________
- financial ____________________________________________________________________

A1C level: ________

Was this done prior to visit or after visit:
- If this was done prior to visit:
  - Provider’s interventions:
    - diet/ physical activity education __________________________
    - oral medication added or adjusted __________________________
    - insulin added or adjusted __________________________

- If this was done after visit:
  - Who notified the patient: __________________________
  - What was done: __________________________
  - Provider’s interventions:
    - diet/ physical activity education __________________________
    - oral medication added or adjusted __________________________
    - insulin added or adjusted __________________________

- When was the patient scheduled for follow-up: ________
  - Did the patient follow-up: YES/ NO
    - If YES – Go to next visit
    - If NO – Missed appointments: no-show/ rescheduled / rescheduled & kept/ cancelled
Appendix B

Interview questions

1. Do you use to any guideline when providing care for patients with T2DM? If so, which one do you use?

2. How often do you refer your patients for diabetes self-management education and what are your thoughts on that?

3. What are some barriers that you have encountered as a provider in helping your patients who have T2DM reduce their A1C level?

4. What are some perceived potential barriers that prevent your patients from adhering to their treatment plan? Such as cultural/religious, emotional (e.g., fear of needles), lack of desire to learn, depression, mental disability, family dynamic, physical impairment (speech/visual/hearing), financial, health literacy, or other?

5. What educational materials do you provide to your patients that have T2DM? Do you utilize the printed educational material in the after-visit summary or other?

6. Do you think that providing printed educational materials to patients with T2DM is helpful in reinforcing the successful management of T2DM? (list 7 core behaviors of ADA) (healthy eating, being active, monitoring, taking medication, problem solving, reducing risks and healthy coping.

7. For your patients, what is the usual A1C goal?

8. What are your recommendations for improving current practice of diabetes self-management in patients that are not reaching their A1C goal?
Appendix C
IRB Letter of Approval

TO: Hoang Ngo, RN, DNP
Nursing Academic Operations
202 CON Bldg.
Phone #: (302)417-9368

FROM: Chairperson/Vice Chairperson
Medical Institutional Review Board (IRB)

SUBJECT: Approval of Protocol Number 16-0302-P1G

DATE: June 8, 2016

On May 27, 2016, the Medical Institutional Review Board approved your protocol entitled:

"Norton: An Evaluation of Providers' Interventions and Patients' Adherence to Diabetes Treatment"

Approval is effective from May 27, 2016 until May 26, 2017 and extends to any consent/assent forms, cover letter, and/or consent letter. If applicable, attached is the IRB approved consent/assent document(s) to be used when enrolling subjects. [Note: subjects can only be enrolled using consent/assent forms which have a valid "IRB Approval" stamp unless special waiver has been obtained from the IRB.] Prior to the end of this period, you will be sent a Continuation Report Form which must be completed and returned to the Office of Research Integrity so that the protocol can be reviewed and approved for the next period.

In implementing the research activities, you are responsible for complying with IRB decisions, conditions and requirements. The research procedures should be implemented as approved in the IRB protocol. If the principal investigator has responsibility to ensure any changes planned for the research are submitted for review and approval by the IRB prior to implementation. Protocol changes made without prior IRB approval to eliminate apparent hazards to the subject(s) should be reported in writing immediately to the IRB. Furthermore, discontinuing a study or completion of a study is considered a change in the protocol's status and therefore the IRB should be promptly notified in writing.

For information describing investigator responsibilities after obtaining IRB approval, download and read the document "PI Guidance to Responsibilities, Qualifications, Records and Documentation of Human Subjects Research" from the Office of Research Integrity's IRB Survival Handbook web page [http://www.research.uky.edu/ori/IRB-Survival-Handbook.html#PIResponsibilities]. Additional information regarding IRB review, federal regulations, and institutional policies may be found through ORI's website [http://www.research.uky.edu/ori]. If you have questions, need additional information, or would like a paper copy of the above mentioned document, contact the Office of Research Integrity at (859) 257-9428.

Ellen Hahn, PhD, RN/CP
Chairperson/Vice Chairperson

An Equal Opportunity University

38
Appendix D

Sample of Consent Form

Consent to Participate in a Research Study

AN EVALUATION OF PROVIDER'S INTERVENTIONS & PATIENT'S ADHERENCE TO DIABETES TREATMENT

WHY ARE YOU BEING INVITED TO TAKE PART IN THIS RESEARCH?

You are being invited to take part in a research study about an evaluation of primary care provider's interventions and patient's adherence to diabetes treatment. You are being invited to take part in this research study because your experience as a Norton primary care provider can contribute much to the understanding and recognition of potential barriers to diabetes treatment.

WHO IS DOING THE STUDY?

The person in charge of this study is Hoang Ngo, a DNP student of University of Kentucky, Department of Nursing. She is being guided in this research by Dr. Judi Daniels. There may be other people on the research team assisting at different times during the study.

WHAT IS THE PURPOSE OF THIS STUDY?

By doing this study, we hope to learn more about standard diabetes management for patients at a primary care practice setting.

The research procedures will be conducted at the Norton Community Medical Associates Shepherdsville. It will consist of one visit that will take about 15 minutes in total. The total amount of time you will be asked to volunteer for this study is 15 minutes.

ARE THERE REASONS WHY YOU SHOULD NOT TAKE PART IN THIS STUDY?

You should not take part in this study if you are not a part time or full time provider at Norton Medical Associates Shepherdsville.

WHERE IS THE STUDY GOING TO TAKE PLACE AND HOW LONG WILL IT LAST?

The research procedures will be conducted at Norton Community Medical Associates Shepherdsville. The interview will take place at the same location, in your office room. It will consist of one visit that will take about 15 minutes in total. The total amount of time you will be asked to volunteer for this study is 15 minutes over the next 6 months.
WHAT WILL YOU BE ASKED TO DO?

If you accept to be a part of this study, you will be asked to participate in an interview with myself. During the interview, I will sit down with you in a comfortable room located at the Norton Community Medical Associates Shepherdsville building. If it is better for you, the interview can take place in your office. The interview will have open ended questions regarding your perspectives on type 2 diabetes mellitus treatment protocols/guidelines, perceived barriers, and your utilization of self-management program.

WHAT ARE THE POSSIBLE RISKS AND DISCOMFORTS?

To the best of our knowledge, the things you will be doing have no more risk of harm than you would experience in everyday life.

You may find some questions we ask you to be upsetting or stressful. You do not have to answer any question or take part in the interview if you don’t wish to do so. You do not have to answer any question or take part in the interview if you feel the question(s) are too personal or if talking about them makes you uncomfortable. You do not have to give us any reason for not responding to any question, or for refusing to take part in the interview.

WILL YOU BENEFIT FROM TAKING PART IN THIS STUDY?

You will not get any personal benefit from taking part in this study. Your willingness to take part, however, may, in the future, help improve the quality of diabetes healthcare services and clinical outcomes.

DO YOU HAVE TO TAKE PART IN THE STUDY?

If you decide to take part in the study, it should be because you really want to volunteer. You will not lose any benefits or rights you would normally have if you choose not to volunteer. You can stop at any time during the study and still keep the benefits and rights you had before volunteering. If you decide not to take part in this study, your decision will have no effect on your job or job-related evaluations in any way.

IF YOU DON'T WANT TO TAKE PART IN THE STUDY, ARE THERE OTHER CHOICES?

If you do not want to be in the study, there are no other choices except not to take part in the study.

WHAT WILL IT COST YOU TO PARTICIPATE?

There are no costs associated with taking part in the study.

WILL YOU RECEIVE ANY REWARDS FOR TAKING PART IN THIS STUDY?

You will not receive any rewards or payment for taking part in the study.

WHO WILL SEE THE INFORMATION THAT YOU GIVE?

We will make every effort to keep confidential all research records that identify you to the extent allowed by law.

Your information will be combined with information from other people taking part in the study. When we write about the study, we will share it with other researchers, we will write about the combined information we have gathered. You will not be personally identified in these written materials. We may publish the results of this study; however, we will keep your name and other identifying information private.

We will make every effort to prevent anyone who is not on the research team from knowing that you gave us information, or what that information is. No private health information will be collected from you. Any information about you will include a number on it instead of your name. Only the PI will know what your number is and that information will be kept in an identity authenticated secure, firewall protected research folder at Norton.
We will keep private all research records that identify you to the extent allowed by law. However, there are some circumstances in which we may have to show your information to other people. We may be required to show information which identifies you to people who need to be sure we have done the research correctly; these would be people from such organizations as the University of Kentucky and Norton Healthcare Office of Research Administration. Officials from the University of Kentucky may look at or copy pertinent portions of records that may identify you.

**CAN YOUR TAKING PART IN THE STUDY END EARLY?**

If you decide to take part in the study you still have the right to decide at any time that you no longer want to continue. You will not be treated differently if you decide to stop taking part in the study.

**ARE YOU PARTICIPATING OR CAN YOU PARTICIPATE IN ANOTHER RESEARCH STUDY AT THE SAME TIME AS PARTICIPATING IN THIS ONE?**

You may take part in this study if you are currently involved in another research study. It is important to let the investigator know if you are in another research study. You should also discuss with the investigator before you agree to participate in another research study while you are enrolled in this study.

**WHAT ELSE DO YOU NEED TO KNOW?**

There is a possibility that the data collected from you may be shared with other investigators in the future. If that is the case the data will not contain information that can identify you unless you give your consent or the UK Institutional Review Board (IRB) approves the research. The IRB is a committee that reviews ethical issues, according to federal, state and local regulations on research with human subjects, to make sure the study complies with these before approval of a research study is issued.

**WHAT IF YOU HAVE QUESTIONS, SUGGESTIONS, CONCERNS, OR COMPLAINTS?**

Before you decide whether to accept this invitation to take part in the study, please ask any questions that might come to mind now. Later, if you have questions, suggestions, concerns, or complaints about the study, you can contact the investigator, Hoang Ngo at 502-417-0368 or hoang.ngo@uky.edu. If you have any questions about your rights as a volunteer in this research, contact the staff in the Office of Research Integrity between the business hours of 8am and 5pm EST, Mon-Fri at the University of Kentucky at 859-257-9428 or toll free at 1-866-400-9428. I will give you a signed copy of this consent form to take with you.

*When developing the consent form, please format to ensure the signature lines fall on a page containing text.*

<table>
<thead>
<tr>
<th>Signature of person agreeing to take part in the study</th>
<th>Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Printed name of person agreeing to take part in the study</td>
<td></td>
</tr>
<tr>
<td>Name of (authorized) person obtaining informed consent</td>
<td>Date</td>
</tr>
</tbody>
</table>