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Evaluation of Educational Intervention and Management of Patients with Type II Diabetes Mellitus

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Final DNP Project Report

Evaluation of Educational Intervention and Management of Patients with Type II Diabetes

Mellitus

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College of Nursing

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Dedication

This manuscript is dedicated to my husband, Kyle Johnson, who has supported me, in every way, along my journey to DNP. His dedication to me and my success has helped me to believe in myself and arrive at this wonderful place in life.

Acknowledgments

I am grateful for the assistance and support from my academic advisor and committee chair, Dr. Judith Daniels. Dr. Daniels encouraged me to succeed with sound advice and a little humor, to keep things in perspective. Her support and encouragement have been crucial for the completion of this project.

Special recognition also goes to my advisor at the start of this DNP project, Dr. Sharon Lock.

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To my clinical advisor, Dr. Julie Ossege for all of her encouragement, time, and expertise.

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Many, heartfelt thanks to my fellow pioneers on this journey to DNP. The difficult times were much easier thanks to your advice, suggestions, and moral support.

Special recognition goes to my family – my husband and two stepsons, my parents, my sister, brother-in-law and beautiful nephew, and all of my friends and family, who have sacrificed time together, to allow me time to complete my studies for this program. I would not be the person I am today without their love and commitment to me and my success.

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Abstract

Background: Diabetes is a costly disease with devastating consequences. Patients with poor glucose control whether due to inadequate medical care or limited self-care are most at risk for complications. Evidence supports the efficacy of multifaceted interventions in the treatment of type II diabetes mellitus (T2DM). Patient education, assessing behavioral and psychosocial elements, and focusing on lifestyle change (e.g. diet and exercise) are interventions shown to enhance self-efficacy and promote patient empowerment (Knight, Dornan, & Bundy, 2005).

Study Design: A retrospective chart review of 104 patients with established T2DM was conducted along with a qualitative interview with providers focused on management practices. Data were analyzed by SPSS software version 22 using Chi-square tests and the paired t-test.

Objectives: The goals of this project were to report the current usage of available educational materials for T2DM and the effect of that education on glycated hemoglobin A1C levels (HgA1C) and weight. Additionally the utilization of glucose lowering medications was reviewed for adherence to guidelines from the American Diabetes Association.

Results: There was a significant reduction in HgA1C in those patients who received printed educational materials. Although not statistically significant, patients who received weight management materials had a weight reduction. Providers voiced not knowing the best methods for delivery of diabetic education.

Conclusions: The gap analysis for this project has shown that education and medication interventions have a positive influence on the management of patients with T2DM. Providers, though committed to education, need a consistent approach.

Keywords: type 2 diabetes mellitus, education, intervention, medication, complication prevention

Introduction and Background

The purpose of this project was to examine how T2DM is managed at Norton Healthcare (NH). Ultimately, the goal is to promote the utilization of successful, evidence-based interventions to enhance blood glucose control and prevent complications. Diabetes is a costly disease with devastating consequences. Patients with poor glucose control whether due to inadequate medical care or limited self-care are most at risk for complications (American Diabetes Association, 2002). Education is a key factor in the successful management of diabetes (Braun et al., 2008). Often though, patients are overwhelmed by the complexity of their disease and unable to retain all of the education they receive in an office visit. Further, providers need to be engaged in the education process to assist patients in managing their disease.

Data from the Department for Public Health estimates there are 603,000 Kentucky adults living with prediabetes and diabetes, the majority of which developed diabetes in adulthood (Cabinet for Health and Family Services, Department for Public Health, Department of Medicaid Services, Office of Health Policy, and the Personnel Cabinet [CHFS, DPH, DMS, OHP, and PC], 2013). The yearly cost of preventing or treating the complications of T2DM is alarmingly high. In 2011, Kentucky hospitals reported over 183 million dollars spent on in-patient care associated with diabetes. These costs are slightly higher than the 169 million spent on hospital care in 2010. Kentucky Emergency Department visits due to diabetes resulted in charges totaling $23,709,718 in 2011 (CHFS, DPH, DMS, OHP, and PC, 2013).

One cannot contemplate the monetary cost associated with diabetes without taking into consideration the human cost of the disease. Diabetes remains the seventh leading cause of death in the United States, with a significant number of people newly diagnosed every year (American Diabetes Association [ADA], 2014). In 2009 the mortality rate due to complications of diabetes was estimated to be 29 per 100,000 adult Kentuckians.

Diabetes is associated with complications other than death; these complications impede the individual's quality of life. Depression and anxiety are common psychological comorbidities seen in these patients (Chew, Shariff-Ghazali, & Fernandez, 2014). The physiological problems linked with uncontrolled glucose levels include: peripheral vascular disease, renal disease, cardiovascular complications, and eye disease. Vascular disease, for example, is estimated to effect one of every three people with diabetes over the age of 55 (American Diabetes Association [ADA], 2014). Evidence supports the efficacy of multifaceted interventions in the treatment of T2DM. Patient education, assessing behavioral and psychosocial elements, and focusing on lifestyle change (e.g. diet and exercise) are interventions shown to enhance self-efficacy and promote patient empowerment (Knight, Dornan, & Bundy, 2005).

Initial therapy for patients with T2DM should begin with lifestyle changes, which include lifestyle counseling, setting physical activity goals, and weight loss education (American Diabetes Association, 2016). Education about T2DM management and lifestyle interventions should be reinforced at every follow-up visit. Patients should consider self-care management equal to prescribed medications for the management of diabetes.

In the Norton Healthcare (NH) system T2DM is considered a significant problem among the adult patient population. Per clinical observation, and conversations with NH patients and providers, there appears to be a lack of consistency in providing patients with lifestyle education regarding T2DM. Potential contributing factors include inefficient use of technology and lack provider knowledge of available resources.

In the NH system there is educational information available in EPIC (the Norton Healthcare electronic medical record). The information may be added electronically to the patient's after visit summary (AVS) and given to them upon discharge. The Shepherdsville

office (designated clinic for this gap analysis) has employed a fulltime "Nurse Navigator" as an educator and additional patient resource. The question remains how well the available resources are being utilized.

In addition to self-care management, it is important that patients with diabetes be on the appropriate medication regimen to manage their disease and maintain a state of wellness. For this to happen, therapy must be tailored to the individual. According to Nainggolan (2016), "The mantra is to individualize. It's called patient-centric therapy" (Nainggolan, 2016, p. 1). Guidelines from the ADA (2016) recommend that the medication chosen to treat T2DM is dependent on a variety of patient- and disease-specific factors. As such, the organization's treatment algorithm reflects the need for individualized care plans.

Significance

Chronic diseases are the leading cause of death and disability in the US. Conditions, such as heart disease, stroke, T2DM, and obesity, are among the most common, costly, and preventable of all health problems. The ADA reports the total cost associated with diabetes alone, in the US, was $245 billion in 2012 (American Diabetes Association [ADA], 2015).

Obesity is often a contributing factor for the development of diabetes and heart disease. Obesity is defined as a body mass index (BMI) greater than or equal to 30 kg/m2. From 2009 to 2010, more than one-third of adults, or about 78 million people were obese; this number continues to grow annually (Centers for Disease Control and Prevention [CDC], 2016). The single best predictor of T2DM is obesity. Nearly 90% of people living with type 2 diabetes are overweight or have obesity (Obesity Society, 2015). Educational intervention, regarding diet and exercise, is vital to improve patient outcomes and lower healthcare costs associated with uncontrolled T2DM.

Studies have shown that people with T2DM have concerns about the progression of their disease, following dietary advice, and the damage caused by diabetes (Rygg, Rise, Gronning, & Steinsbekk, 2011). Patients want concrete, day-to-day advice on how to manage their disease. Effective management requires careful consideration of the patient's health-state and anticipation of measures needed for their individualized health plans. This necessitates education and open communication between the healthcare provider and the patient regarding expectations and outcomes.

Several of the primary care offices within the studied healthcare organization have been designated a patient centered medical home (PCMH). The primary care office studied meets criteria to be designated a PCMH. As such, they have employed a fulltime "Nurse Navigator" as an educator and additional patient resource.

Purpose

The aims of this project were to assess the current use of diabetic teaching materials given to patients with uncontrolled diabetes and the utilization of glucose lowering medications for those patients not at goal. The ADA maintains that the ultimate goal for controlled diabetes, in most patients, is a HgA1C of less than 7%. These interventions, the use of educational materials and medication use were evaluated in relation to their effect on patient outcomes.

The specific objectives of this gap analysis were:

- To determine what T2DM information uncontrolled diabetic patients receive in their after visit summary (AVS). Specifically:
  - Whether or not the provider documented that T2DM education intervention was provided.

- o Whether or not the provider documented the type educational materials were supplied to patient, if not included on AVS.

- o Whether or not the provider documented the plan for support staff (i.e. diabetic educator, RN, or other) to provide patient with educational intervention.

- Assess weight and HgA1C levels for the patient population included in this study before and after education and medication intervention.

- Review provider ratings of patient's adherence to T2DM management.

- Through interview, determine how providers educate their patients about T2DM, their awareness of available materials and whether they feel the materials are user friendly and effective.

Review of Pertinent Literature

A comprehensive search of CINAHL, EBSCO, Medline, and PubMed databases was conducted to assess the role of education in improving glycemic outcomes in patients with T2DM. Keywords used in the search include: patient education, diabetes education, educational intervention, education, type 2 diabetes mellitus, diabetes control, glucose control, and medication. The search was limited to studies conducted from 2008 to present. Inclusion criteria was focused on studies regarding the efficacy of educational intervention. Only articles written or translated in English were utilized.

Current research supports the importance of educating patients with T2DM. A multifaceted educational approach is recommended. Education should be focused on monitoring glucose levels to prevent hyperglycemia. Further, diet and exercise are essential, along with medication adherence, to reduce glucose variation (Sperl-Hillen et al., 2013).

Patel (2008) found those with uncontrolled T2DM are at risk for complications due to: muted immune response; the effects of hyperglycemia on neutrophil function and pathogen proliferation; and the effects of diminished perfusion (Patel, 2008). There are less diabetic complications when the HgA1C is at or below seven percent (ADA, 2015). This goal necessitates enhanced communication between the provider and patients. According to Aliha and associates (2013), continuous, dynamic communication between patients with T2DM and health professionals, is imperative to improve glucose control.

Education is an effective intervention, often associated with little cost. Per Urbanski, Wolf, and Herman (2008), diabetes self-management education is cost effective and associated with favorable changes in knowledge and clinical outcomes. Similarly, the studies by Pottie, Hadi, Welch, and Hawthorne (2013) and Braun et al. (2008) support custom, patient-specific education programs, to improve glycemic control and health outcomes.

Individualized education, resulted in significant and sustained improvements in self-efficacy and also reduced diabetes distress (Sperl-Hillen et al., 2013). Similarly, the importance of patient-tailored education was discovered by Chrvala, Sherr, and Lipman (2015). They reviewed 118 educational interventions and their effect on glucose control. They discovered "robust data demonstrating that engagement in diabetes self-management education results in a statistically significant decrease in HgA1C levels" (Chrvala, Sherr, & Lipman, 2015, p. 926). The importance of ongoing educational reinforcement to achieve long-term behavioral change and glucose control is imperative.

The studies reviewed for the purpose of this practice improvement project, support education as an effective intervention for the management of T2DM. Glycemic control is one of the strongest predictors of disease progression and development of microvascular and

macrovascular complications for those who have T2DM (Chrvala et al., 2015). Given the

chronic nature of diabetes, focused attention is required from the patient and medical staff. The

need for continuing education to improve patient's care and adherence to treatment plans is

essential.

<div align="center">**Design**</div>

This project employed a mixed method model, using both quantitative and qualitative

designs. A retrospective chart review of 104 patients at a primary care office, associated with a

large medical center, was followed by a qualitative interview with providers was conducted. The

quantitative data obtained, included educational interventions and currently prescribed diabetic

medications. Documented education interventions included: verbal education on lifestyle

modification (diet, exercise and weight management), referral to diabetic educator, referral for

nutrition consult, and discussion of foot care and referral to podiatry.

The inclusion criteria for the patient population was adult males and females, over age of

18, of any ethnic background, who speak English or Spanish, and whose HgA1C was greater

than 7% seen in clinic between January 1, 2015 and December 31, 2015. Exclusion criteria for

the patient population was as follows: children under age 18 and patients with diagnosis of

complicated mental illness (e.g. schizophrenia). Patients with complicated mental illness were

excluded as medications they may be prescribed can further complicate glucose and weight

control. All of the six providers at the selected primary care office were asked to participate in

the interview session.

Methods

Quantitative study. Using a chart review process an Excel spreadsheet (Appendix E)

was designed to capture the current education and management of patients with uncontrolled

T2DM. Descriptive statistics were used to compare weight and HgA1C levels at time of the

educational or medication intervention and at the next follow-up appointment. Percentages of reduction, if any, in both categories were calculated. Results were then analyzed to determine what educational interventions were currently being utilized by providers.

   Qualitative study. Three physicians and two nurse practitioners from the studied primary care office were consented and interviewed for the qualitative portion of this study. Providers were individually recruited for interviews after they completed their morning patient appointments. The interview questions asked were as follows:

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?

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?

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?

Protection of Human Subjects

Approval from the University of Kentucky (UK) Medical Institutional Review Board (see appendix A) and the Norton Healthcare Office of Research Administration (NHORA) (see appendix B) was granted. A waiver for patient informed consent was requested, as the research involved no more than minimal risk to the study subjects. The rights and welfare of subjects were not adversely affected, as all information collected was de-identified.

Each patient record was accessed through EPIC, an electronic, secure, encrypted, firewall protected electronic medical record system at NH. The medical record number of each patient who met the study criteria was linked to a unique study number. During data collection the PI accessed patient records using the Norton medical record number, abstracted the data listed above (description of population section) from the record, and transferred the data to an electronic spreadsheet. The data on the spreadsheet was linked only to the patient's unique study number.

A cross-walk table was developed with the patient's unique study number linked to the medical record number. The health information for each patient on the spreadsheet was linked to the patient's unique study number. The crosswalk table and the spreadsheet were stored in separate files on the PI's identity authenticated secure firewall protected research folder at Norton Healthcare. This folder was only accessible to the PI, NH Information Services representative(s), and NH University of Kentucky School of Nursing Academic Partnership network administrators, trained to establish file folder access for the students.

Instruments Used

A Microsoft Excel spreadsheet was used for the purposes of data collection and reporting. A comprehensive spreadsheet housed all pertinent data to this study (See Appendix E). The PI requested data from Norton Healthcare's health information department, using the data request form (see Appendix C). A Microsoft Excel spreadsheet of the requested data was returned to the PI. An online data randomizer, called "Research Randomizer," was used to obtain a random sample of 125 charts.

Data Analysis

Descriptive statistics, including means and standard deviations or frequency distributions, were used to summarize the study sample characteristics. The chi-square test of association was used to test for an association between patient education and reduction in HgA1C (yes/no) and weight (yes/no). Data analysis was conducted using SPSS version 22; an alpha level of .05 was used to determine significance throughout.

A chi-square test for independence was performed, to determine whether or not there was a significant relationship between printed education (via the AVS) and HgA1C reduction. In the patient population who received printed diabetes education a paired-samples T-test was used to compare Mean HgA1C before and after educational intervention. A second chi-square test was performed to evaluate the relationship between patients who had a HgA1C reduction and received any documented educational intervention. The relationship between weight and education was examined utilizing the chi-square test for independence.

Results

Quantitative Results

The data request for this project returned a total of 714 potential patients. One hundred twenty-five patients were randomly selected to include in this study. There were a total number of 104 patients who met the inclusion criteria. Twenty-one charts were excluded due to the following reasons: the patient had type I diabetes mellitus, the patient's HgA1C was less than 7%, or the patient had no HgA1C or weight recorded for 2015.

The average age was 61.7 years (range from 34-93), 59% of patients were male, and all were Caucasian. The majority of patients were married. Only 13.5% of the patients were reported smokers (See Table 1). The average BMI was 34.1 and 98% were overweight or obese. Comorbid conditions of hyperlipidemia and hypertension were diagnoses listed for 90% of the sample.

More than half of the patients (56%) sampled had documentation that printed educational material about their disease was provided. This included information on diet, exercise, and glucose monitoring. EPIC educational information was embedded in their discharge summary, there was also evidence that patient education materials from the ADA were supplied.

In addition to printed materials, all of the educational interventions (verbal education on lifestyle modification, verbal education on medications, referral to diabetic educator, referral to nutritionist, or referral to podiatry) documented by providers were reviewed (See Table 2). Verbal medication education was the second most common intervention (15%) after printed materials. Approximately 27% of patients did not receive any sort of educational intervention when they were not at goal. Forty-three percent of patients experienced a reduction in HgA1C and only 19% had a decrease in weight.

Table 3 provides a list of the medications prescribed by the studied primary care office providers. Most patients were on more than one medication. Metformin was the most commonly prescribed medication (76%), followed by sulfonylureas (35%) and insulin (30%).

Data was collected on providers' subjective evaluation of patient adherence to recommended treatment plans (See Table 4). No documentation was evident regarding patient adherence 67% of the time. Providers believed that 18% of patients were compliant with their treatment plans all of the time.

Patient follow-up visits were also reviewed for this analysis. Ninety-eight percent of patients were scheduled for T2DM follow-up appointments. The majority (92%) of patients kept their follow-up appointments. Additionally, approximately 81.7% of patients with T2DM follow-up every three to six months for their disease.

Printed education and HgA1C. Patients who received printed diabetes education were evaluated to determine if HgA1C levels decreased. A paired-samples T-test was used to compare mean HgA1C before and after education. There was a significant reduction ($t = -2.5$, $p = 0.016$), in mean HgA1C of 0.56% after patients received printed diabetes education.

Verbal education or referrals and HgA1C. The relationship between verbal education and HgA1C reduction was examined. A chi-square test was performed. There was not a significant difference in the percent of patients with an A1C reduction among those who received verbal education or referral and those who did not. ($p=.91$; see Table 4).

Printed education vs. verbal education. The relationships between HgA1C reduction and patients who received printed education and those who received verbal education were evaluated. Chi square tests were used. Printed education and HgA1C reduction are more closely correlated ($p=.25$) than verbal education and HgA1C reduction ($p=.91$).

Education and weight. The relationship between weight and education was examined. Fourteen of the twenty patients who had a weight reduction received weight management education. A chi-square test revealed no significant differences between these two groups (p=.15; see Table 5).

Qualitative Study Results

Five providers were interviewed for the purpose of understanding their management of T2DM. All providers interviewed stated they used recognized guideline for the management of T2DM. The majority cited using ADA guidelines. Four providers refer all of their newly diagnosed diabetics and those not at goal to the Nurse Navigator for continuing diabetes management and nutrition counseling. There were no newly diagnosed patients in the sample used for this project and no documentation of referral to the nurse navigator.

A number of barriers were cited in helping patients who have T2DM reduce their HgA1C level. Multiple providers concluded that mental health problems and financial concerns were a barrier for a large portion of the diabetic population they care for. Limited health-literacy, lack of motivation and depression were some of the mental complications discussed. Financial barriers included difficulty affording: prescribed medications, insurance coverage, and healthy food items. Additionally physical ability of patients determines the level of adherence to lifestyle changes, such as increasing physical activity and exercise. These barriers were also cited as obstacles for patient adherence to prescribed treatment plans.

All but one of the providers stated they supply printed education to their patients via the After Visit Summary (AVS). A few providers were unsure if the patient actually gets the AVS at every visit. Of those who knew their patients got an AVS, all were unsure of whether or not the patients actually read their AVS's. Only one provider did not utilize the printed AVS, rather

supplies his/her patients with an educational packet put together by the Nurse Navigator employed at their office.

The providers felt there was value in providing patients with diabetes education. Reasons cited were that printed educational materials help patients understand their disease and guide them in asking questions at follow-up visits. There was concern that information presented to patients via the AVS was too lengthy and that their patients were more likely to read and retain shorter, less detailed instructions.

Providers were asked what HgA1C goal they set for most of their patients. Many stated that seven percent was not realistic in the population they serve. Most providers felt that less than 8-8.5% was more likely an obtainable goal.

When asked about suggestions for future diabetes care and improvements in patient education, a variety of answers were fielded and were as follows:

- Close follow-up and continuing education at every visit.

- Provider education on best practices and nutrition counseling.

- Follow-up visits and HgA1C checks every 3 months.

- Utilization of the Nurse Navigator for newly diagnosed patients for diabetes education.

- Focus on physical activity & weight control education.

Discussion

Summary of results

The epidemiological demographics of this sample is not unlike that reported in the literature. T2DM is an adult prevalent disease in the overweight/obese population (Obesity Society, 2015). Similar to the adult population with T2DM this sample had the most common comorbidities of obesity, hypertension and hyperlipidemia. Patients seen at the primary care office used for this study are not unlike other clinical practices that manage T2DM.

There were two different types of education provided to patients, written and/or verbal. In the group who received written educational interventions, a significant reduction in HgA1C was noted. This was in contrast to patients who only received verbal instructions. An assumption would be that those who received the written materials also had verbal instructions to explain the printed education. This was not looked at separately and so is an assumption of this project. These results reflect what is also reported in current literature, wherein printed materials were significantly correlated to improved T2DM management (Urbanski, Wolf, & Herman, 2008).

The relationship between education and weight were not statistically significant. However, there was clinical significance, as shown by the reductions in weight, post-educational intervention. Seventy percent of the patients who received printed education on diet and weight loss realized weight reductions. Weight is a complex problem that requires multiple interventions, not only a printed handout. Weight reduction in diabetics is challenging, as many of the medications prescribed are fat storing (Craig, 2010). Despite the lack of significance a percentage did have reduction reinforcing that every opportunity must be taken to discuss weight loss.

There are many perceived barriers that prevent patients from following treatment plans. Interestingly, providers not only revealed barriers they find, but also the obstacles their patients face. The personal barrier that providers cited was having to deal with the perception that some of their patients lacked the motivation to comply with their treatment plans. Intrinsic within that lack of motivation are providers citing the obstacles that patient face, which they link to the patient's motivation. These providers felt their patients were limited by their health literacy levels and their financial situations. The personal financial burden of diabetes has been recognized within the literature as a significant issue (Busko, 2013).

Financial burden becomes a two-pronged problem. One is the additional money spent by patients when HgA1C is not a goal. Patients spend more money on monitoring supplies, medications and more frequent office visits. The greater the complications experienced the more of a financial burden the disease becomes. Patients need to understand the relationship between controlled diabetes and disease cost. The second prong is the providers having an understanding of what their patients can and cannot afford. Prescribing costly, non-covered, out-of-network medications may force patients to be creative in how they take their medications. This has been reported in the literature (New England Healthcare Institute, 2009).

The providers at the studied primary care office believe there is value in providing patients with educational materials. The type of educational material that is most effective remains unknown among providers (Cavanaugh, 2011). The studied primary care office has many interventions available, however it appears they are not being fully utilized.

Study Limitations

This gap analysis has a variety of limiting factors. The limited sample size and the homogenous demographics do not allow for the application to the general population, but does

hold significance for this particular clinic. As such, much of the statistical analyses performed for this study were not significant.

Comprehensive education regarding a disease state, at the time of diagnosis or soon after, has great potential to positively influence the course of disease management. Initially the goal was to evaluate what type of education newly diagnosed diabetics received at the time of diagnosis. It was not possible to retrieve this information from the EPIC electronic medical record. There is no ICD-10 diagnosis code associated with a newly diagnosed T2DM patient. As such, the focus was turned to what type of education patients are getting when their disease is uncontrolled, at a HgA1C level greater than 7%. It is unknown how patients are managed at the onset of disease, which would impact the course of their disease.

The EPIC electronic medical record needs improvement in terms of medications. It was very difficult to interpret which medications patients were currently taking and when they were initially prescribed. The medication list includes historical medications, discontinued/expired medications, and patient reported medications. It was difficult to determine when medication additions and adjustments took place.

It was assumed that those who received printed education also received verbal education. It is equally unknown what the content of the verbal instructions were. Woven into all of this education was not knowing the health literacy of these patients.

Conclusions

A large percentage of patients seen at the studied primary care office are receiving educational intervention when they are not meeting treatment goals. Providers at NH believe that continuing education, for patients and providers, is necessary for improved glycemic control in patients with T2DM. This gap analysis demonstrates the positive influence diabetes education

has on weight and HgA1C levels. A greater percentage of patients who received printed diabetes education had a reduction in HgA1C than those who did not receive printed education. Nurses have influential roles to provide education to patients about managing their disease and must seize every opportunity to assist patients in understanding a preventing the complications of T2DM.

Table 1

Descriptive Summary of Study Sample (N=104).

Variable	%
Sex	
Male	58.7
Female	41.3
Ethnicity	
Caucasian	100
Other	0
Marital Status	
Married	64.0
Widowed	14.0
Single	10.0
Divorced	9.0
Legally Separated	3.0
Smoking Status	
Smoker	13.5
Non-smoker	86.5

Table 2

General Statistics (N=104)

Variable	%
<u>Received Printed Education</u>	
Yes	55.8
No	44.2
<u>Received Any Educational Intervention and Referrals</u>	
Yes	73.1
Printed	*55*
Verbal education on medications	*15*
Verbal education on lifestyle modification	*10*
Referral to diabetic educator	*8*
Referral to nutritionist	*8*
Referral to podiatry	*4*
No	26.9
<u>A1C reduction</u>	
Yes	43.3
No	56.7
<u>Weight Reduction</u>	
Yes	19.2
No	80.8

Table 3

Currently Prescribed Diabetes Medications (N=104)

Medication/Medication Class	% of patients on medication
Metformin	76
Sulfonylureas	35
Insulin	30
Dipeptidyl peptidase-4 inhibitors (DPP-4)	23
Thiazolidinediones (TZDs)	10
Glucagon-like peptide-1 receptor agonists (GLP-1)	8
Sodium-glucose co-transporter 2 (SGLT2)	7

Table 4

Providers Subjective Evaluation of Compliance (N=104).

Level of Compliance	%
Not documented in chart	67
All of the time	18
Most of the time	7
None of the time	4
Some of the time	4

Table 5

Comparison of Verbal Education/Referrals and A1C reduction (N=104)

	A1c reduction		p
	Yes (n=45) n (%)	No (n=59) n (%)	
Received Verbal **Education or Referral**			.91
Yes	11 (42.3%)	15 (57.7%)	
No	34 (43.6%)	44 (56.4%)	

Table 6

Comparison of Patient Education and Weight Reduction (N=104)

	Weight Reduction		
	Yes (n=45) n (%)	No (n=59) n (%)	*p*
Received Education			
Yes	14 (24.1%)	44 (75.9%)	.15
No	6 (13.0%)	40 (87.0%)	

Appendices

Appendix A: NHORA Approval Letter

NORTON® HEALTHCARE

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NHORA# 16-N0070 /IRB #16-0283-P2H / Norton Evaluation of Educational Intervention and Management of Patients Diagnosed with Type II Diabetes Mellitus

Dear Ms. Johnson:

The Norton Healthcare Office of Research Administration (NHORA) is pleased to notify you that your application to conduct the above-mentioned research study in the following Norton Healthcare (NHC) facility has been approved.

- **Norton Community Medical Associates (NCMA) Shepherdsville**

Please note: NHORA approval reflects permission to conduct the study within a Norton Healthcare facility from a regulatory and contractual perspective, and is independent of approval by the sponsor for initiation of the study. The sponsor or site may have additional requirements to address before the study can begin.

The following items must be submitted to the NHORA if your study continues to be conducted in a NHC facility and are applicable to your study:

- **Annual Progress Report/Continuation Review form**
- **Annual Approval letters and current Informed Consent Forms approved by the IRB, if applicable**
- **Amendments and Amendment Approval letters**
- **Revised HIPAA documents such as revised Partial Waivers/Complete Waivers of authorization for each change in personnel**
- **Changes in the Conflict of Interest status**
- **Status change of study, i.e. closed to enrollment, study termination etc.** To comply with HIPAA regulations:
- **A copy of the Partial Waiver of Authorization must be filed with the medical record of every patient screened for the study, if applicable.**
- **For retrospective chart reviews, a copy of the Complete Waiver of Authorization must be filed with the medical record of every patient whose chart is reviewed for the study.**

For studies utilizing an Informed Consent Form, **a signed copy of the Informed Consent Form and Research Authorization must be filed with the medical record of each subject enrolled in your study in a NHC facility.**

If applicable, the Research Patient ID form must be submitted to NHORA Billing daily with reportable activity. Please email the form to NHORABilling@nortonhealthcare.org. Please contact Regina Schaefer at 502-629-3580 for specific instructions regarding the notification of your subject enrollment at NHC.

If the study will include the use of sponsor provided and/or personal equipment of any type (for example: tablets, ECG machines, ePROs, personal laptops etc.), that equipment must be checked, tracked and/or inspected by Norton Healthcare's Clinical Engineering department prior to its use or placement in a patient care setting. Request an initial incoming inspection of the equipment as follows:

- Norton employed researchers – contact Clinical Engineering on NSITE at http://nsite/departments/clinicalengineering/SitePages/Home.aspx
- Non-Norton employed researchers – contact Clinical Engineering by calling 502-629-3590

In the event your study will utilize personal and/or sponsor provided equipment, please ensure that you comply with the procedure outlined above.

We look forward to the successful completion of your study. If you have any further questions or need assistance, please contact the NHORA at (502) 629-3501.

Please let us know how we are doing. Follow the link https://www.surveymonkey.com/s/NHORAsatisfaction to complete the NHORA Satisfaction Survey in less than two minutes. Your feedback helps NHORA improve the services we provide and meet the needs of the research community.

Sincerely,

Rhonda Hoffman
System Director Research

Norton Hospital • Kosair Children's Hospital • Norton Audubon Hospital
Norton Suburban Hospital • Norton Immediate Care Centers • Norton Brownsboro Hospital

Appendix B: IRB Approval Letter

U·K·
UNIVERSITY OF
KENTUCKY®

Office of Research Integrity
IRB, IACUC, RDRC
315 Kinkead Hall
Lexington, KY 40506-0057

859 257-9428
fax 859 257-8995

www.research.uky.edu/ori/

Initial
Review

IRB
Approval Ends   Number
June 10, 2017   16-0283-
P2H

Elissa Johnson, RN
TO: CON Academic Operations
c/o Tricia MacCallum
202 CON 0232
PI phone #: (502)435-3510

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

SUBJECT: Approval of Protocol Number 16-0283-P2H

DATE: June 14, 2016

On June 11, 2016, the Medical Institutional Review Board approved your protocol entitled:

Norton Evaluation of Educational Intervention and Management of Patients Diagnosed with Type II Diabetes Mellitus

Approval is effective from June 11, 2016 until June 10, 2017 and extends to any consent/assent form,
cover letter, and/or phone script.   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 Review 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. It is the principal investigators 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 web site [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, RN, PhD/jh*_____
Chairperson/Vice Chairperson

An Equal Opportunity University

160283P2H

Norton Evaluation of Educational Intervention and Management of Patients Diagnosed with Type II Diabetes Mellitus

Verified "Consent Authorized" Y

			Trained:	Date:	DunnChad:	Citi:	Other Test	Authorized
PI	Johnson	Elissa	Y	11/08/15	N	Y	N	
	elissa.johnson@uky.edu						Unassigned	
							RN	

KP Daniels	Judi	Y	09/28/14	Y	Y		Y
Jadani0@uky.edu					Advisor		
					PhD, APRN		

KP Jensen	Lynne	Y	12/15/14	Y	N		Y
lajens2@uky.edu					Mentor		
					PhD,RN,APR		

Appendix C: Research Data Request Form

Section 1: To be completed by requestor			
Name	Johnson, Elissa	Norton Employee AHSN: _AHSNKVPC_____ Non-Norton Employee: _____ Employer: (NHC, UOFL, UK, Others Specify) School: University of Kentucky Degree/Program: DNP	
Unit\Facility	NCMA Shepherdsville	EmailAddress: Phone number:	elissa.johnson@uky.edu 502-435-3510
Purpose/Scope (What the data is required for)	Completion of UK DNP Degree – Capstone project		
Description of Information Required *(Please include dates elements including ICD-10/DRGs/CPTs codes /timeframes, and other specific inclusion/exclusion criteria required in the data)*	See attached data collection "Form M" Facility data is being requested from: NCMA Shepherdsville Dates: January 1, 2015 – December 31, 2015 Patients with ICD-10 Diagnosis Codes: E11.65, E11.69, E11.8, E11.9, E11.40, E11.51, and E11.59 Patients with ICD-9 Diagnosis Codes: 250.00, 250.02, 250.40, 250.42, 250.50, 250.52 250.70, 250.72, 250.80, 250.82, 250.90, 250.92 Patient data: Patient Identifier (EP #) Diagnosis Code (one of the above ICD codes) Gender Age (greater than or equal to 18) Race/ethnicity Primary Language (Spanish or English only) Medical coverage Marital status Height Weight Last visit weight BMI Smoking status Medications Other diagnoses Provider level HgA1C (all those greater than 7%) Fasting blood glucose (FBG) Glucose monitoring regimen Follow-up visit(s) I will need access to the AVS and provider notes		
Is any financial information required?	No	Approved By	Norton Entity Name
Principle Investigator Name	Elissa Johnson	**IRB Status: Approved**	

IRB Number	16-0283-P2H	Approval Date	6/14/2016
How will this research assist Norton Healthcare improve?	X Patient Experience / X Quality / Efficiency / X Health Outcomes/others (check all that apply)		
Request Date	*6/14/2016*	Required Date	*As soon as possible*
To be used in (presentation, report, publication etc) – please specify	Presentation prior to graduation and manuscript reporting findings	**Intended Audience (if appropriate)**	Norton/UK DNP program faculty, attendees of DNP project presentation prior to graduation

Appendix D: Research Data Request Form

Consent to Participate in a Research Study

EVALUATION OF EDUCATIONAL INTERVENTION AND MANAGEMENT OF PATIENTS DIAGNOSED WITH TYPE II DIABETES MELLITUS

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

You are being invited to take part in a research study about the effectiveness of educational intervention in patients with type two diabetes mellitus. You are being invited to take part in an interview related to this research study, because you provide direct care and management of patients diagnosed with type two diabetes mellitus. If you volunteer to take part in this study, you will be one of six providers to do so at Norton Healthcare.

WHO IS DOING THE STUDY?

The person in charge of this study is Elissa Johnson, 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?

This project aims to examine the current usage of available educational materials for T2DM in EPIC (Norton Healthcare's electronic medical record).

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

The interview will be conducted at Norton Community Medical Associates (NCMA) Shepherdsville office. You will need to be at the office one time during the study for a short, 10 minute interview session. This visit will take no longer than 15 minutes. The total amount of time you will be asked to volunteer for this study is10-15 minutes in one meeting session.

WHAT WILL YOU BE ASKED TO DO?

Participate in an interview session where you will answer the open ended questions as follows:

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?

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.

Answers to the questions asked will not be used for or result in any disciplinary action to you or the other providers in the office

In addition to the risks listed above, you may experience a previously unknown risk or side effect.

WILL YOU BENEFIT FROM TAKING PART IN THIS STUDY?

There is no guarantee that you will get any benefit from taking part in this study. Your willingness to take part, however, may, in the future, help society as a whole better understand this research topic.

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 the quality of care, services, etc., you receive.
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 to 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.

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.

WHAT HAPPENS IF YOU GET HURT OR SICK DURING THE STUDY?
It is important for you to understand that the University of Kentucky does not have funds set aside to pay for the cost of any care or treatment that might be necessary because you get hurt or sick while taking part in this study. Also, the University of Kentucky will not pay for any wages you may lose if you are harmed by this study.

Medical costs that result from research related harm can not be included as regular medical costs. Therefore, the medical costs related to your care and treatment because of research related harm.

will be your responsibility; **or**

will be paid by the sponsor (*only option if industry sponsored and industry trial) (insert sponsor's name here*) has agreed to pay for medical expenses incurred by treating injuries that directly result from participating in the study, with some exceptions. The exceptions are instances such as your failure to follow the sponsor's directions or the investigator's failure to follow the sponsor's directions. **or**

may be paid by your insurer if you are insured by a health insurance company (you should ask your insurer if you have any questions regarding your insurer's willingness to pay under these circumstances); **or**

may be paid by Medicare or Medicaid if you are covered by Medicare, or Medicaid (if you have any questions regarding Medicare/Medicaid coverage you should contact Medicare by calling 1-800-Medicare (1-800-633-4227) or Medicaid 1-800-635-2570.

A co-payment/deductible from you may be required by your insurer or Medicare/Medicaid even if your insurer or Medicare/Medicaid has agreed to pay the costs. The amount of this co-payment/deductible may be substantial.

You do not give up your legal rights by signing this form.

WHAT IF NEW INFORMATION IS LEARNED DURING THE STUDY THAT MIGHT AFFECT YOUR DECISION TO PARTICIPATE?

If the researcher learns of new information in regards to this study, and it might change your willingness to stay in this study, the information will be provided to you. You may be asked to sign a new informed consent form if the information is provided to you after you have joined the 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.

Contacting Research Subjects for Future Studies

Do you give your permission to be contacted in the future by Elissa Johnson regarding your willingness to participate in future research studies about how to manage type two diabetes mellitus?

☐ Yes   ☐ No   _____Initials

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, Elissa Johnson at 502-435-3510. If you have any questions about your rights as a volunteer in this research, contact the staff in the Office of Research Integrity at the University of Kentucky between the business hours of 8am and 5pm EST, Mon-Fri. at 859-257-9428 or toll free at 1-866-400-9428. We 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.

_____   _____
Signature of person agreeing to take part in the study   Date

_____
Printed name of person agreeing to take part in the study

_____   _____
Name of (authorized) person obtaining informed consent   Date

Appendix E: Data Collection Tool

	A	D	E	G	I	J	N	P	S	AB	AD	AF	AG	AH	AI	AJ	A
1		Gender	Race/ Ethnicity	Marital status	Previous Weight	Current Weight	Smoking status	Medications	Subjective evaluation of compliance with recommended treatment	Prior A1C Level	Current A1C	Did the patient receive printed DM education	Provider intervention	Was pt scheduled for follow-up	Did pt go to follow-up	Does pt follow-up every 3-6 mos for DM	No
2			Caucasian, African-American, Hispanic, Asian, Other	married, single, divorced			Yes/No		all of the time, most time, some of time, none of the time				Lifestyle modification, education, referral to DSME, oral med added/adjusted, insulin added/adjusted	yes/no	yes/no	yes/no	
3	1	FEMALE	CAUCASIAN	WIDOWED	170	182	N	Metformin	Most time	6.9	6.5	Y	DSCE - AVS, oral med adjustment	Y	Y	Y	Pt had d/c'd metfor diarrhea - trial of Metfo vi
4	2	FEMALE	CAUCASIAN	WIDOWED	274	279	Y	Metformin, Lantus, Novolog	All of the time	9	6.8	N	med added	Y	Y	Y	Bydureon (G
5	3	FEMALE	CAUCASIAN	SINGLE	208	216	N	Metformin, Insulin NPH 70/30, Januvia	Unknown	8.2	7.8	N	increased metformin and Januvia, Ambulatory referral to Nutrition Services	Y	Y	Y	Pt was not maxed on r visit, and should/

Charts from NH Orig | Results | Data Collection | Acronyms and Meanings | Demographic Data | Paired T Test Data

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