

IMPLEMENTING A COMPREHENSIVE DIABETES AND DEPRESSION PROGRAM AT A
FEDERALLY QUALIFIED HEALTHCARE CENTER

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Implementing a Comprehensive Diabetes and Depression Program at a
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State University's regulations and meets the accepted standards for the degree of

DOCTOR OF NURSING PRACTICE

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ABSTRACT

The purpose of this project was to improve outcomes of patients with type 2 diabetes and depression at a federally qualified healthcare center (FQHC) primary care clinic by creating and implementing a functional, sustainable and collaborative program facilitated by the diabetic educator, clinical pharmacist, and primary care. Expectantly, participants of the Comprehensive Diabetes and Depression Program (CDDP) would have better control of their chronic diseases, as well as improved satisfaction, activation and self-efficacy.

The CDDP was implemented in February 2016 and data was collected until January 31, 2017. The FQHC providers and staff were educated on the importance of depression screening, detection, and management in all type 2 diabetic patients. The FQHC personnel were given a pre-implementation survey to gain their thoughts and concerns towards implementing the CDDP, as well as a six-month post-implementation survey. There was a decrease in FQHC staff and provider participation with the six-month post-implementation survey, however, the results received showed staff satisfaction was virtually unchanged from the pre-implementation survey.

All patients with type 2 diabetes were screened for depression at every clinic visit using the Patient Health Questionnaire (PHQ-9). Any patient with a PHQ-9 of 10 or higher was referred to the CDDP to meet with a clinical pharmacist to discuss lifestyle changes and possible medication adjustments. Once enrolled into the CDDP, patients were administered a Patient Activation Measure (PAM) survey to identify their level of health activation, that was repeated after six months. As of January 31, 2017, only one patient had completed their six-month PAM survey, which showed a slight decline in their score. However, over a 100% increase was seen in the number of patients with type 2 diabetes who were referred to the clinical pharmacist, qualified for the CDDP, and referred specifically for the CDDP.

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CHAPTER 1. INTRODUCTION

Background and Significance

Type 2 diabetes is an increasingly prevalent chronic disease in the United States (U.S.). In 2014, the Center for Disease Control (CDC) estimated that 29.1 million American's were living with diabetes and approximately 27.85 million of these people had type 2 diabetes. Living with chronic disease can be taxing on one's physical and mental health and patients living with type 2 diabetes are not immune. Diabetes is a chronic disease that can lead to numerous other health problems, even if it is well controlled. Depression is just one among a myriad of chronic diseases that co-exists with diabetes. Diabetes can lead to other health complications such as heart disease, kidney disease, blindness and nerve pain, which may also contribute to or worsen depression. Managing diabetes can be demanding and stressful which may also lead to the development or worsening of depression. Patients with diabetes are one and a half to two times more likely to have depression than those without diabetes (Markowitz, Gonzalez, Wilkinson, & Safren, 2011).

The relationship between diabetes and depression is considered to be bidirectional (Pan et al., 2010). Patients with diabetes are at a higher risk of developing depression than patients without diabetes. Likewise, patients with depression are at a higher risk of developing diabetes as well. Diabetics with depressive symptoms also have poorer glycemic control and those with poor glycemic control have more severe depressive symptoms. Diabetics are also known to have higher incidences of disability and a decreased quality of life, partially due to the burden of disease management and to the additional co-morbidities that occur alongside of diabetes (Goldney, Phillips, Fisher, Hons, & Wilson, 2004; Laiteerapong, et al., 2011). Similarly, depression can also lead individuals towards making poorer lifestyle choices such as lack of

exercise and poor nutrition that can lead to weight gain, which in turn can worsen diabetes outcomes (Knol et al., 2006).

Problem Statement

Patients with diabetes are at a higher risk for depression yet they are not getting routinely screened for depression. In 2014, a retrospective study found that 36.3% of the diabetic patients at the participating primary care Federally Qualified Health Center (FQHC), had major depressive disorder (Barnacle, Strand, Werremeyer, Maack, & Petry, 2016). Barnacle et al. (2016) found that only 31% of these patients had a documented Patient Health Questionnaire (PHQ-9) done to assess their current depression status.

The FQHC's quality metrics were based upon the measures defined in the Uniform Data System (UDS) set forth by the federal agency, Health Resources and Services Administration (HRSA), as well as requirements necessary to maintain their level three Patient Centered Medical Home (PCMH) certification. An FQHC goal for PCMH was to have less than 20% of their diabetic patients maintain an A1C greater than 9.0, and they had yet to meet this requirement.

Another one of the FQHC's measures was to screen all patients 12 years and older for depression using a standardized tool. Providers also needed a follow-up plan documented if patients are considered depressed. The goal was to have 75% of patients meet this requirement and the FQHC did not meet this obligation in 2015. Greater than 90% of the FQHC patients with an active diagnosis of depression were to receive a follow-up PHQ-9 every year to assess needs for change in medications, referrals to behavior health and to ensure 50% of the PHQ-9 scores were less than 12, and again, the facility did not achieve that measure in 2015.

In an often-cited article, diabetic patients with depressive symptoms also have poorer clinical outcomes (Katon et al., 2005). A substantial scarcity of mental health professionals exists in North Dakota along with the rest of the United States, and the FQHC is not immune to the mental health dilemma. During this project, the behavioral health specialist at the FQHC left due to a lack of funding for the position. This shortage left the burden of managing mental illness weighing heavily on primary care providers' shoulders. These combined problems required the cooperation and collaboration of multiple disciplines to successfully manage patients with compounded chronic diseases. Investigators looked at the FQHC patient data and discovered out of 641 type 2 diabetic visits to the FQHC in a 6-month period, only 87 of those patients saw the diabetic educator and 22 patients saw the clinical pharmacist.

Project Purpose

The magnitude of the disparity in the FQHC's quality measures in comparison to the lack of referrals suggested an opportunity for improvement within clinical practice. The purpose of the practice-improvement project was to work alongside the FQHC administration, providers and staff to establish a comprehensive diabetes and depression program that not only improved patient outcomes and quality, but was also functional and sustainable long term. The hope was that by creating a collaborative program between primary care, the diabetic educator, and the clinical pharmacist, patients would have better control of their chronic diseases, as well as improved satisfaction, activation, and self-efficacy.

Project Objectives

Objective One

The first objective of the practice-improvement project was to educate the Family Health Care providers and staff on the importance of depression screening, detection, and management in all type 2 diabetes patients.

Objective Two

The second objective was to integrate the comprehensive diabetes and depression program into Family Health Care's daily practice to promote sustainability.

Objective Three

The third objective was to improve patient activation and self-efficacy through increased engagement with their healthcare facility and collaborative team.

CHAPTER 2. LITERATURE REVIEW

Problems Associated with Type 2 Diabetes

Introduction

A literature review was conducted to review and summarize existing depression prevention and management strategies, as well as widely used screening tools and collaborative care practices among the diabetic population. The search was conducted using several electronic databases including Academic Search Premier, ScienceDirect, and PubMed. The key words contained in the search included, “diabetes, depression, implementation, program, PHQ-9”. The search included international publications as well as additional comorbid diseases such as cardiovascular disease and obesity. However, data regarding type 1 diabetes and gestational diabetes was excluded.

The purpose was to gather information to aid in determining the most effective comprehensive management program for implementation at Family Health Care. According to the International Diabetes Federation (2012), type 2 diabetes is a widespread chronic disease that affects more than 371 million people worldwide. Individuals burdened with diabetes are at an increased risk for developing other comorbid conditions, including depression. Patients with type 2 diabetes are estimated to have a rate of major depression 1.6 to 2 times higher than those without diabetes (Markowitz et al., 2011). Research shows a compounded effect between type 2 diabetes and depression that correlates with poorer management of disease, decreased quality of life, higher overall healthcare costs, and increased mortality (Katon et al., 2005). Diabetes and depression can be treated in a variety of different manners, yet about half of patients with depression don't receive treatment because they are undiagnosed or undertreated (Osborn, Kazak, & Wagner, 2010). Many different barriers exist that prevent providers from addressing

depression in diabetic patients. The significant nationwide lack of mental health providers has put the responsibility to manage depression largely on the primary care providers' shoulders. Coupled with a lack of training, providers feel pressured to see more patients in a shorter period of time, resulting in a lack of time to adequately screen their patients and address depression at each diabetic visit (Osborn et al., 2010). The strong correlation between diabetes and depression paired with the high number of unidentified and untreated patients highlights the obligation to implement collaborative disease management programs to increase screening, prevention, detection, and treatment of coexisting chronic diseases.

Collaborative Care

Traditionally, the diabetic educator is the person primarily responsible for coordinating diabetic patients' care. Diabetic educators work cooperatively with primary care providers to educate, coordinate, and provide follow up care for diabetic patients. Many diabetic educators are registered nurses that are trained to use motivational interviewing techniques during office visits or telephone calls with diabetics and individuals at high risk of developing diabetes (Bogner, Morales, de Vries, & Cappola, 2012; Katon et al., 2010). The diabetic educator follows evidence-based practice guidelines to fulfill their main goal of monitoring the patient's health status and adherence to their management plan (Bogner et al., 2012).

Diabetic educators are able to serve as an adjunct for depression prevention and management by helping patients develop a personalized management plan by discussing goals, educating on medication regimens and adherence, teaching stress reduction techniques and identify worsening depression symptoms and glycemic control (Bogner, Morales, de Vries, & Cappola, 2012; Katon et al., 2010). Several studies have proven when diabetic educators assist with coordinating their patients' care, there is an increase in patient satisfaction and medication

adherence, improvement in PHQ-9 scores, hemoglobin A1C numbers, LDL cholesterol levels, and systolic blood pressure, when compared with diabetics that received standard therapy only (Bogner et al., 2012; Katon et al., 2010). Katon et al., (2010) stressed that despite all the positive factors diabetic educators bring forth, their services are often time consuming, intensive, and costly.

Healthcare costs and the demands on the healthcare system are on the rise. Cross training and collaboration of the multidisciplinary team is crucial in order to provide adequate, comprehensive care to patients with comorbid diabetes and depression. Patients that attended collaborative, multidisciplinary medical appointments led by a clinical pharmacist were shown to have better glycemic control, improvement in depression symptoms, and lower healthcare costs at the Veterans Administration (Taveira, Dooley, Cohen, Khatana, & Wu, 2011). However, collaborative programs require adequate training and education of healthcare workers on the management of multiple comorbidities in order for the patients and the program to be successful. Glied, Herzog, and Frank, (2010) found that the more expensive an intervention was, such as ensuring staff receive adequate training to detect and manage depression, the more beneficial it was at treating depression, in contrast to prescribing medication, therapy or other treatment modalities by themselves. Osborn et al. (2010) echoed that an improvement in providers' practices was demonstrated through the implementation of continuing education elements, which concentrated on detection, treatment of depression, and imploring behavioral change. Osborn et al. (2010) found by providing adequate training and education on depression screening and treatment, providers also offered depression education to patients more frequently.

Depression Screening in Primary Care

The American Diabetes Association (ADA) has established a Grade B recommendation for the routine screening and assessment of depression in diabetic patients (American Diabetes Association [ADA], 2015). The ADA (2015) places an even higher priority on screening for depression in diabetic patients who are 65 years of age and older. Patients with severe, progressive, uncontrolled, complex medication regimens, and hypoglycemic episodes are at a greater risk of depression than controlled diabetics (Reedy et al., 2010; Kinder et al., 2006; Katon et al., 2013). Many diabetes patients aren't routinely screened for depression by their providers, despite the ADA recommendations (ADA, 2015). Osborn et al. (2010) uncovered that only half of healthcare workers who regularly work with diabetic patients admitted to using depression screening questionnaires and only 28% of them used them on a regular basis. Currently, there are no recommendations from the ADA on which screening tool to use, which may be one of the barriers leading to poor compliance with screening diabetic patients for depression.

As stated above, a multitude of screening tools exist for primary care and could be a potential barrier to depression screening. The various depression screening tools, ranging from the Beck Depression Inventory, which is 21 questions long and more time consuming to complete, to the quicker, 5 item World Health Organization-5 Well-Being Index (Kroenke, Spitzer & Williams, 2001). However, the scale that is most commonly used in the primary care setting is the Patient Health Questionnaire-9 (PHQ-9). The easy to use PHQ-9 is comprised of nine questions and is highly sensitive and selective in diagnosing depression. A PHQ-9 score of 12 or more is diagnostic of depression (Van Steenberg-Weijnenburg et al., 2010). Kroenke et al. (2001), who created the PHQ-9 questionnaire, conveys the PHQ-9 has been validated as an

effective depression-screening tool in patients with diabetes and other complex medical illnesses, as well as in the geriatric and obstetric populations.

Utilizing the PHQ-9 in the primary care setting is suggested to improve management of both depression and diabetes as well as to improve recognition and early treatment of depression. Van Steenbergen-Weijnenburg et al. (2010) implemented the PHQ-9 in an outpatient clinic setting and identified 37 diabetes patients, or 18.8% of the study population, to have uncontrolled Major Depressive Disorder (MDD). Although several studies have examined the validity of the PHQ-9 for identifying depression, there is little circulated evidence on the effect of the PHQ-9 on utilization of healthcare services and cost savings. Traditionally, the PHQ-9 has been widely used for both depression screening and management; however, the PHQ-9 is validated for depression screening only, and there hasn't been a concise tool validated for depression management.

Recently, the National Committee for Quality Assurance ([NCQA], 2015) announced that in 2016, their Healthcare Effectiveness Data Information Set (HEDIS) measures would include utilizing the PHQ-9 as a tool to monitor depression symptoms in adolescents and adults. This new measure was created to encourage routine monitoring of depression symptoms for those with depression and as a building block measure to advance the capabilities of evaluating depression outcomes (NCQA, 2015). Along with the recent HEDIS measures, reputable evidence provides support for the PHQ-9 to be utilized in both screening and management of comorbidities, assuming adequate mental health services are available when needed (Van Steenbergen-Weijnenburg et al., 2010).

Current Gaps in Literature

Limitations were found throughout the studies highlighted in this literature review. Each study that employed collaboration of care as a way to treat and manage chronic disease had a unique implementation method, making comparisons among various sites difficult. Some of the different approaches included patient phone interviews, watching videotapes, different choices of medication or problem solving treatment, visits with a nurse or a depression care manager, and each treatment option lasted different lengths of time. Also, the studies were not independent of other comorbidities, including obesity and cardiovascular disease, which can add greater complexity to disease state management than depression alone. The existing research on depression in diabetics exposes the gaps in literature. There is still a lack of research regarding current practices and the impact of using the PHQ-9 screening tool. Additional research also needs to be done on the cost comparison of a collaborative care and PHQ-9 implementation to that of traditional care, examining primary care appointments, possible hospitalization, and mortality. Finally, the numerous types of collaborative care need to be assessed to determine the best approaches to improve population health.

The exponential increase of chronic diseases within the U.S. expresses a great need for collaborative care programs in order to diminish disease burden and healthcare costs. Depression is a widespread chronic disease that commonly occurs in diabetic patients, and is often disregarded by primary care providers due to a lack of time during clinic appointments and the intricacy of managing multiple comorbidities. The implementation of effective comprehensive disease management programs including collaborative care and screening tools are necessary to address the population health needs, decrease gaps in research and confront rising health care costs.

CHAPTER 3. THEORETICAL FRAMEWORK

The Model for Improvement

Theoretical framework was necessary to direct and ensure the success of the practice-improvement project. The Model for Improvement was selected as a tool to help guide the project. The model was developed by Langley et al. (2009), and has been utilized by countless healthcare organizations over the years to successfully facilitate change. The Model for Improvement is comprised of three questions directed at process improvement as well as the Plan, Do, Study, Act (PDSA) Cycle. The PDSA Cycle was initially developed as the Plan, Do, Check, Act (PDCA) by Walter Shewhart. W.E. Deming (2000) adopted his mentor Shewhart's concept and changed it to the PDSA Cycle that exists today.

Forming a Team

Maintaining consistency with The Model for Improvement, the first step of the project was to form an interdisciplinary team of people invested in helping the FHQC successfully facilitate change. The student project leader of the practice-improvement project joined a team comprised of the clinical pharmacist and diabetic educator at the FQHC, faculty from the North Dakota State University (NDSU) School of Pharmacy and the School of Nursing, along with an NDSU PharmD student serving as a research assistant. Together, the team collaborated and developed what is now called the Comprehensive Diabetes and Depression Program (CDDP) at the FHQC. The FQHC providers, nursing and support staff, as well as clinic executives, and the dissertation project committee of NDSU worked together to develop a project that was widely supported and feasible.

Setting Aims

As aforementioned, contained within the first portion of the model were three fundamental questions that had to be asked to determine what the organization hoped to achieve and change. The questions included: “what are we trying to accomplish, how will we know that a change is an improvement, and what changes can we make that will result in improvement” (Langley et al., 2009). The first question required setting aims that would improve patient health outcomes along with quality of care. The project aims needed to be time-specific and measurable, while also defining the specific population of patients that would be affected.

Establishing Measures

The second question required the utilization of quantitative measures to determine if the changes made would lead to improvement (Langley et al., 2009). This step ensured the project outcomes were measurable. Measurements were determined in relationship to the project objectives. The goal of the practice-improvement project was to assist staff of the FQHC to successfully implement and sustain the CDDP in the long term. Additionally, the project leader hoped the practice-improvement project would lead to improved patient activation and self-efficacy through an increased number of referrals to collaborative care, such as the diabetic educator and clinical pharmacist.

Selecting Changes

Based on the review of literature, changes to implement a collaborative care approach to manage diabetes and detect and address co-morbid depression were needed and appropriate. The CDDP team met bi-weekly to gather data, share ideas, and brainstorm to choose a plan that was best for the FQHC. The CDDP group met with the FQHC key stakeholders and discussed the project plan. Opportunities for improvement and points where breakdowns occurred in their

existing process were identified. Overall, the project was well received and feedback and suggestions from the FQHC staff were integrated into the plan.

Testing Changes

The PDSA cycle was the second part of the Model for Improvement. This method allows an organization to plan, try, observe results, and act on what is learned. The cycle was a modified version of the scientific method that allows organizations to trial a change in practice and to also ensure the change was an actual improvement in practice (Langley et al., 2009).

Plan. This stage was where the team determined what exactly was going to be done and what changes were going to be trialed. This phase included determining who was responsible for specific actions and the timeframe that they were to complete it. Predictions of expected outcomes were made, and overall project timeline, resources and data to be collected were discussed (Langley et al., 2009).

Do. This phase described what occurred when the project was carried out on a small scale. In this phase, necessary data that was identified during the ‘plan’ stage was collected; observations were documented, as well as any problems and unexpected findings (Langley et al., 2009).

Study. The ‘study’ portion of the cycle is where results are described and compared to predictions. Data was analyzed to determine if the changes resulted in the expected outcomes of the project implementation. Also included in this section were summaries of what was learned, as well as any unintended consequences, surprises, feats or failures of the project (Langley et al., 2009).

Act. This section describes what changes were going to be made based on the findings from the project implementation. Any modifications to the project were made from what was learned and were to be applied to the next PDSA cycle (Langley et al., 2009).

Implementing Changes

After the project was tested on a small scale, lessons were learned, and changes were made throughout several PDSA cycles. Following this, the team could implement the change on a larger scale. Based on what was learned, the project could be adapted, adopted or abandoned, depending on whether any changes need to be made. If the project was determined to be unsuccessful, then appropriate changes could be made and the PDSA cycle could be repeated (Langley et al., 2009).

Spreading Changes

The last step of the Model for Improvement was to spread changes. After a successful execution of a practice change, the change could be extended to other parts of the organization. The change could also be implemented among outside organizations as well (Langley et al., 2009).

Congruence of the Project to the Participating Organization's Goals

The purpose and aim of this practice-improvement project aligned well with the FQHC's organizational goals and mission. The participating FQHC's mission is to provide affordable, quality health care for every person. The FQHC's values include dedication, innovation, compassion and excellence. The participating clinic expressed interest in implementing an intervention to improve depression screening, diagnosis, and treatment in their type 2 diabetic patient population. A meeting was held with the FQHC key stakeholders and the project proposal

was well received. The project leader shared the implementation site with the CDDP team with the mutual goal of improved patient outcomes and quality care.

CHAPTER 4. PROJECT DESIGN AND IMPLEMENTATION

Project Design

A retrospective data analysis showed great disparities in diabetes and depression detection and control in the patient population at the FQHC. Given the current gap of depression screening and management among patients with type 2 diabetes, the practice-improvement project leader, in conjunction with the FQHC's clinical pharmacist, Brody Maack, PharmD, NDSU Pharmacy and Nursing faculty, developed the Comprehensive Diabetes and Depression Program (CDDP) to address these disparities. The FQHC clinic was chosen as an implementation site due to a documented need, the presence of primary care services to at-risk populations, the presence of willing administrators, providers and staff, and a willing team to assist with developing a comprehensive, multidisciplinary program.

The project proposal was well-received by the FQHC administration, providers and staff. The Model for Improvement, containing the PDSA Cycle, guided the practice-improvement project. The model fit the project very well and helped the project grow and develop throughout planning and implementation. The project design focused on the implementation and evaluation of the CDDP and utilized the PHQ-9 screening tool among all patients with type 2 diabetes. The PHQ-9 was used to address depression screening and monitoring in diabetic patients, based on HEDIS recommendations and current ADA (2015) guidelines.

Evidence-Based Project Implementation

The project was designed to restructure primary care in order to increase education and service connection in a patient-centered medical home model. Successful implementation of the CDDP required the feedback, training and cooperation of the entire FQHC staff. Prior to development, the CDDP team studied the current flow of the clinic and planned an intervention

that could be easily integrated into the existing workflow of the clinic. LPN staff were trained to identify and highlight all type 2 diabetes patients for the next clinical day and incorporate this step into their current chart prepping practices. The LPN distributed a PHQ-9 to all type 2 diabetes patients to complete. Then, the LPN communicated to the RN case manager regarding which patients were given a PHQ-9 to complete. The RN case manager monitored for patients with type 2 diabetes who scored a 10 or greater on the PHQ-9. Then, the nurse recruited them for the program and ensured a referral to the clinical pharmacist was placed to inform them the patient met inclusion criteria. The CDDP was advertised around the clinic in exam rooms and on educational televisions as an additional recruitment tool for the program, encouraging patients to ask their nurse or PCP if they qualified for the study.

The primary care provider (PCP) continued to function within their usual scope of practice and provided patients with standard education, appropriate lab work and screenings, and referrals based on their clinical judgment. The PCP evaluated and reviewed the PHQ-9 with the patient and ensured patients met inclusion criteria as well. Once patients were recruited into the program, they met with the clinical pharmacist to review informed consent for the study. Patients were given a Patient Activation Model (PAM) Survey and satisfaction survey upon program enrollment. This data was collected upon enrollment, six months into the program, and again at conclusion of the study. If not previously ordered by the PCP, patients had baseline testing done including a Hemoglobin A1c (Hgb A1C), LDL cholesterol, blood pressure, and BMI/weight, and proceeded to the lab after their visit if necessary.

Once enrolled in the program, patients could speak with the RN case manager to discuss any concerns they had regarding their chronic disease management. The RN case managers were involved throughout the study period in their role as PCMH care coordinator. As mentioned

previously, RN case managers reviewed patient charts after their visits to ensure necessary referrals and lab orders were placed. Based upon PCP recommendations and lab/assessment criteria, the RN case manager helped the patient determine which of the intervention clinicians they should visit with first. RN case managers continued to follow the Patient Centered Medical Home model, and made follow-up phone calls to patients to assist with scheduling next appointments, answer questions, coordinate lab work, and screen charts for any needed PHQ-9 follow up at their next appointment.

Patients in the study could be referred to a behavioral health specialist when deemed necessary by the PCP. A referral to the diabetes educator could be made by any of the clinicians at any point during the study period, including when a patient's hemoglobin A1C was above 7 or above their goal as determined by their PCP. If the patient was on one or more medications to treat diabetes and/or depression, a referral could also be placed to the clinical pharmacist.

A PHQ-9 was completed at each referral visit with the clinical pharmacist and diabetic educator, if a PHQ-9 had not been completed within the last four weeks. When one of the intervention clinicians saw a CDDP patient, they could refer the patient back to their PCP or on to another one of the remaining clinicians, on a subsequent date, if deemed necessary. They could also make recommendations to the PCP for changes to current medication regimens when appropriate. Once patients were enrolled into the CDDP, the multidisciplinary team helped to manage their care for up to one year, at which time their depression and diabetes measures were reassessed. After completion of the one year program, RN case managers will continue to play an integral role in monitoring patients' chronic disease by following the PCMH model.

Timeline of Project Phases

February-March 2015

- Expressed interested in the current diabetes and depression research project
- Met with Mykell Barnacle, DNP to learn more about the project
- Met with the group of NDSU faculty involved in the project
- Discussed project expectations and role as DNP student

September-November 2015:

- FQHC orientation and tour, gained computer access
- Bi-weekly CDDP meetings with NDSU faculty to develop the CDDP
- Initial meeting with FQHC director, CEO, COO, CMO and clinical director to obtain buy in and approval of the CDDP
- Met with IT at FQHC to discuss ways to run reports and obtain data
- Met at FQHC to educate and train providers and RN's, gather ideas and suggestions, obtain buy-in
- Developed dissertation proposal

December 2015

- CDDP meeting
- Proposal meeting
- Met at FQHC to train LPN's, also meet with RN case managers and clinical director

January 2016

- Submitted IRB application, received IRB approval

February 2016

- Distributed pre-implementation surveys to FQHC providers and staff

- CDDP commenced
- Data collection began

March-April 2016

- Checked in with FQHC staff to ask about any problems or suggestions
- Data collection
- Initial poster presentation

May-July 2016

- Checked in with FQHC staff to discuss any CDDP problems or suggestions
- Data collection

August 2016:

- Checked in with FQHC staff to discuss any CDDP problems or suggestions
- CDDP meeting
- Patients began to reach six-month enrollment mark, 2nd PAM survey administered
- Distributed post-implementation surveys

September-December 2016

- Checked in with FQHC staff to discuss any CDDP problems or suggestions
- Gathered post-implementation surveys
- CDDP meeting
- Data collection

January 2017

- Meeting at FQHC
- Data collection ended
- Met with committee chair to discuss dissertation progress

February 2017

- Compiled and analyzed data

March 2017

- Final poster presentation
- Final dissertation written
- Held CDDP meeting to review & discuss data
- Dissertation defense

Project Resources

The greatest resource for the project was the time and efforts of the CDDP team, as well as the student practice-improvement project leader. The project leader was involved in dispensing pre- and post-implementation satisfaction surveys to FQHC staff, providers and administration, as well as trending patient activation data obtained throughout the project. Members of the dissertation committee also volunteered their time to offer suggestions and feedback to the project leader on any necessary changes to the dissertation. Staff, providers and administrators of the FQHC also sacrificed their time to assist with implementation of the project. The CDDP team applied for and obtained a grant to help defray any costs of paper supplies, printing, and training that occurred as part of the practice improvement process.

Protection of Human Subjects

Involvement and Characteristics of Subjects

The Comprehensive Diabetes and Depression Program included patients with type 2 diabetes at Family Health Care ranging from 45-75 years of age that scored a 10 or higher on the PHQ-9 questionnaire. The sample of patients was a convenience sample up to the first 100 patients with diabetes to enroll in the CDDP at the FQHC. In addition to this population, the

practice-improvement project, as part of the CDDP, included administration, providers and staff who were employed at the FQHC. Following suit with traditional medical research, participation in the CDDP was voluntary and confidential.

Potential Risks

Potential hazards of the practice-improvement project included possible harm or discomfort to CDDP participants' privacy and psychological well-being. The practice-improvement project leader, as well as members of the CDDP, had access to patients' ethnicity, insurance status, gender, weight, height, age, form of treatment, level of service, economic status, outcomes data (PHQ-9, HbA1c), duration of diagnosed DM, care provided in the past 12 months, fasting blood glucose, blood pressure, lipid profile, co-morbidities, activity level, smoking status, and other pharmacotherapy information to be used throughout the project. The data was required to describe patient care for diabetic patients with co-morbid depression, and identify potential differences between subpopulations of these patients. However, these potential risks were minimized by assuring participants that no personal identifiers existed in the patient data stored electronically at the FQHC and the data was secured by password protection by the principle investigator of the CDDP. Any paper copies that were generated had all identifiers removed or were stored in a locked file. Potential risks for FQHC administration, providers and staff included possible emotional or psychological effects. Staff received a cover letter explaining the extent of the practice-improvement project and were asked to take a pre and post-implementation survey. The cover letter stated that completing the pre and post-implementation surveys signified their consent to participate in the project.

Recruitment and Informed Consent

Administering a PHQ-9 questionnaire to all type 2 diabetic patients was the entry point for the project. If the patient scored a 10 or higher, they were invited to join the program based on provider discretion. Advertisements in the FQHC waiting rooms and exam rooms welcomed type 2 diabetic patients to inquire about the program and to see if they qualified. The clinical pharmacist obtained informed consent at the first follow up visit after the initial primary care provider (PCP) visit. Medically trained translators were available at the FQHC and informed consent was verbally translated into the patient's primary language as necessary. A translated short form was also used to obtain consent from non-English-speaking participants.

Protection Against Risk

Patients who were not able to make their own medical decisions or understand, comprehend, and sign the informed consent for any reason were excluded from participation in the program. Patients were able to withdraw their consent at any time throughout the study. If a patient experienced any emotional distress throughout their enrollment in the program, their primary care provider and clinical pharmacist were available to counsel them, including explaining their right to withdraw from the program. In addition, the FQHC was a comprehensive clinic that was fully capable to provide medical care to any patient who may have unexpected experiences. Although the project leader and members of the CDDP team frequently audited records to ensure accuracy and consistency of data entry, patient information was protected at all times. Any identifying patient information was removed and destroyed and/or was kept in a locked box in the CDDP principal investigator's office, to protect patients' personal information and identities.

Potential Benefits of the Project

There were many potential direct and indirect benefits of the practice-improvement project, encompassed within the CDDP. The direct beneficiaries of the project were the 16 diabetic patients with co-existing depression that enrolled in the CDDP. The anticipated outcome was that quality of life and health outcomes among diabetic patients with depression would improve, and adverse outcomes related to the burden of disease would decrease. Implementing a collaborative diabetic and depression management program also had the potential to improve patient activation and self-efficacy. A potential indirect benefit of the project was an increase in job satisfaction in FQHC providers and staff by working at the top of their scope of practice and witnessing an improvement in patient outcomes and care.

Importance of the Knowledge to Be Gained

Once the CDDP was thoroughly implemented at the FQHC and demonstrated an improvement in depressive symptoms and glycemic control among diabetics, the clinic could potentially fund and implement the model as the standard of care for other areas of the clinic to improve the overall health of the population served. Program participants assisted in adding to the amount of awareness regarding models for managing diabetes in North Dakota clinics, which could also result in improved approaches towards caring for patients with chronic disease as well as improved patient outcomes.

Inclusion of Women, Minorities and Children

Patients between the ages of 45-75 years old were recruited to be CDDP participants. The only data that was obtained from the CDDP, for the sole purpose of the practice-improvement project, was patient activation data pre-implementation and six months post-implementation.

Women and minorities were invited to participate in the project; however, children and pregnant women were excluded from the CDDP.

The second component of the practice-improvement project was to educate and train the FQHC administrators, providers and staff on the CDDP process. The inclusion of women and minorities was allowed within the practice-improvement project as both women and/or minorities were employed at Family Health Care as either an administrator, provider, and/or staff member and received the education and training of the CDDP, however children were excluded. The goal of the process improvement project was to educate adult healthcare providers and staff on the importance of depression screening in diabetic patients and assist them with implementing a sustainable and comprehensive care model.

Institutional Review Board Approval

Approval for protocol #PH16166 was received from the North Dakota State University Institutional Review Board (Appendix A) on January 25, 2016. This practice-improvement project was certified as exempt under category #2b and IRB certification expires on January 24, 2019.

Methods

Although the CDDP didn't launch until February 2016, meetings and discussion began February 2015. Various meetings were held throughout all stages of the project. During development of the program, the project leader met with key stakeholders from the FQHC numerous times to hear any concerns or feedback regarding the proposed project. Immediately before the CDDP was implemented, pre-implementation surveys were administered to the FQHC administration, providers and staff to assess their views on the CDDP. Once the CDDP began, nursing staff and providers identified patients with type 2 diabetes and administered a PHQ-9 to

them at every visit, if not previously completed within the last 2 weeks. Diabetic patients who scored a 10 or greater on the PHQ-9 were identified by either nurses or providers and recruited to participate in the CDDP. Nursing staff ensured a referral to the clinical pharmacist was placed to inform them the patient met inclusion criteria. Patients occasionally saw the clinical pharmacist on the same day they were referred to the CDDP. Otherwise, the referral was sent to the FQHC referral department, an appointment was scheduled and a letter was mailed to the patient informing them of their appointment date and time.

The project leader met with key stakeholders again at 1, 2, 3, and 6 months post-implementation to assess the need for any changes with the current project. After several months, an attempt was made to recruit more patients. Following the PDSA cycle, the recruitment process was changed by sending a letter to patients informing them of the referral and asking them to call and schedule an appointment with the clinical pharmacist. Further PDSA review led to another process change in an attempt to recruit more patients. Following referral to the CDDP, a phone call was made to the patients to inform them of the referral and asking them to schedule an appointment with the clinical pharmacist over the phone. Patients were administered a PAM survey at enrollment into the program and six months later. Patient surveys were de-identified and coded in order to preserve confidentiality. The sample size totaled sixteen patients after one year of CDDP implementation.

Six months after the CDDP began, the FQHC administration, providers and nurses completed a post-implementation survey to assess their current views of the CDDP and compare results to the initial surveys. One year after the project started, IT personnel reports showed the number of patients referred to the clinical pharmacist during the year the CDDP was implemented as well as the year prior to project implementation. The project leader performed

chart reviews on these patients to determine if the CDDP resulted in more patients with type 2 diabetes seeing the clinical pharmacist and CDE. The data obtained from the surveys and reports will be discussed further in results and discussion.

CHAPTER 5. EVALUATION

The “study” portion of the PDSA cycle was carried out in the evaluation portion of the project. The data from the project were evaluated for any unintended results, surprises or achievements, and to ultimately determine if the project objectives were met.

Objective One

Educate the Family Health Care providers and staff regarding the importance of depression screening, detection, and management in all patients with type 2 diabetes.

As part of the CDDP, the PHQ-9 questionnaire was administered to all patients with type 2 diabetes, along with an algorithm for staff to guide diabetes management and the referral process for collaborative care services. Satisfaction surveys were distributed to the FQHC administration, providers and staff at CDDP initiation. These surveys sought to understand any concerns the staff had and the anticipated ease of implementation of the project. The surveys consisted of a number of questions with responses measured on a Likert scale, as well as an opportunity for staff to provide some qualitative comments. Feedback from FQHC administration, staff and providers was utilized to assist in making the CDDP a seamless process for the clinic and the patients.

Objective one was evaluated by administering the same surveys to administration, providers and staff again after six months into the project. The project leader also met with the FQHC nurses and providers 1, 2, 3, and 6 months after implementation to elicit any suggestions or concerns regarding the project. The pre- and post-implementation satisfaction scores were also compared with the hope that overall staff satisfaction and confidence in the implementation process would improve and staff would feel empowered and motivated to sustain the CDDP long term. Objective one was also evaluated based on the number of referrals made to the clinical

pharmacist and CDE during the first year of the CDDP, and compared to the number of referrals made one year prior to implementation of the project, in order to portray the level of staff and provider buy-in and support for the program. See Appendix D-I for pre- and post-implementation administration, provider, and staff surveys, and Figure 4 for a comparison of the clinical pharmacist referrals.

Objective Two

Integrate the Comprehensive Diabetes and Depression Program into the FQHC's daily practice.

The desire was to make the referral process more streamlined and systematic, as well as sustainable. The numbers of referrals made to the clinical pharmacist were measured for one year prior to the implementation of the project and one year after project commencement. Any suggestions or concerns were also elicited from the FQHC nurses and providers 1, 2, 3 and 6 months after implementation. The objective was evaluated by key stakeholders' feedback, comparing the number of patient referrals to the clinical pharmacist, as well as the number of patients who saw the diabetes educator and were enrolled in the CDDP. (See Figure 4).

Objective Three

Improve patient activation and self-efficacy.

Patient activation was measured using the Patient Activation Measure (PAM), the gold standard for measuring patient activation. According to Insignia Health's website (2014), the developers of PAM, "each point increase in PAM score correlates to a 2% decrease in hospitalization and 2% increase in medication adherence." For the purpose of this practice-improvement project, the PAM was administered to patient participants at the time of enrollment in the program and six months after enrollment. The desired outcome was that through visits

with collaborative care staff and motivational interviewing, patients would realize and identify their own innate values and goals to encourage a health behavior change through improved nutrition and eating behaviors and help patients explore and resolve any uncertainties about these changes in behaviors. Objective three was evaluated by comparing patients' initial PAM scores to PAM scores six months after enrollment in the CDDP (see Appendix L).

CHAPTER 6. RESULTS

This practice-improvement project consisted of three main parts. Based upon current evidence-based research, all patients with type 2 diabetes need to be routinely screened for depression. Qualitative and quantitative data were collected regarding the perceptions of the FQHC providers, administration and staff on their satisfaction with the current level of care for patients with type 2 diabetes, as well as the proposed CDDP. The initial results were compared with survey responses six months after implementation of the CDDP to assess if their perceptions had changed.

The second part of the project was to calculate the number of referrals made to the clinical pharmacist, as well as the number of patients who saw the CDE and were enrolled in the CDDP during the first year of the project. The number of referrals were compared to the number of referrals in the previous year and assess the percent of change. The final component of the project was to assess patient activation and self-efficacy at the beginning of the program. Comparisons were made of patients' initial PAM scores to their PAM scores after six months to determine if enrollment in the CDDP increased patient activation.

As previously discussed, FQHC monitors UDS quality metrics set forth by HRSA, as well as to maintain their level three Patient Centered Medical Home (PCMH) certification. The FQHC's goal for PCMH was to have 80% of their diabetes patients maintain an A1C less than 9.0. While the FQHC quality metrics weren't intended to evaluate the success of the CDDP, the results are worth noting. Although the clinic still did not meet their goal, the statistics improved from 2015 to 2016 (see Table 1 below).

Table 1

Percentage of patients with AIC <9

	2015	2016	%
Quarter 1	56%	55%	-1%
Quarter 2	50%	67%	17%
Quarter 3	54%	78%	24%
Quarter 4	57%	75%	18%

Note. FQHC Quality Metrics Goal $\geq 80\%$.

Pre- and Post-Implementation Surveys

Specific pre-implementation surveys were distributed to three cohorts: FQHC administrators, providers and staff, on February 1, 2016. Eight nurses, six providers, and three administrative staff completed their initial respective surveys, however, only four nurses, three providers, and two administrative staff completed their six-month post-implementation surveys. The project leader also met with key stakeholders at 1, 2, 3, and 6 months post-implementation to elicit any feedback, comments or concerns with the project. The following graphs (Figures 1, 2 and 3) show the comparison of the pre and post-implementation surveys for each cohort.

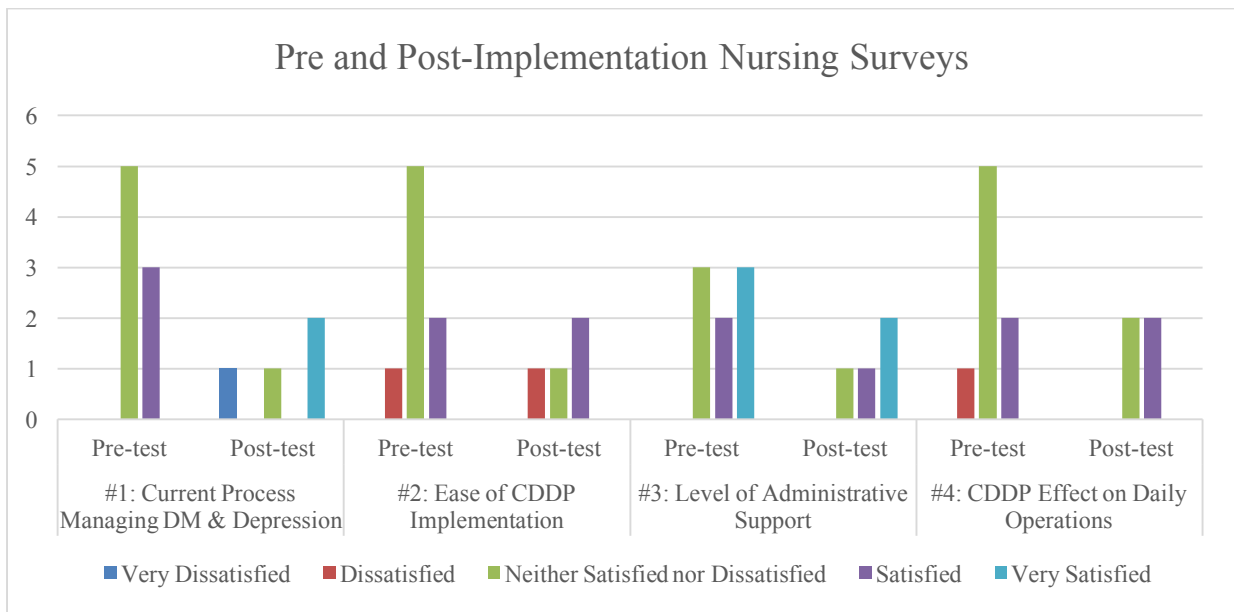


Figure 1. Pre and post-implementation nursing surveys.

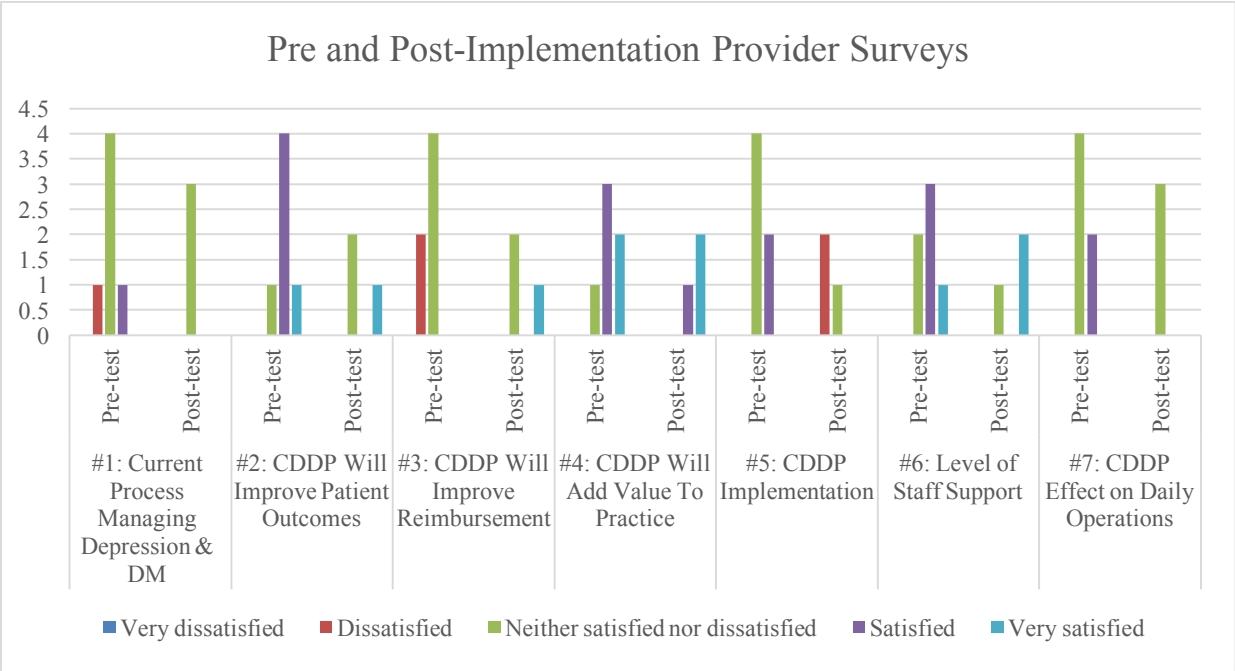


Figure 2. Pre and post-implementation provider surveys.

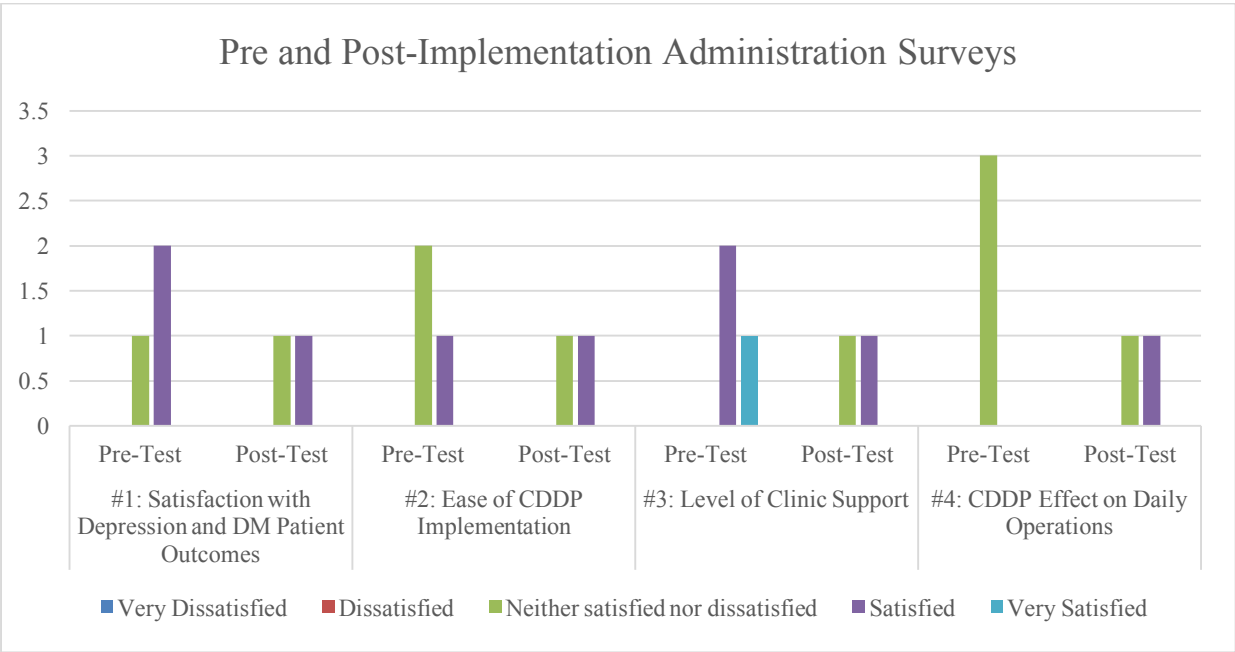


Figure 3. Pre and post-implementation administration surveys.

All three cohorts were also asked to make any suggestions or comments on their pre- and post-surveys regarding the CDDP. Only one comment was made on an administration post-implementation survey and it was that “IT setup was easy.” Comments made by providers on their initial surveys included concern for: “patient resistance through denial or feeling overwhelmed by self-management, patient resistance due to transportation and finance issues, lack of reimbursement, use of more nursing time, no show rates, sustainability, collaboration and coordination of care, and time increase during patient visits.”

Provider comments made on the six-month post implementation survey included: “patients are referred but often don’t follow through or show up for pharmacy visits, high no show rates and patients don’t tend to keep their appointments.” Positive provider comments on post-implementation surveys include: “noticed improved collaboration, project has potential value if patients are able to keep their appointments, good staff collaboration.” Provider recommendations on post-implementation surveys include: “there needs to be more provider “buy-in” so patients are more informed of the benefit and importance that the program provides,” and a suggestion to “provide follow up with patients to encourage them to keep appointments.”

Pre-implementation nursing concerns included: “time, more time added to chart prep, limited rooming time, increased time having to enter referrals, sustainability, patient resistance to change, patients not wanting to fill out the PHQ-9, and patients not understanding the purpose of the program.” Six-month post implementation nursing comments were: “some patients got upset when they answered ‘no’ to the initial depression screening question and still had to do the PHQ-9, and few patients had a PHQ-9 of 10 or greater.” Also, when the project leader met with key stakeholders at 1, 2, 3, and 6 months post-implementation, the feedback received at each interval

was positive. Staff members said the project implementation was easy. They also commented that the project didn't seem to add any additional prep time to their day and denied any concerns.

Initial Chart Review

IT created a report with a list of all referrals made to the clinical pharmacist between February 1, 2015 and January 31, 2016, the year prior to the start of the CDDP. A chart review was conducted by the project leader to determine what the patients were referred for, how many of these patients had type 2 diabetes, a diagnosis of depression, a PHQ-9 on file, a PHQ-9 of 10 or higher, and whether they saw the CDE or clinical pharmacist, or if they cancelled or no showed their appointment. Twenty-three patients had type 2 diabetes and eight out of the twenty-three patients met criteria for and could benefit from the upcoming CDDP.

Final Chart Review

Table 2

Percentage of patients referred to pharmacy pre and post-CDDP

	2/1/15-1/31/16	2/1/16-1/30/17	%
Referred to pharmacist	23	57	147.8%
Referred for DM/CDDP	21.7%	65%	43.3%
Saw diabetic educator	8.7%	14%	5.3%
Qualified for CDDP	n/a	73.7%	n/a
Saw pharmacist	75%	40.5%	-34.5%
Later enrolled in CDDP	2	n/a	n/a
Qualified and enrolled	n/a	38.1%	n/a
Never saw pharmacist	25%	59.5%	34.5%
No PHQ-9 on file	26%	8.8%	-17.2%
PHQ-9 <10	34.8%	12.3%	-22.5%

Another report was created by IT with a list of all referrals made to the clinical pharmacist between February 1, 2016 and January 31, 2017, the year after the start of the CDDP. The project leader conducted another chart review to determine what the patients were referred

for, how many of these patients had type 2 diabetes, a diagnosis of depression, a PHQ-9 on file, a PHQ-9 of 10 or higher, and whether they saw the CDE or clinical pharmacist, or if they cancelled or no showed their appointment. There was a 147.8% increase in the number of patients with type 2 diabetes who were referred to the clinical pharmacist for any reason during the first year of the CDDP compared to the year prior. Additionally, the number of patients with type 2 diabetes who were referred to the clinical pharmacist and had no PHQ-9 results on file decreased by 17.2%. The following chart compares the referral results from one year prior to the start of the CDDP to results one year after the CDDP commenced.

Initial and Final PAM Survey Results

The final component of the project was to assess patient activation and self-efficacy at the beginning of the program. Comparisons were made of patients' initial PAM scores to their PAM scores after six months to determine if enrollment in the CDDP increased patient activation. Fifteen out of the sixteen CDDP participants completed their initial PAM surveys upon enrollment into the program. To date, only one patient has completed their six-month follow up PAM survey. This patient had a decrease in their overall PAM score as well as their PAM level. See Appendix L for PAM survey results.

CHAPTER 7. DISCUSSION AND RECOMMENDATIONS

Interpretation of Results

The results of the practice-improvement project show the importance of obtaining staff and provider buy-in when implementing a new process or program. The initial sample sizes for the three FQHC cohort surveys were less than ten each. Also, the completion rate of all FQHC staff and provider post-implementation surveys was down nearly 50% compared to the initial surveys, so it was difficult to make any statistically significant determinations based on their responses to the Likert survey questions. However, there was still evidence of staff and provider buy-in for the CDDP and meeting the first project objective. Because the project leader provided education and met with providers and staff frequently on developing a practical and sustainable process, they were more invested in making the new program work. Also, if there was a process that wasn't working well, FQHC staff could provide feedback and then changes were made to improve the process.

As a result of this close working relationship, there were nearly 1.5 times more patients with type 2 diabetes referred to the clinical pharmacist for any reason during the first year of the CDDP compared to the year prior. The number of patients who were referred to the clinical pharmacist as well as the CDE also increased. One caveat to mention is the number of patients who were referred to the CDE alone were not tracked. The increase in the number of referrals to the clinical pharmacist and CDE suggests that the FQHC providers and staff understand the importance of depression screening and management in patients with type 2 diabetes, and are incorporating this into everyday practice. Also, the number of patients with type 2 diabetes that were referred to the clinical pharmacist and had no PHQ-9 results on file decreased by 17.2%. The decrease in patients without a PHQ-9 on file shows staff and provider buy-in and

understanding of the importance of depression screening, detection, and management in all patients with type 2 diabetes. These results indicate the CDDP design and implementation was successful.

The FQHC administration, providers, and staff were also invited to make comments on their surveys. On the pre-implementation surveys, staff and providers voiced concern for having little time to add anything new to their day. However, when staff completed post-implementation surveys, time was no longer listed as a barrier or concern anymore. FQHC providers and staff also provided verbal feedback during several meetings throughout the project and voiced that the project had been very easy to implement and time wasn't a barrier. Staff also commented they saw an increase and improvement in team collaboration. The most frequently listed barrier witnessed by staff and providers were the high patient no show rates. One could explore the patient no-show rate at the FQHC and compare to other local clinics to determine if these patients have a tendency to have higher no-show rates. Patient time and financial constraints could possibly contribute to higher no-show rates.

After one year of operation, only sixteen patients had enrolled in the CDDP. Many patients who were referred to the program were either classified as no show or cancelled their appointments multiple times. Other patients reported they didn't have enough time to come in for their appointment and a couple of patients qualified but moved out of the area. Six months after enrollment, patients were supposed to complete another PAM survey to assess for any change in their self-efficacy. However, one year after implementation, only one participant had done so. The small sample sizes are likely related to the high volume of patient no show rates. The sample size makes it impossible to make any determinations on patient activation, however, one could hypothesize that patients are more engaged at the beginning of the program and their drive and

determination decreases as the program progresses. The small sample sizes for both the FQHC provider and staff surveys as well as PAM surveys made it difficult to obtain meaningful outcomes data.

Nonetheless, the implementation of the project went smoothly and was successful as evidenced by the increased number of patient referrals to the clinical pharmacist and decrease in the number of patients without a PHQ-9 on file. Also, since the CDDP began, an unforeseen result occurred with the FQHC's quality metrics. FQHC patients with diabetes showed an overall improvement in A1C levels from 2015 to 2016, as listed in the results section. Since the CDDP launched on February 1, 2016, one could speculate the project may have positively impacted the FQHC quality metrics. However, the improvement in quality numbers is difficult to credit entirely to the CDDP without being able to identify and isolate these results from all other factors.

Project Limitations

After the design, implementation and evaluation of the project, several limitations were identified. The pre- and post-implementation surveys were not tested for external validity and reliability. In addition, the FQHC administration, provider and staff post-implementation surveys were completed at about half of the percentage of the pre-implementation surveys. The small sample size of the pre- and post-implementation surveys made it difficult to determine any significant meaning. Again, after one year of operation, only sixteen patients had enrolled in the CDDP and only one of those patients had completed their six-month PAM survey. The small sample size is likely related to the high volume of no show rates. Also, the number of patients who saw the CDE were only tracked if they were also referred to the clinical pharmacist. The biggest barrier and limitation identified by analyzing the data as well as the provider and staff

comments were the high number of patient no show rates as well. The small sample sizes for the FQHC surveys and PAM surveys made it difficult to obtain meaningful outcomes data. Time limitations associated with this project likely contributed to the small sample size as well.

Recommendations for Project Site

This practice-improvement project focused very little attention on patient outcomes after their enrollment and participation in the CDDP for two main reasons. A separate project at the FQHC is already underway to assess the impact of the CDDP on patient outcomes. Secondly, evidence-based research has already astoundingly shown improved patient outcomes with a comprehensive diabetes and depression program (Bogner et al., 2012; Katon et al., 2010; Taveira et al., 2011).

Enhanced patient contact through a comprehensive program is hypothesized to improve outcomes over the long-term. However, the time limitations associated with this project as well as current sample size make it difficult to obtain meaningful outcomes data. The primary goal associated with this particular area of the project involved assisting the clinic staff and providers with developing, implementing and sustaining the CDDP. Despite the lack of statistically significant data from pre- and post-implementation surveys as well as PAM surveys, qualitative results still showed improved collaboration between the FQHC staff and providers. In the future, a more qualitative approach to data collection could be considered, especially when working with a smaller sample size. Possible data collection methods to incorporate in future projects include interviews and focus groups.

Given the significant increase in patients with type 2 diabetes referred to the clinical pharmacist, as well as a decrease in the number of these patients without a PHQ-9 on file, the project was successful and the project leader recommends this project continue. The

improvement in appropriate referrals to the clinical pharmacist as well as higher rates of PHQ-9 screening among individuals with T2DM indicates that clinical providers and staff are committed to improving diabetes care. Expanding the project could potentially improve the management of patients with type 2 diabetes in other departments and clinics, as well as improve providers' practice and potential reimbursement. Providing staff with education and a thorough explanation of a project's significance, as well as rationale as to why a process is changing is essential to obtain buy-in. When staff and providers are invested, and understand a project's potential impact on patient outcomes, the project is more likely to succeed and be sustained.

Using the PDSA cycle can be very advantageous when implementing any new project. This process was followed throughout the project and resulted in several changes to the way patients were informed about their appointments. Initially, patients received a letter in the mail with a date and time for an appointment of which they were not necessarily aware. The process changed to mailing patients a letter with information on the project and invited them to call to schedule an appointment. The process transformed again so patients were called, informed of the program, and asked if they were interested in participating. When they agreed to participate, an appointment date and time that worked for them was scheduled. Finally, the patient received a letter in the mail with further information regarding the project as well as an appointment reminder. The final process change slightly improved appointment show rates. However, further research still needs to occur to discover ways to improve patient activation and decrease patient no show rates.

Several opportunities for improvement were elicited one year post-implementation. When able, providers should assess the patients' willingness to participate as well as increase the amount of patient education regarding the CDDP, at the time the referral is placed. To increase

patient engagement, every effort should be made to schedule their appointments on dates and times that work for them. Another possibility to improve patient show rates are to provide reminder phone calls to patients the day before their appointment. Finally, several patients were offered the opportunity to have a phone call visit with the clinical pharmacist. Attempting to provide any of these options have the potential to improve patient engagement and show rates.

Implications for Practice and Future Research

Results of this practice-improvement project were disseminated to several audiences in various forms. A poster was created to represent the initial project design and was presented at the College of Health Professions poster presentation in April 2016. A second poster was created to showcase data analysis and final project outcomes, and was presented again at the College of Health Professions poster presentation in March 2017. A three-minute video was also recorded to provide a synopsis of the practice-improvement project in non-technical language. The video will be kept in North Dakota State University's online repository, so it may be referred to in the future by any NDSU faculty member or student with interest in the topic and/or project.

After evaluating this project, clear benefits and barriers became evident. Providing comprehensive care to patients with type 2 diabetes, including screening for and managing depression, is essential to providing holistic care and improving patient outcomes. Information learned throughout this project will only improve the project leader's practice and potential reimbursement as a future primary care provider. In addition to keeping abreast of the latest evidence-based practice guidelines, further research related to this project should include ways to improve patient activation as well as improve patient show rates for appointments.

If able to do things differently, the project leader would have been more assertive to ensure post-implementation surveys were completed and turned in. Getting patients enrolled into the program as well as getting them to show up for their appointments was more than difficult. Another recommendation for future work with this project is to keep track of every meeting date, who was involved, what was discussed, and if anything was changed with a process or within the project.

Looking back, the project leader also would have performed more research on ways to decrease patient no show rates, in an attempt to increase the project sample size. To increase patient engagement, every effort should be made to schedule their appointments on dates and times that work for them. Another possibility to improve patient show rates are to provide reminder phone calls to patients the day before their appointment. Finally, several patients were offered the opportunity to have a phone call visit with the clinical pharmacist. Attempting to provide any of these options have the potential to improve patient engagement and show rates.

Any future DNP students who wish to continue working on this project should place an emphasis on researching ways to improve patient show rates and other means to increase their sample size. Also, conducting a six-month follow-up meeting with clinic providers and staff may help to improve the return rate of post-implementation surveys.

Application to Other Doctor of Nursing Practice Roles

The research, development, implementation, evaluation, and dissemination of this practice-improvement project supported the project leader in the development of various fundamental characteristics for the Doctor of Nursing Practice (DNP) role. A DNP prepared nurse practitioner (NP) is viewed as a leader in their field. They are known for their emphasis on health promotion and disease prevention, as well as staying up to date with continued education

and the latest guidelines and evidence-based practice. The execution of the practice-improvement project was instrumental in the development of these characteristics. The project leader was able to research the latest evidence-based practice on co-morbid diabetes and depression, assist the FQHC providers and staff with implementing the current recommendations for those patients, and therefore, achieved the main goal of this project.

REFERENCES

- American Diabetes Association. (2015). Standards of medical care in diabetes. *Diabetes Care*, 38(1).
- Barnacle, M., Strand, M.A., Werremeyer, A., Maack, B., & Petry, N. (2016). Depression screening in diabetes care to improve outcomes: Are we meeting the challenge? *The Diabetes Educator*, 42(5), 646-651.
- Bogner, H.R., Morales, K.H., de Vries, H.F., & Cappola, A. (2012). Integrated management of type 2 diabetes mellitus and depression treatment to improve medication adherence: A randomized controlled trial. *Annals of Family Medicine*, 10(1), 15-22.
- Centers for Disease Control and Prevention. (2014). National diabetes statistics report. Retrieved from <http://www.cdc.gov/diabetes/pubs/statsreport14/national-diabetes-report-web.pdf>
- Deming, W.E. (2000). *The new economics for industry, government, and education*. Cambridge, MA: The MIT Press.
- Glied, S., Herzog, K., & Frank, R. (2010). Review: The net benefits of depression management in primary care. *Medical Care Research and Review*, 67(3), 251-274.
- Goldney, R., Phillips, P., Fisher, L., Hons, B., & Wilson, D. (2004). Diabetes, depression, and quality of life. *Diabetes Care*, 27(5), 1066-1070.
- Insignia Health. (2014). Patient activation measure (PAM). Retrieved from <http://www.insigniahealth.com/products/pam-survey>
- International Diabetes Federation. (2012). *IDF Diabetes Atlas*, (5th ed.).
- Katon, W.J., Lin, E.H., Von Korff, M., Ciechanowski, P., Ludman, E.J., Young, B., ... McCulloch, D. (2010). Collaborative care for patients with depression and chronic illnesses. *New England Journal of Medicine*, 363(27), 2611-2620.

- Katon, W.J., Rutter, C., Simon, G., Lin, E.H., Ludman, E., Ciechanowski, P., ... Von Korff, M. (2005). The association of comorbid depression with mortality in patients with type 2 diabetes. *Diabetes Care*, 28(11), 2668-2672.
- Katon, W.J., Young, B.A., Russo, J., Lin, E.H., Ciechanowski, P., Ludman, E.J., & Von Korff, M.R. (2013). Association of depression with increased risk of severe hypoglycemic episodes in patients with diabetes. *Annals of Family Medicine*, 11(3), 245-250.
- Kinder, L.S., Katon, W.J., Ludman, E., Russo, J., Simon, G., Lin, E.H., ... Young, B. (2006). Improving depression care in patients with diabetes and multiple complications. *Journal of General Internal Medicine*, 21(10), 1036-1041.
- Knol, M., Twisk, J., Beekman, A., Heine, R.J., Snoek, F.J., Pouwer, F. (2006). Depression as a risk factor for the onset of type 2 diabetes mellitus: A meta-analysis. *Diabetologia*, 49(5), 837-845.
- Kroenke, K., Spitzer, R.L., & Williams, J.B. (2001). The PHQ-9: validity of a brief depression severity measure. *Journal of General Internal Medicine*, 16(9), 606–613.
- Laiterapong, N., Karter, A.J., Liu, J.Y., Moffet, H.H., Sudore, R., Schillinger, D., ... Huange, E.S. (2011). Correlates of quality of life in older adults with diabetes: the diabetes & aging study. *Diabetes Care*, 34(8), 1749–1753.
- Langley, G.L., Moen, R., Nolan, K.M., Nolan, T.W., Norman, C.L., & Provost, L.P. (2009). *The improvement guide: A practical approach to enhancing organizational performance*. (2nd ed.). San Francisco, CA: Jossey-Bass Publishers.
- Markowitz, S., Gonzalez, J.S., Wilkinson, J.L., & Safren, S.A. (2011). Treating depression in diabetes: Emerging findings. *Psychosomatics*, 52(1), 1-18.

- National Committee for Quality Assurance. (2015). NCQA updates HEDIS quality measures for 2016. Retrieved from <http://www.ncqa.org/Newsroom/NewsArchive/2015NewsArchive/NewsReleaseJuly12015.aspx>
- Osborn, C.Y., Kazak, C., & Wagner, J. (2010). Theory in practice: Helping providers address depression in diabetes care. *The Journal of Continuing Education in Health Professionals, 30*(3), 172-179.
- Pan, A., Lucas, M., Sun, Q, Van Dam, R., Franco, O., Manson, J., ...Hu, F. (2010). Bidirectional association between depression and type 2 diabetes in women. *Archives of Internal Medicine, 170*(21), 1884-1891.
- Reedy, P., Ford, D., & Dunbar, J.A. (2010). Improving the quality of diabetes care in general practice. *Australian Journal of Rural Health, 18*(5), 187-193.
- Taveira, T.H., Dooley, A.G., Cohen, L.B., Khatana, S.A., & Wu, W.C. (2011). Pharmacist-led group medical appointments for the management of type 2 diabetes with comorbid depression in older adults. *The Annals of Pharmacotherapy, 45*(11), 1346-1355.
- van Steenberg-Weijnenburg, K.M., de Vroege, L., Ploeger, R.R., Brals, J.W., Vloedveld, M.G., Veneman, T.F., ...van der Feltz-Cornelis, C.M. (2010). Validation of the PHQ-9 as a screening instrument for depression in diabetes patients in specialized outpatient clinics. *BMC Health Services Research, 10*(1), 235.

APPENDIX A. INSTITUTIONAL REVIEW BOARD APPROVAL



January 25, 2016

Dr. Mykelle Barnacle
School of Nursing

Re: IRB Certification of Exempt Human Subjects Research:
Protocol #PH16166, "Implementing a Comprehensive Diabetes and Depression Program at Family Health Care"

Co-investigator(s) and research team: Lindsay Alexander

Certification Date: 1/25/2016 Expiration Date: 1/24/2019
Study site(s): Family HealthCare, Fargo, ND
Sponsor: n/a

The above referenced human subjects research project has been certified as exempt (category # 2b) in accordance with federal regulations (Code of Federal Regulations, Title 45, Part 46, Protection of Human Subjects). This determination is based on the original protocol (received 1/19/2015) and revised information sheet (received 1/25/2016).

Please also note the following:

- If you wish to continue the research after the expiration, submit a request for recertification several weeks prior to the expiration.
- The study must be conducted as described in the approved protocol. Changes to this protocol must be approved prior to initiating, unless the changes are necessary to eliminate an immediate hazard to subjects.
- Notify the IRB promptly of any adverse events, complaints, or unanticipated problems involving risks to subjects or others related to this project.
- Report any significant new findings that may affect the risks and benefits to the participants and the IRB.

Research records may be subject to a random or directed audit at any time to verify compliance with IRB standard operating procedures.

Thank you for your cooperation with NDSU IRB procedures. Best wishes for a successful study.

Sincerely,

A handwritten signature in black ink that reads "Kristy Shirley".

Digitally signed by Kristy Shirley
DN: cn=Kristy Shirley, o=NDSU,
ou=Institutional Review Board,
email=kshirley@irb.ndsu.edu, c=US
Date: 2016.01.25 13:38:24 -0600

Kristy Shirley, CIP, Research Compliance Administrator

For more information regarding IRB Office submissions and guidelines, please consult http://www.ndsu.edu/research/integrity_compliance/irb/. This Institution has an approved FederalWide Assurance with the Department of Health and Human Services: FWA00002439.

INSTITUTIONAL REVIEW BOARD

NDSU Dept 4000 | PO Box 6050 | Fargo ND 58108-6050 | 701.231.8995 | Fax 701.231.8098 | ndsu.edu/irb

Shipping address: Research 1, 1735 NDSU Research Park Drive, Fargo ND 58102

NDSU is an EO/AA university.

APPENDIX B. LETTER OF AGREEMENT



"To provide affordable quality healthcare for every person."

301 NP Ave Fargo ND 58102
phone: 701.271.3344 • fax: 701.271.1480
www.famhealthcare.org

October 30, 2015

Brody Maack, PharmD, CTTS
Research Investigator
Assistant Professor of Practice / Pharmacy Practice
Clinical Pharmacy Specialist / Family HealthCare
School of Pharmacy, College of Health Professions
North Dakota State University
Sudro 118L, Dept 2660, PO Box 6050
Fargo, ND 58108-6050

Dear Dr. Brody Maack,

With regards to your proposed research project involving comprehensive diabetes and depression care at Family HealthCare, this letter is to inform you of permission from Family HealthCare to access the electronic medical records of the included patients using Centricity. Full access to the medical record will be granted for the entire duration of the research project. Access shall be granted with the agreement that all information shall be accessed and used in compliance with the HIPAA Privacy Rule and the Common Rule regarding research participants.

We will also work with you to support your research needs and research implementation at our site. We appreciate your interest in research with Family HealthCare, and please let me know if you have any further questions or need additional information.

Sincerely,



Patrick Gulbranson
Chief Executive Officer
Family HealthCare

Accredited by the Joint Commission



APPENDIX C. PARTICIPANT INFORMED CONSENT

NDSU

North Dakota State University

School of Nursing
1401 Albrecht Blvd
103 Sudro Hall
NDSU Dept. 2670
PO Box 6050
Fargo, ND 58108-6050
701.231.6257

Comprehensive Diabetes and Depression Program

Dear Family Health Care Providers, Administration and Staff:

My name is Lindsay Alexander, and I am a graduate student in the Doctor of Nursing Practice program at North Dakota State University. Along with clinical pharmacist Brody Maack and the NDSU team's current research study, I am conducting a practice-improvement project to improve identification, treatment, and management of major depression in the high-risk diabetic population.

You are invited to participate in this project where you will be asked to complete a survey to coincide with implementation of Brody's research study. You are also invited to repeat the survey at 6 months to assess for change. Each survey will take approximately 5-10 minutes of your time. Participation is entirely your choice, and you may change your mind or quit participating at any time, with no penalty to you. It is not possible to identify all potential risks in research procedures, but we have taken reasonable safeguards to minimize any known risks. These known risks include: emotional or psychological distress.

We aim to use a multidisciplinary approach to depression management with a high likelihood of establishing a sustainable, system-wide change in care. This project will implement a systematic approach to depression management among primarily uninsured patients. It is our hope that this project can enhance clinical practice by demonstrating improvement in overall diabetes and depression management and patient outcomes.

You may not get any benefit from being in this study, however, benefits to others are likely to include advancement of knowledge, and possible benefits to persons in the prospective subject's position.

Your confidentiality is of utmost importance to us. Any personal identifiers will be removed from your survey and coded in a way that your individual pre and post survey responses can be compared to assess the functionality and efficiency of the program. Your willingness to complete the pre and post-implementation surveys will signify your consent to participate.

If you have any questions about this project, please contact myself at 701-639-3244 or lindsay.alexander@ndsu.edu, or contact my advisor Mykell Barnacle, DNP at 701-231-7730 or mykell.barnacle@ndsu.edu

You have rights as a research participant. If you have questions about your rights or complaints about this research, you may talk to the researcher or contact the NDSU Human Research Protection Program at 701.231.8908, toll-free at 1-855-800-6717, by email at ndsu.irb@ndsu.edu, or by mail at: NDSU HRPP Office, NDSU Dept. 4000, P.O. Box 6050, Fargo, ND 58108-6050.

Thank you for your taking part in this research. If you wish to receive a copy of the results, please email Lindsay Alexander at lindsay.alexander@ndsu.edu

APPENDIX D. NURSING PRE-IMPLEMENTATION SURVEY

1. What is your current level of satisfaction with the overall process of managing depression and diabetes care at FHC?

1. Very dissatisfied
2. Dissatisfied
3. Neither satisfied nor dissatisfied
4. Satisfied
5. Very satisfied

If dissatisfied or very dissatisfied, please explain.

2. To what extent do you anticipate the ease of implementation of the comprehensive diabetes and depression program?

1. Very difficult
2. Difficult
3. Neutral
4. Easy
5. Very easy

If difficult or very difficult, please explain.

3. What do you anticipate will be the level of support from clinic administration and management regarding the implementation of the comprehensive diabetes and depression program?

1. Strongly opposed
2. Somewhat opposed
3. Neutral
4. Somewhat in favor
5. Strongly in favor

If opposed or strongly opposed, please explain.

4. How do you anticipate the implementation of the comprehensive diabetes and depression program will affect normal clinic daily operations?

1. Very negatively
2. Somewhat negatively
3. Neutral
4. Somewhat positively
5. Very positively

If very negatively or negatively, please explain.

5. Please describe any anticipated barriers you foresee with implementing the comprehensive diabetes and depression program.

Financial:

Collaboration:

Staff resistance:

Patient resistance:

Time:

Sustainability:

Other:

APPENDIX E. NURSING POST-IMPLEMENTATION SURVEY

1. What is your current level of satisfaction with the overall process of managing depression and diabetes care at FHC?

1. Very dissatisfied
2. Dissatisfied
3. Neither satisfied nor dissatisfied
4. Satisfied
5. Very satisfied

If dissatisfied or very dissatisfied, please explain.

2. How would you describe the ease of implementing the comprehensive diabetes and depression program?

1. Very difficult
2. Difficult
3. Neutral
4. Easy
5. Very easy

If very difficult or difficult, please explain.

3. To what extent was the level of support from the clinic administration and management regarding the implementation of the comprehensive diabetes and depression program?

1. Strongly opposed
2. Somewhat opposed
3. Neutral
4. Somewhat favored
5. Strongly favored

If opposed or strongly opposed, please explain.

4. To what extent did the overall implementation of the comprehensive diabetes and depression program affect normal clinic daily operations?

1. Very negatively
2. Somewhat negatively
3. Neutral
4. Somewhat positively
5. Very positively

If very negatively or negatively, please explain.

5. Please describe any barriers that were encountered with implementing the comprehensive diabetes and depression program.

Financial:

Collaboration:

Staff resistance:

Patient resistance:

Time:

Sustainability:

Other:

6. What is the likelihood you will be able to continue and sustain the comprehensive diabetes and depression program in your future practice?

1. Extremely unlikely
2. Somewhat unlikely
3. Neutral
4. Somewhat likely
5. Very likely

If extremely unlikely or somewhat unlikely, what barriers do you foresee? Please explain.

APPENDIX F. PROVIDER PRE-IMPLEMENTATION SURVEY

1. What is your current level of satisfaction with the overall process of managing depression and diabetes care at FHC?

1. Very dissatisfied
2. Dissatisfied
3. Neither satisfied nor dissatisfied
4. Satisfied
5. Very satisfied

If dissatisfied or very dissatisfied, please explain.

2. What do you feel is the likelihood that the comprehensive diabetes and depression program (CDDP) will improve your patient outcomes and quality numbers?

1. Very unlikely
2. Unlikely
3. Neither likely or unlikely
4. Likely
5. Very likely

If unlikely or very unlikely, please explain.

3. What do you feel is the likelihood that the CDDP will improve your reimbursement rates?

1. Very unlikely
2. Unlikely
3. Neither likely or unlikely
4. Likely
5. Very likely

If unlikely or very unlikely, please explain.

4. How much value do you feel the CDDP will bring to your practice?

1. No value at all
2. Very little value
3. Little value
4. Some value
5. Very much value

If no value or very little value, please explain.

5. To what extent do you anticipate the ease of implementation of the CDDP?

1. Very difficult
2. Difficult
3. Neutral
4. Easy
5. Very easy

If difficult or very difficult, please explain.

6. What do you anticipate will be the level of support from the clinic/nursing staff regarding the implementation of the CDDP?

1. Strongly opposed
2. Somewhat opposed
3. Neutral
4. Somewhat in favor
5. Strongly in favor

If opposed or strongly opposed, please explain.

7. How do you anticipate the implementation of the CDDP will affect normal clinic daily operations?

1. Very negatively
2. Somewhat negatively
3. Neutral
4. Somewhat positively
5. Very positively

If very negatively or negatively, please explain.

8. Please describe any anticipated barriers you foresee with implementing the CDDP.

Financial:

Collaboration:

Staff resistance:

Patient resistance:

Time:

Sustainability:

Other:

APPENDIX G. PROVIDER POST-IMPLEMENTATION SURVEY

1. What is your current level of satisfaction with the overall process of managing depression and diabetes care at FHC?

1. Very dissatisfied
2. Dissatisfied
3. Neither satisfied nor dissatisfied
4. Satisfied
5. Very satisfied

If dissatisfied or very dissatisfied, please explain.

2. What do you feel is the likelihood that the CDDP will improve your patient outcomes and quality numbers?

1. Very unlikely
2. Unlikely
3. Neither likely or unlikely
4. Likely
5. Very likely

If unlikely or very unlikely, please explain.

3. What do you feel is the likelihood that the CDDP will improve your reimbursement rates?

1. Very unlikely
2. Unlikely
3. Neither likely or unlikely
4. Likely
5. Very likely

If unlikely or very unlikely, please explain.

4. How much value do you feel the CDDP will bring to your practice?

1. No value at all
2. Very little value
3. Little value
4. Some value
5. Very much value

If no value or very little value, please explain.

5. How would you describe the ease of implementing the comprehensive diabetes and depression program?

1. Very difficult
2. Difficult
3. Neutral
4. Easy
5. Very easy

If difficult or very difficult, please explain.

6. To what extent is the level of support from the clinic/nursing staff regarding the implementation of the comprehensive diabetes and depression program?

1. Strongly opposed
2. Somewhat opposed
3. Neutral
4. Somewhat in favor
5. Strongly in favor

If opposed or strongly opposed, please explain.

7. To what extent is the implementation of the comprehensive diabetes and depression program affecting normal clinic daily operations?

1. Very negatively
2. Somewhat negatively
3. Neutral
4. Somewhat positively
5. Very positively

If very negatively or negatively, please explain.

8. Please describe any barriers encountered with implementing the comprehensive diabetes and depression program.

Financial:

Collaboration:

Staff resistance:

Patient resistance:

Time:

Sustainability:

Other:

9. What is the likelihood you will be able to adopt and sustain the CDDP in your practice?

1. Extremely unlikely
2. Somewhat unlikely
3. Neutral
4. Somewhat likely
5. Very likely

If extremely unlikely or somewhat unlikely, what barriers do you foresee? Please explain.

10. What suggestions do you have to improve the CDDP program and process?

APPENDIX H. ADMINISTRATION PRE-IMPLEMENTATION SURVEY

1. What is your current level of satisfaction with depression and diabetes patient outcomes at FHC?

1. Very dissatisfied
2. Dissatisfied
3. Neither satisfied nor dissatisfied
4. Satisfied
5. Very satisfied

If dissatisfied or very dissatisfied, please explain.

2. How do you anticipate the ease of implementation for the comprehensive diabetes and depression program (CDDP)?

1. Very difficult
2. Difficult
3. Neutral
4. Easy
5. Very easy

If difficult or very difficult, please explain.

3. What do you anticipate will be the level of support from the clinic staff regarding the implementation of the CDDP?

1. Strongly opposed
2. Somewhat opposed
3. Neutral
4. Somewhat in favor
5. Strongly in favor

If somewhat or strongly opposed, please explain.

4. How do you anticipate the implementation of the CDDP will affect normal clinic daily operations?

1. Very negatively
2. Somewhat negatively
3. Neutral
4. Somewhat positively
5. Very positively

If very negatively or negatively, please explain.

APPENDIX I. ADMINISTRATION POST-IMPLEMENTATION SURVEY

1. What is your current level of satisfaction with depression and diabetes patient outcomes at FHC?

1. Very dissatisfied
2. Dissatisfied
3. Neither satisfied nor dissatisfied
4. Satisfied
5. Very satisfied

If dissatisfied or very dissatisfied, please explain.

2. How would you describe the ease of implementing the CDDP?

1. Very difficult
2. Difficult
3. Neutral
4. Easy
5. Very easy

If very difficult or difficult, please explain.

3. What do you feel was the level of support from the clinic staff regarding the implementation of the CDDP?

1. Strongly opposed
2. Somewhat opposed
3. Neutral
4. Somewhat favored
5. Strongly favored

If somewhat or strongly opposed, please explain.

4. How did the overall implementation of the CDDP affect normal clinic daily operations?

1. Very negatively
2. Somewhat negatively
3. Neutral
4. Somewhat positively
5. Very positively

If very negatively or somewhat negatively, please explain.

5. What is the likelihood your organization will be able to adopt and sustain the CDDP in the future?

6. Extremely unlikely
7. Somewhat unlikely
8. Neutral
9. Somewhat likely
10. Very likely

If extremely unlikely or somewhat unlikely, what barriers do you foresee? Please explain.

APPENDIX J. PAM SURVEY RESULTS

Pt #	PAM 10 Score	Level	PAM 1	PAM 2	PAM 3	PAM 4	PAM 5	PAM 6	PAM 7	PAM 8	PAM 9	PAM 10
1	59.3	3	4	3	4	3	4	4	2	2	3	2
2	50	2	3	3	3	3	3	3	2	3	3	2
3	68.9	3	3	4	3	4	4	4	3	3	3	3
4	59.3	3	4	3	3	4	4	3	2	3	2	3
6	65.8	3	4	4	3	4	3	3	3	3	3	3
7	42.9	1	4	4	4	2	3	2	1	1	3	1
8	72.1	3	4	4	3	3	4	3	3	4	3	4
9	59.3	3	3	3	3	3	3	3	3	3	3	4
10	47.4	2	4	4	3	3	3	3	1	2	2	2
11	52.9	2	4	4	2	3	3	3	2	3	3	2
12	56	3	4	4	3	4	4	3	1	3	2	2
13	79.2	4	4	4	4	4	4	4	3	3	3	4
14	50	2	4	3	2	3	4	2	3	3	2	2
15	68.9	3	4	4	4	4	4	4	2	4	2	2
16	59.3	3	3	3	2	2	3	3	4	4	5	4
Avg	59.42	2.67	3.73	3.6	3.07	3.27	3.53	3.13	2.33	2.93	2.8	2.67
Low	42.9	1	3	3	2	2	3	2	1	1	2	1
High	79.2	4	4	4	4	4	4	4	4	4	5	4
6 Mo. PAM												
4	50	2	3	3	1	3	3	3	3	3	3	3
5: No PAM on file												

APPENDIX K. PATIENT HEALTH QUESTIONNAIRE

PATIENT HEALTH QUESTIONNAIRE (PHQ-9)

NAME: _____ DATE: _____

Over the *last 2 weeks*, how often have you been bothered by any of the following problems?
(use “✓” to indicate your answer)

	Not at all	Several days	More than half the days	Nearly every day
1. Little interest or pleasure in doing things	0	1	2	3
2. Feeling down, depressed, or hopeless	0	1	2	3
3. Trouble falling or staying asleep, or sleeping too much	0	1	2	3
4. Feeling tired or having little energy	0	1	2	3
5. Poor appetite or overeating	0	1	2	3
6. Feeling bad about yourself—or that you are a failure or have let yourself or your family down	0	1	2	3
7. Trouble concentrating on things, such as reading the newspaper or watching television	0	1	2	3
8. Moving or speaking so slowly that other people could have noticed. Or the opposite—being so fidgety or restless that you have been moving around a lot more than usual	0	1	2	3
9. Thoughts that you would be better off dead, or of hurting yourself in some way	0	1	2	3

add columns: + +

(Healthcare professional: For interpretation of TOTAL, please refer to accompanying scoring card.) **TOTAL:**

10. If you checked off *any* problems, how *difficult* have these problems made it for you to do your work, take care of things at home, or get along with other people?

Not difficult at all _____
Somewhat difficult _____
Very difficult _____
Extremely difficult _____

PHQ-9 is adapted from PRIME MD TODAY, developed by Drs Robert L. Spitzer, Janet B.W. Williams, Kurt Kroenke, and colleagues, with an educational grant from Pfizer Inc. For research information, contact Dr Spitzer at rls8@columbia.edu. Use of the PHQ-9 may only be made in accordance with the Terms of Use available at <http://www.pfizer.com>. Copyright ©1999 Pfizer Inc. All rights reserved. PRIME MD TODAY is a trademark of Pfizer Inc.

ZT274388

APPENDIX L. PATIENT ACTIVATION MEASURE



Below are some statements that people sometimes make when they talk about their health. Please indicate how much you agree or disagree with each statement as it applies to you personally by circling your answer. Your answers should be what is true for you and not just what you think the doctor wants you to say.

If the statement does not apply to you, circle N/A.

1. When all is said and done, I am the person who is responsible for taking care of my health	Disagree Strongly	Disagree	Agree	Agree Strongly	N/A
2. Taking an active role in my own health care is the most important thing that affects my health	Disagree Strongly	Disagree	Agree	Agree Strongly	N/A
3. I know what each of my prescribed medications do	Disagree Strongly	Disagree	Agree	Agree Strongly	N/A
4. I am confident that I can tell whether I need to go to the doctor or whether I can take care of a health problem myself.	Disagree Strongly	Disagree	Agree	Agree Strongly	N/A
5. I am confident that I can tell a doctor concerns I have even when he or she does not ask.	Disagree Strongly	Disagree	Agree	Agree Strongly	N/A
6. I am confident that I can follow through on medical treatments I may need to do at home	Disagree Strongly	Disagree	Agree	Agree Strongly	N/A
7. I have been able to maintain (keep up with) lifestyle changes, like eating right or exercising	Disagree Strongly	Disagree	Agree	Agree Strongly	N/A
8. I know how to prevent problems with my health	Disagree Strongly	Disagree	Agree	Agree Strongly	N/A
9. I am confident I can figure out solutions when new problems arise with my health.	Disagree Strongly	Disagree	Agree	Agree Strongly	N/A
10. I am confident that I can maintain lifestyle changes, like eating right and exercising, even during times of stress.	Disagree Strongly	Disagree	Agree	Agree Strongly	N/A

Insignia Health. "Patient Activation Measure; Copyright © 2003-2011, University of Oregon. All Rights reserved."
Contact Insignia Health at www.insigniahealth.com

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APPENDIX M. PAM LICENSE PACKAGE



NON-EXCLUSIVE COPYRIGHT LICENSE

License Fee. As good and valuable consideration for the license granted herein, you shall pay to Insignia Health, LLC ("Insignia") the payment as shown in your shopping cart above (the "License Fee").

License Terms. Subject to the terms of this Agreement, you have the right to administer the PAM Materials (as defined herein) to up to the number of survey participants selected in your shopping cart and as defined below ("Participants"), beginning on the date of your online license purchase ("Effective Date") and ending twelve (12) months thereafter ("End Date").

DEFINITIONS

"PAM Materials" means the Patient Activation Measure (PAM) survey tool, the PAM survey scoring table; four different levels in which to classify people participating in a PAM survey, guidelines for responding to people in each level, benchmark score and level data and if selected, the Coaching for Activation online nurse/coach guidance, PAM online survey administration tools, and/or online e-learning tools.

A "Participant" is defined as any individual consumer or potential consumer of health care services who is provided access to the PAM Materials, up to the maximum number of participants you selected in your shopping cart.

TERMS AND CONDITIONS

This Agreement is a grant of a non-exclusive, non-transferable copyright license to use the PAM Materials for the purpose of assessing and modifying the level of health engagement of Participants, subject to the terms and restrictions set forth herein (the "Agreement"). Use of the PAM Materials for any purpose other than those described herein is expressly prohibited without the written consent of Insignia. For clarity, the rights granted herein DO NOT include the right to:

- Copy, reproduce, publish, disseminate, or otherwise publicly display the PAM Materials or any part thereof outside of the scope of this Agreement;
- create derivative works or make alterations to the PAM Materials or any part thereof;
- use the PAM Materials or any part thereof, including but not limited to the PAM survey, to develop, validate or optimize a new or existing assessment of consumer health engagement, motivation, activation or similar assessment tool;
- sublicense the PAM Materials; or
- reverse engineer, reverse translate, decompile, disassemble or in any manner decode the PAM Materials or any part thereof, or any of the algorithms contained therein.

1. **Rights Granted.** Insignia hereby grants to you a non-exclusive, personal and non-transferable right to reproduce, distribute, and display the PAM Materials for the purpose of administering the PAM survey and collecting information related thereto to no more than the number of Participants defined by your on-line Participant range selection. Using PAM with Participants beyond that Participant range is a violation of this Agreement.

2. Your Obligations.

2.1. You agree not to alter, add, change, or remove any identification marks, including copyright or trademark notices, from the PAM Materials. You further agree that if you reference the PAM Materials to Participants in written materials, publish any studies or findings relating to your use of the PAM Materials, or in any other way publicize your use of the PAM Materials, you shall refer to the PAM survey as the "Patient Activation Measure®" or "PAM®." You further agree to obtain any consents from Participants that are necessary to allow the PAM Materials to be provided to them.

2.2. Reporting Upon End Date.

(i) You shall provide to Insignia a written report in an electronic format approved by Insignia identifying the number of Participants who were given the PAM survey during the term of this Agreement. You further agree to maintain records supporting such report(s) for at least one (1) year following submission; and



(II) Subject to the confidentiality requirements of Section 3, you agree to share with Insignia non-personally identifiable, individual data ("Data") generated from your use of the PAM Materials. The Data shared shall include individual level data records containing answers to each of the PAM questions, and, if captured, (i) demographic variables, health status and condition variables, (ii) specific outcome variables including health behaviors, self-management behaviors and whether patients using PAM improved the self-management aspects of their health care, and (iii) the PAM Materials' effect on or relationship to patient health care utilization and costs. Such Data shall be reported to Insignia at least annually in the electronic format agreed upon by the parties to this Agreement. You hereby grant Insignia a royalty free, perpetual license to use such Data for its product improvement efforts.

3. Confidentiality. Both you and Insignia each acknowledge that either party may receive confidential and proprietary information of the other party including, without limitation, (i) technical information, including functional and technical specifications, analysis, research, processes, computer programs, job control language, communications scripts, methods, ideas, "know how" and the like; (ii) business information, including sales and marketing research, materials, plans, provider and beneficiary demographics, provider-specific information and the like; (iii) electronic media claims data in accordance with the Federal Privacy Act of 1974, as amended; (iv) the PAM Materials and all algorithms utilized by Insignia in the provision of the services set forth in this Agreement; (v) Data; and (vi) other information designated in writing by the owner as confidential at the time of delivery of such information to the recipient (collectively "Confidential Information").

Except for Protected Health Information (as defined by the Health Insurance Portability and Accountability Act of 1996, Public Law 104-191 (HIPAA)), Confidential Information of a party hereto shall not include information that: (a) becomes generally available to the public other than as the result of unauthorized disclosure by the recipient; (b) is independently derived by the recipient without the aid, application or use of the disclosing party's Confidential Information; or (c) was received by the recipient on a non-confidential basis prior to receipt from the disclosing party from a third-party lawfully possessing and lawfully entitled to disclose such information.

4. Covenant Not to Disclose. Except as provided in Section 2.2, each party receiving Confidential Information from the other party hereby agrees that it shall not use, commercialize or disclose such Confidential Information to any person or entity, without prior written permission of the non-disclosing party. Each party shall use at least the same degree of care in safeguarding the other party's Confidential Information as it uses in safeguarding its own Confidential Information.

5. Ownership of the PAM Materials. The State of Oregon, acting by and through the State Board of Higher Education on behalf of the University of Oregon, owns the copyright, title, and other related rights in and to the Patient Activation Measure ("PAM") and related guidance (collectively referred to as the "PAM Guidance") developed by Dr. Judith Hibbard and others. Insignia is the exclusive licensee of certain rights related to the PAM Guidance and is the owner of all trademark rights associated with this technology. All rights not otherwise granted to you in this agreement are reserved by Insignia and/or the University of Oregon.

6. Indemnification and Limitation of Liability.

6.1. You agree to indemnify and hold harmless both Insignia and the University of Oregon and their respective members, directors, officers, governing board members, agents, employees, students, volunteers, and assigns against any and all claims, demands, damages, liability, losses, causes of action, costs and expenses arising out of or in any way related to the use, reproduction, distribution or public display of the PAM Materials by you or any of your Participants, or your failure to comply with applicable privacy laws.

6.2. INSIGNIA AND THE UNIVERSITY OF OREGON PROVIDE ACCESS TO THE PAM MATERIALS ON AN "AS IS, WITH ALL DEFECTS" BASIS. NEITHER INSIGNIA NOR THE UNIVERSITY OF OREGON MAKE ANY REPRESENTATIONS OR WARRANTIES, EXPRESS OR IMPLIED. BY WAY OF EXAMPLE, BUT NOT LIMITATION, INSIGNIA AND THE UNIVERSITY OF OREGON MAKE NO REPRESENTATIONS OR WARRANTIES OF MERCHANTABILITY OR FITNESS FOR ANY PARTICULAR PURPOSE (EVEN IF INSIGNIA OR THE UNIVERSITY OF OREGON KNOW OF SUCH PURPOSE), OR THAT THE USE OF THE PAM MATERIALS WILL NOT INFRINGE ANY PATENTS, COPYRIGHTS, TRADEMARKS OR OTHER RIGHTS OF THIRD PARTIES. YOU HEREBY AGREE TO SAVE, HOLD HARMLESS, DISCHARGE AND RELEASE INSIGNIA AND THE UNIVERSITY OF OREGON AND ALL OF THEIR RESPECTIVE AGENTS, SERVANTS, EMPLOYEES AND VOLUNTEERS, FROM ANY AND ALL LIABILITY, CLAIMS, CAUSES OF ACTIONS, DAMAGES OR DEMANDS OF ANY KIND AND NATURE WHATSOEVER WHICH MAY ARISE FROM OR IN CONNECTION WITH YOUR USE OF THE PAM MATERIALS.



7. Term and Termination.

7.1. The term of this Agreement shall commence on the Effective Date and shall continue until the End Date or until terminated in accordance with this Section 7, whichever is earlier ("Term").

7.2. Insignia may terminate this Agreement and the license granted herein for Insignia's convenience, by providing not less than ten (10) days advance written notice to you by electronic communication or otherwise.

7.3. Upon termination or expiration of this Agreement you shall cease using, reproducing, distributing, or publicly displaying any portion of the PAM Materials.

7.4. You acknowledge and agree that termination of Insignia's agreement with the State of Oregon for the right to use and sublicense the PAM survey and PAM Guidance shall terminate this Agreement; provided however that you may request continuation of this Agreement by making written request to the State of Oregon within sixty (60) days of your receipt of written notice of such termination. Such written request for license continuation shall include your agreement to assume with respect to the State of Oregon all obligations (including obligations for payment) contained in this Agreement with Insignia. In such case, the State of Oregon may in its sole discretion agree to accept or decline such request for assignment of this Agreement. Such written request shall be made to Director, Office of Technology Transfer, 1238 University of Oregon, Eugene, Oregon, 97403-1238.

8. **Return or Destruction of Information.** Except for the Data provided by you pursuant to Section 2.2, upon the expiration or termination of this Agreement, you and Insignia shall, within twenty (20) days, each return or destroy all Confidential Information of the other party; provided, however, that the receiving party may keep one copy of the Confidential Information for archival purposes so long as such archived Confidential Information is safeguarded against disclosure and use prohibited hereunder. In either case, upon request, the recipient shall provide the disclosing party with written certification that all Confidential Information has been returned or destroyed, as the case may be. Despite such a return or destruction, the parties' obligations under this Section shall survive indefinitely.

9. **Remedies for Breach of Confidentiality.** Each party hereby acknowledges that the violation by it of the restrictions imposed hereunder would cause irreparable harm to the owner of such Confidential Information and that remedies at law would be inadequate to redress any actual or threatened violation of this agreement. Each party agrees that, in addition to other relief that may be available, the foregoing restrictions may be enforced by temporary and permanent injunctive relief. Any award of relief to the owner of such Confidential Information in an action in which the owner substantially prevails shall include recovery of such owner's costs and expenses of enforcement (including attorneys' fees, including attorneys' fees and any costs associated with appeal).

10. General Provisions.

10.1. **Assignment.** The rights granted hereunder and this Agreement may not be assigned, transferred, or sublicensed directly or indirectly, by operation of law, contract or otherwise, by you except with the express written consent of Insignia, which consent may be withheld at Insignia's sole discretion.

10.2. **Entire Agreement, Modification, and Waiver.** This Agreement replaces and supersedes any prior agreements between the parties and sets forth the entire agreement between the parties with respect to the subject matter hereof, and may not be modified or amended except by written agreement executed by the parties hereto. No waiver, consent, modification, or change of any terms of this Agreement shall be binding unless the same is in writing and signed by both parties and all necessary approvals have been obtained. Such express waiver, consent modification, or change, if made, shall be effective only in the specific instance and for the specific purpose set forth in such signed writing.

10.3. **Governing Law.** This Agreement shall be construed and enforced in accordance with the laws of the State of Oregon, without giving effect to the conflict of law principles thereof, and applicable federal law. Any action or suit brought by the parties relating to this Agreement shall be brought and conducted solely and exclusively in the state and federal courts in Multnomah County in the State of Oregon in Portland, Oregon. You hereby waive any objection to venue in such courts, and waive any claim that such forum is an inconvenient forum. BY EXECUTION OF THIS AGREEMENT, YOU HEREBY CONSENT TO THE PERSONAL JURISDICTION OF SUCH COURT.

10.4. **Notice.** Any notice under this Agreement shall be in writing and be delivered in person or by public or private courier service (including U.S. Postal Service Express Mail) or by certified mail with return receipt



requested or by electronic mail. Notice to you shall be addressed to the contact information you provided above, notice to Insignia shall be addressed to the following address or at such other address as Insignia may from time to time direct in writing:

For Insignia:

Insignia Health, LLC
Attn: License Department
Street: 10900 Wayzata Blvd., Suite 810
City, State Zip: Minnetonka, MN 55305
Email: info@insigniahealth.com

Any notice shall be deemed to have been given on the earlier of: (i) actual delivery or refusal to accept delivery, (ii) the date of mailing by certified mail, (iii) the day facsimile delivery is verified or (iv) if by email the date sent unless an out of office-type reply is received in which case the notice shall be deemed given when the notice indicates the recipient will return to the office. Actual notice, however and from whoever received, shall always be effective.

10.5. **Severability.** If any one or more provisions of this Agreement shall be adjudicated to be illegal, invalid, or unenforceable in any respect, the validity, legality and enforceability of the remaining provisions shall not in any way be affected or impaired thereby. The parties hereby agree to attempt to substitute for any illegal, invalid, or unenforceable provision a valid or enforceable one, which achieves the economic, legal and commercial objectives of the invalid or unenforceable provision to the greatest extent possible.

10.6. **No Third Party Beneficiaries.** Nothing in this Agreement gives, is intended to give, or shall be construed to give or provide any benefit or right, whether directly, indirectly, or otherwise, to any other third persons.

10.7. **Headings, Drafting, and Counterparts.** This Agreement may be executed electronically and in counterparts, each of which may be an original but all of which, when taken together, shall constitute one and the same instrument. Headings included herein are for convenience only and shall not be used to construe this Agreement. The parties agree that they have participated equally in the formation of this Agreement and that the language herein should not be presumptively construed against either of them.

10.8. **Audits.** You shall create and maintain records as required by this Agreement and you shall grant Insignia reasonable access during normal business hours to examine and take copies of, on no less than ten (10) business days' advance written notice and at Insignia's cost, the records relating to this Agreement, to verify your compliance with the terms and conditions of this Agreement.

10.9. **Survival.** All terms of this Agreement with the exception of Section 1 shall survive the expiration or termination of this Agreement.

APPENDIX N. EXECUTIVE SUMMARY

Background and Significance

Type 2 diabetes is an increasingly prevalent chronic disease in the United States (U.S.). Diabetes is a chronic disease that can lead to numerous other health problems, even if it is well controlled. Depression is just one among a myriad of chronic diseases that co-exists with diabetes. Managing diabetes can be demanding and stressful which may also lead to the development or worsening of depression. Diabetic patients are at a higher risk for depression yet they are not routinely screened for depression. Diabetic quality measures metrics at the participating primary care federally qualified health center (FQHC) suggested an opportunity for improvement within their current clinical practice.

Project Summary

The purpose of the practice-improvement project was to work alongside the FQHC administration, providers and staff to establish a comprehensive diabetes and depression program. The practice-improvement project consisted of three main parts. Based on current evidence-based research, all patients with type 2 diabetes should be routinely screened for depression. FQCH providers and staff were educated on the importance of depression screening, detection, and management in all type 2 diabetes patients.

The project leader distributed pre-implementation surveys to the FQHC providers and staff. Qualitative and quantitative data was collected regarding the perceptions of the FQHC providers, administration and staff on their satisfaction with the current level of care for patients with type 2 diabetes, as well as the proposed Comprehensive Diabetes and Depression Program (CDDP). The initial results were compared with survey responses six months after implementation of the CDDP to assess if their perceptions had changed.

The second part of the project was to calculate the number of referrals made to the clinical pharmacist, as well as the number of patients enrolled in the CDDP during the first year of the project. The number of referrals were compared to the previous year to assess the percent of change as well as FQHC provider and staff buy-in of the project.

The final component of the project was to assess patient activation and self-efficacy at the beginning of the program by administering PAM surveys. Comparisons were made of patients' initial PAM scores to their PAM scores after six months to determine if enrollment in the CDDP increased patient activation. The hope was that by creating a collaborative program between primary care and the clinical pharmacist, patients would have better control of their chronic diseases, as well as improved satisfaction, activation, and self-efficacy.

Results

Pre and Post Implementation Surveys

Specific pre-implementation surveys were distributed to three cohorts: FQHC administrators, providers and staff, on February 1, 2016. Eight nurses, six providers, and three administrative staff completed their initial respective surveys and only four nurses, three providers, and two administrative staff completed their six-month post-implementation surveys.

Since the completion rate for all FQHC staff and provider post-implementation surveys was nearly 50% compared to the initial surveys, determinations of statistical significance were not possible. Participating clinic administration, providers, and staff were also allowed to make comments on their surveys. Prior to implementation, staff and providers voiced concern for having little time to add anything new to their day. However, when staff completed post-implementation surveys, time wasn't listed as a barrier or concern anymore. The largest barrier

witnessed by staff and providers were the high patient no show rates. Staff also commented they saw an increase and improvement in team collaboration.

Initial Chart Review

A report was created by IT with a list of all referrals made to the clinical pharmacist between February 1, 2015 and January 31, 2016, one year prior to the start of the CDDP. A chart review was conducted by the project leader to determine what the patients were referred for, how many of these patients had type 2 diabetes, a diagnosis of depression, a PHQ-9 on file, a PHQ-9 of 10 or higher, and whether or not they saw the clinical pharmacist or if they cancelled or no showed their appointment. Twenty-three patients had type 2 diabetes. Eight out of the twenty-three patients qualified for the CDDP, yet only five of these patients were referred to the clinical pharmacist specifically for their diabetes. Also, more than 25% of the patients with type 2 diabetes who were referred to the pharmacist didn't have a PHQ-9 on file in their chart.

Final Chart Review

Another report was run by IT with a list of all referrals made to the clinical pharmacist between February 1, 2016 and January 31, 2017, one year after the start of the CDDP. The project leader conducted another chart review to determine what the patients were referred for, how many of these patients had type 2 diabetes, a diagnosis of depression, a PHQ-9 on file, a PHQ-9 of 10 or higher, and whether or not they saw the clinical pharmacist or if they cancelled or no showed their appointment. There was a 147.8% increase in the number of patients with type 2 diabetes who were referred to the clinical pharmacist for any reason during the first year of the CDDP compared to the year prior. The number of patients referred specifically for their diabetes increased by 43.3%. Also, the number of patients with type 2 diabetes that were referred to the clinical pharmacist and had no PHQ-9 results on file decreased by 17.2%.

Initial and Final PAM Survey Results

The final component of the project was to assess patient activation and self-efficacy at the beginning of the program. Comparisons were made of patients' initial PAM scores to their PAM scores after six months to determine if enrollment in the CDDP increased patient activation. Fifteen out of the sixteen CDDP participants completed their initial PAM surveys upon enrollment into the program. To date, only one patient completed their six-month follow up PAM survey. This patient had a decrease in their overall PAM score as well as their PAM level. It's difficult to make any determinations on patient activation, however, one could hypothesize that patients were more engaged at the beginning of the program and their drive and determination decreased as the program progressed.

Recommendations and Conclusion

Despite the lack of statistically significant data from pre and post-implementation surveys, qualitative results still showed improved collaboration between the FQHC staff and providers. Given the significant increase in patients with type 2 diabetes referred to the clinical pharmacist, as well as a decrease in the number of these patients without a PHQ-9 on file, the project was successful and the project leader recommends the project continue.

Expanding this project could potentially improve the management of patients with type 2 diabetes in other departments and clinics, as well as improve providers' practice and potential reimbursement. Following the PDSA cycle also proved to be very advantageous with the implementation of this project. This process was followed throughout the project and resulted in several positive changes to the program. Providing staff with education and a thorough explanation of a project's significance and why a process is changing is essential to obtain buy-in. When providers and staff are invested and understand a project's potential impact on patient

outcomes, the project is more likely to succeed and be sustained. Providing comprehensive care to patients with type 2 diabetes, including screening for and managing depression, is essential to providing holistic care and improving patient outcomes. Further research related to this project should be focused on ways to improve patient activation as well as improve patient show rates for appointments.