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# An Examination of Factors Affecting Hemoglobin A1c Levels and Self-Care Behaviors among Type 2 Diabetic Patients in the Primary Care Setting

Courtney Daron Proie

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AN EXAMINATION OF FACTORS AFFECTING HEMOGLOBIN A1C LEVELS AND  
SELF-CARE BEHAVIORS AMONG TYPE 2 DIABETIC PATIENTS IN PRIMARY CARE  
SETTINGS

A Dissertation

Submitted to the School of Nursing

Duquesne University

In partial fulfillment of the requirements for  
the degree of Doctor of Philosophy

By

Courtney Proie

May 2017

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Courtney Proie

2017

AN EXAMINATION OF FACTORS AFFECTING HEMOGLOBIN A1C LEVELS AND  
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CARE SETTINGS

By

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Approved March 22, 2017

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## ABSTRACT

# AN EXAMINATION OF FACTORS AFFECTING HEMOGLOBIN A1C LEVELS AND SELF-CARE BEHAVIORS AMONG TYPE 2 DIABETIC PATIENTS IN PRIMARY CARE SETTINGS

By

Courtney Proie

March 2017

Dissertation supervised by Melanie Turk, PhD, RN

Despite all of the research that has demonstrated the importance of optimal control of diabetes, there are still many people who do not receive adequate care, education, and support in managing their diabetes (Barnard, Peyrot, & Holt, 2012; Rossi et al., 2015). This cross-sectional, descriptive, study examined the effects of the components of the Chronic Care Model on the outcomes of self-care behaviors and HbA1c levels for Type 2 diabetes patients cared for by nurse practitioners and physicians in the primary care setting. Specifically, this study examined the effects of self-management support, conceptualized as patient perceptions of patient activation, participation in decision-making, and practitioner facilitation of patient involvement in care. This study also examined the elements of the model together (community resources, self-management support, decision support, clinical information systems and delivery system design) for their combined and individual effect on patient self-care behaviors and HbA1c levels.

Participants of this study were diagnosed with type 2 diabetes, 18 years of age or older, and currently seeing a physician or nurse practitioner within a primary care setting for the care and management of their type 2 diabetes. Participants (N=82) completed a total of 6 questionnaires which included a demographics form, the Patient Activation Measure (PAM), the Facilitation of Patient Involvement Scale (FPI), the Perceived Involvement in Care Scale (PICS), and Patient Assessment of Care for Chronic Conditions (PACIC), and the Summary of Diabetes Self-Care Activities (SDSCA).

The PACIC was found to have significant associations with General Diet Score ( $p=.020$ ), Specific Diet Score ( $p=.027$ ), exercise ( $p=.032$ ), and blood glucose testing ( $p=.046$ ). The PAM was found to have significant associations with General Diet Score ( $p=.023$ ) and foot care ( $p=.006$ ). The FPI was found to have a significant association with blood glucose testing ( $p=.030$ ). The PICS was found to have a significant association with blood glucose testing ( $p=.046$ ).

The results were helpful to address some of the questions related to HbA1c and self-care behavior practices. Of notable importance, having no statistical significance in the results when comparing nurse practitioner patients and physician patients demonstrates that, in this particular study, there was no difference in the standards and variables that were measured comparing nurse practitioners and physicians. The patients who were cared for by both types of providers experienced similar outcomes with regard to self-care behaviors, HbA1c, levels of patient activation, participation in decision-making, and facilitation of patient involvement in care. Therefore, this is an important finding supporting the notion that care received by nurse practitioner patients and physician patients is not different.

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I would like to thank the various primary care offices who graciously allowed me to collect data at their offices. Without their generosity, I would not have been able to recruit participants for this study.

Lastly, I would like to thank Sigma Theta Tau for granting me a research award. This monetary award provided the gift cards that were given to participants who completed the study. This wonderful award was a wonderful addition to my study.

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## **Chapter 1**

### **Introduction**

This chapter is an introduction to the proposed research study. The background and development of the research questions, along with definitions, assumptions, and limitations will be discussed. The evolution, purpose, and significance of this research study will be introduced and described. The problem that will be examined and assessed by this proposed study will be explained. The need for this proposed study will be introduced and will continue through the review of the literature in chapter 2.

Type 2 diabetes is currently a significant epidemic in the United States of America; and occurs when the body does not produce enough insulin or the cells are not receptive to the insulin that is released in the body (RW.ERROR - Unable to find reference:355; American Diabetes Association, 2016a; US Department of Health and Human Services, 2014). Type 2 is the most common type of diabetes, affecting millions of people, while many others remain unaware they are at risk (American Diabetes Association, 2016a). According to the Centers for Disease Control and Prevention, it is estimated that for every 3 people diagnosed with diabetes, one person goes undiagnosed (2.68:1 ratio of diagnosed to undiagnosed cases in 2011) (Centers for Disease Control and Prevention, 2016). Without the proper utilization of insulin, carbohydrates are converted to glucose and remain in the blood rather than being transported into the cells for energy. The accumulation of glucose in the blood leads to diabetes complications if left untreated (American Diabetes Association, 2016a).

According to the World Health Organization (WHO), the number of worldwide cases of Type 2 diabetes has increased from 170 million in 2000 to 280 million in 2010; and this number is expected to increase to 430 million by the year 2030 (Shaw, Sicree, & Zimmet, 2010; Wild,

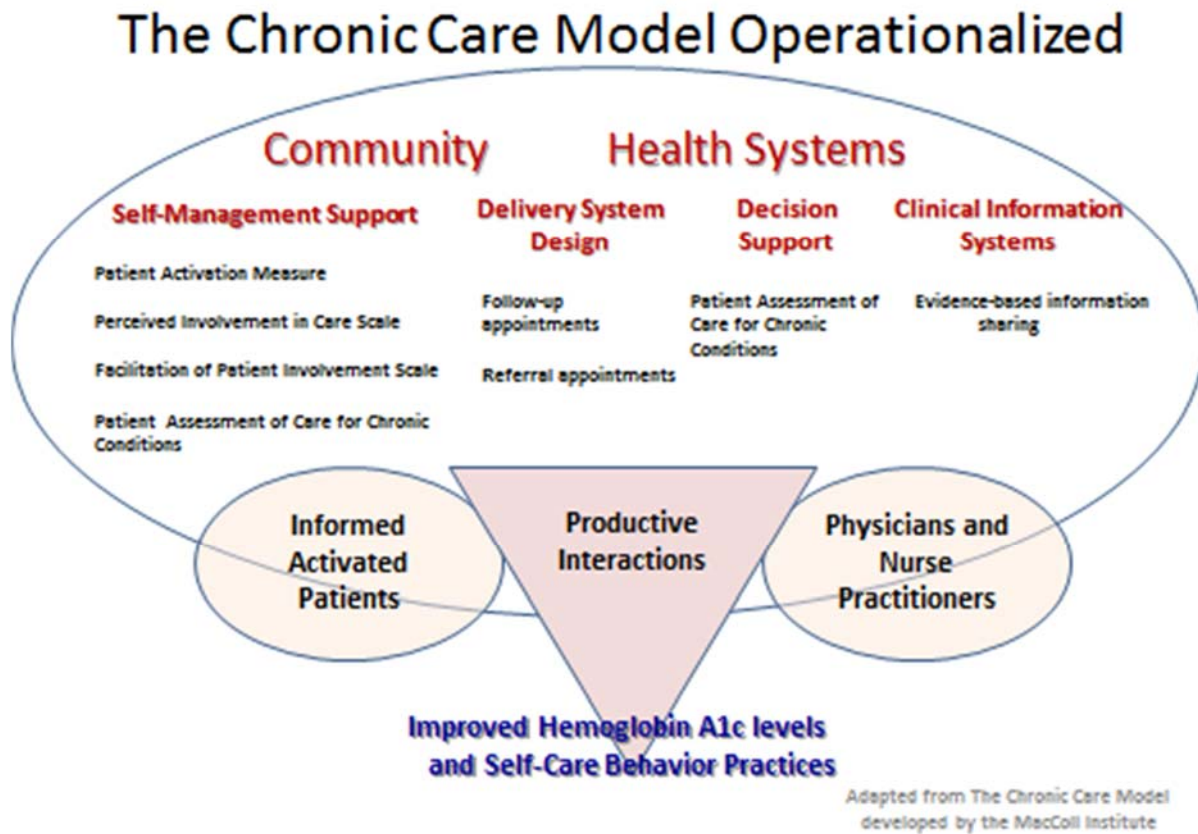
Roglic, Green, Sicree, & King, 2004). There are currently 25.6 million people ages 20 or older who have Type 2 diabetes. In 2010, there were 1.9 million people with a new diagnosis of Type 2 diabetes (US Department of Health and Human Services, 2014). In 2007, diabetes was the seventh leading cause of death based on United States (US) death certificates; and this number is likely to be underestimated, as death related to diabetes is often underreported (US Department of Health and Human Services, 2014). In 2007, a total of 231,404 death certificates listed Type 2 diabetes as either the underlying or direct contributing factor to death (American Diabetes Association, 2016a). Diabetes remains the seventh leading cause of death based on preliminary data for 2011 (Hoyert & Xu, 2012). Diabetes can lead to other complications including heart disease, stroke, high blood pressure, blindness, kidney disease, nervous system disease, retinopathy, and amputations (American Diabetes Association, 2016a; Campbell, 2009).

Despite improvements in care for patients with Type 2 diabetes, in 2008, less than 20% of all diabetes patients reached the desired evidence based goals of management, such as engaging in self-care behaviors to promote target glucose levels and achieving the targeted the HbA1c levels (O'Connor et al., 2011). A more recent study followed 1,343 patients from 2007 through 2010, finding that only 52.5% of the patients achieved Hemoglobin A1c (HbA1c) values of 7% or less with 77.9% of the population studied achieved 8% or less (Casagrande, Fradkin, Saydah, Rust, & Cowie, 2013). The total estimated cost, direct and indirect, related to diabetes in 2012 was \$245 billion, and those with diabetes have medical costs that are 2.3 times higher than those without diabetes, (American Diabetes Association, 2016b; US Department of Health and Human Services, 2014). The incidence of Type 2 diabetes has been linked to a variety of characteristics such as race, age, socioeconomic status, weight, lifestyle, and metabolic disorders (RW.ERROR - Unable to find reference:355; RW.ERROR - Unable to find reference:358;

RW.ERROR - Unable to find reference:354; Alberti, Boudriga, & Nabli, 2007). The prevalence of Type 2 diabetes has increased dramatically over the past twenty years, therefore, research focused on improving both management and outcomes for patients with Type 2 diabetes is needed.

Because Type 2 diabetes is a chronic disease, the Chronic Care Model (CCM) will be used as a guide for the proposed study. The elements of the CCM include the community, the health system, self-management support, delivery system design, decision support, and clinical information systems (Robert Wood Johnson Foundation, 2016a). Through productive interactions between informed and activated patients and prepared, proactive practice teams and the combination of these elements the end result is improved outcomes for patients with chronic conditions. Beneath the surface of the main elements of the CCM are the variables that will be examined in this proposed study. These variables include patient activation, patient participation in decision-making, and participation in self-care behaviors relate directly to the informed, activated patient. Facilitation of patient involvement and variations in practice among types of practitioners relate to the prepared, proactive practice team. The health system encompasses decision support, delivery system design, and clinical information systems. The community element includes available community resources and self-management support (Robert Wood Johnson Foundation, 2016a). These variables will briefly be introduced in this chapter to explain why these variables are important to examine in this proposed study. They will all be explained in detail in chapter 2.

Figure 1. The Chronic Care Model Operationalized



### Background of the Problem

#### **The Health System: Delivery System Design, Clinical Information Systems, and Decision Support**

Delivery system design, clinical information systems, and decision support are an intertwined set of variables that are all individual elements of the CCM (Robert Wood Johnson Foundation, 2016a). These variables are more practitioner focused in terms of how care is delivered to the patients. Characteristics of these variables include evidence-based care, ensuring follow-up care, culturally appropriate care, sharing evidence-based guidelines and information to encourage patient participation in care, integrating specialist expertise in care, using appropriate decision support and reminder tools, facilitating individual care planning, and sharing of

information among patients and providers (Robert Wood Johnson Foundation, 2016b; Robert Wood Johnson Foundation, 2016c; Robert Wood Johnson Foundation, 2016d).

Delivery system design is especially important for patient with Type 2 diabetes who require continuing management and occasional involvement from other practitioners or specialists. The delivery system design relates to how the patient can access necessary services and/or the way they are referred to additional services. Having organized and well managed care is important for patients with diabetes, and a team based approach including a dietician and certified diabetes educator has been shown to improve outcomes (Dancer & Courtney, 2010; National Institutes of Health and the Centers for Disease Control and Prevention, 2011).

A component of an organized delivery system design involves the use of clinical information systems. The clinical information system should be a readily available database relating to each individual patient, such as an electronic health record (EHR). This type of database can remind practitioners to order specific tests or address specific issues for each individual patient, based on the information in their individual record. Having an electronic based system can also provide easy access for other practitioners or specialists who are treating the patient to access information related to other patient consultations or treatments that have been carried out. This type of documentation and easily accessible electronic information is especially important in patients, including those with Type 2 diabetes, because of the complexity of care for some of these patients (Dancer & Courtney, 2010; Siminerio, Zgibor, & Solano, 2004).

Decision support and evidence based guidelines can be tied to the use of electronic health records. The use of clinical information systems and electronic decision support tools has been shown to improve practitioner performance. However, research related to patient outcomes and

use of decision support systems has been insufficient and the data that has been analyzed has been inconsistent. Measured outcomes, including glycosylated hemoglobin (HbA1c) levels, have shown little or no improvement in studies examining the effect of decision support systems on patient outcomes (Crosson, Ohman-Strickland, Cohen, Clark, & Crabtree, 2012; Frijling et al., 2002; Garg et al., 2005; Hunt, Haynes, Hanna, & Smith, 1998; Jaspers, Smeulers, Vermeulen, & Peute, 2011; Keyhani et al., 2008; Lau et al., 2012; McCoy et al., 2012; O'Connor et al., 2011; Poon et al., 2010; Romano & Stafford, 2011; Smith et al., 2008).

### **The Community: Community Resources and Self-Management Support**

Effective management of chronic diseases, like Type 2 diabetes, requires the delivery system design also be linked to community resources. Awareness of cultural and ethnic backgrounds of patients and their ties to the community can be useful in determining potential community resources for patients. There may be disease-specific support groups within neighborhoods that may be more appropriate for patients, as they can be engaged in their community and a setting in which they are comfortable (Austin, Wagner, Hindmarsh, & Davis, 2000). The success of delivery system designs can be improved by establishing links to the community resources to support patients in their self-management endeavors. Resources relevant to diabetes management such as peer groups, exercise classes, or home nursing care within local communities can be valuable to patients, especially those who have limited access to transportation and vulnerable populations such as the elderly, children, low-income, and underserved areas (Glasgow, Tracy Orleans, Wagner, Curry, & Solberg, 2001).

The CCM is different from traditional models and approaches to management of chronic diseases because two of the main foci are self-management training and counseling (Siminerio et al., 2004). Benefits related to Diabetes Self-Management Education have been recognized by the

American Diabetes Association and are considered an integral piece of diabetes care to strengthen the ability of patients to self-manage (Siminerio et al., 2006; Siminerio et al., 2004; Wagner, 1998). Self-management support prepares patients to take an active role in the management of Type 2 diabetes (Glasgow et al., 2001). Successful self-management and education programs help the patient to better understand the goals, priorities, barriers, and potential problems that can arise when dealing with Type 2 diabetes (Glasgow & Anderson, 1999; Glasgow et al., 2001; Von Korff & Gruman, 1997). The use of patient education brochures, referrals to other care team members, phone support hotlines, group and/or one-on-one counseling, and referrals to diabetes education classes can all aid in increasing self-management support for patients with Type 2 diabetes (RW.ERROR - Unable to find reference:1044; Solberg et al., 2006).

### **Informed, Activated Patients: Patient Activation and Participation in Decision-Making**

Patient activation can be defined as “developing experience with question formulation and building information-seeking skills that results in increased collaboration with the health care provider (Alegria et al., 2008, p. 247).” Hibbard, Stockard, Mahoney, and Tusler (2004) described the process for conceptualizing and operationalizing what it means for a patient to be “activated,” and found that this process involves four stages. The four stages of activation include “believing the patient role is important, having the confidence and knowledge necessary to take action, actually taking action to maintain and improve one’s health, and staying the course, even under stress (Hibbard et al., 2004, p. 1016).” Research has found that patients who are more engaged, informed, activated, and confident are more likely to perform self-care behaviors to promote their health (Lorig et al., 1999; Mosen et al., 2007; Remmers et al., 2009; Von Korff & Gruman, 1997). Patients who are found to have higher levels of activation also have better outcomes (Hibbard et al., 2004; Hibbard & Tusler, 2007; Mosen et al., 2007).

Patient activation and patient participation in the medical decision-making process have many noted benefits and implications related to self-management of diseases. McEwen et al. (RW.ERROR - Unable to find reference:791) asserts that patient participation has many benefits, including increased patient responsibility with a commitment to health and health promoting behaviors. Other authors report that increased patient participation enables more effective self-management of diseases (RW.ERROR - Unable to find reference:796; RW.ERROR - Unable to find reference:285; Golin, DiMatteo, & Gelberg, 1996; Heisler, Bouknight, Hayward, Smith, & Kerr, 2002). Patient activation and participation not only encompasses the decision-making process, it extends into all aspects of care: compliance with treatment plans, self-medication, medication adherence, patient education, information sharing, and taking part in physical care (RW.ERROR - Unable to find reference:801; RW.ERROR - Unable to find reference:285; RW.ERROR - Unable to find reference:804; RW.ERROR - Unable to find reference:321; RW.ERROR - Unable to find reference:802; RW.ERROR - Unable to find reference:803; Glasgow et al., 2002; Hibbard et al., 2004; Lorig et al., 1999; Wolpert & Anderson, 2001).

Patient activation and participation in the medical decision-making process is important for Type 2 diabetes because this particular disease requires the patient to do a significant amount of self-management related to individual lifestyles and personal goals of disease management (RW.ERROR - Unable to find reference:314). If patients are to learn to self-manage Type 2 diabetes, which involves glucose monitoring, diet modification, and exercise habits patients should take an active role in their health and participate in the decisions made during consultations with a healthcare practitioner related to defining mutually agreeable management goals.



## **Prepared, Proactive, Practice Team: Facilitation of Patient Involvement in Care and Differences among Types of Practitioners**

The effect of healthcare practitioners on the outcomes and satisfaction for patients with Type 2 diabetes is also important. Current literature remains inconclusive whether patient outcomes and/or patient satisfaction is influenced by the type of practitioner a patient sees. One study examined patient satisfaction with primary care practitioners for patients with chronic diseases, finding that patients were more satisfied with the care they received from nurse practitioners, except in the cases of patients with Type 2 diabetes (Roblin, Becker, Adams, Howard, & Roberts, 2004). Those patients preferred the care of a physician. Other studies, looking only at patients with Type 2 diabetes, had varying results in terms of outcomes (Horrocks, Anderson, & Salisbury, 2002).

There are also variables related to health care practitioners that may impact health outcomes. Health care practitioners can actively facilitate, or encourage, patients to be involved in their own healthcare (Martin, DiMatteo, & Lepper, 2001). Behaviors, such as suggesting the patient ask questions, listening to the patient's concerns, and providing as much information as possible to the patient, can facilitate the patient's involvement in managing their health (Martin et al., 2001). Martin, DiMatteo, and Lepper (2001) have suggested that when patients recognize that their health care provider has facilitated their involvement in care; patients tend to be more satisfied with care and better adhere to treatment plans.

### **Improved Outcomes: HbA1c and Self-Care Behavior Practices**

The HbA1c test, also known as glycated hemoglobin, glycosylated hemoglobin, glycohemoglobin, A1c, or HbA1c, is a way to measure blood glucose management over a two- to three-month period. This blood test should be done every three to six months for patients with

diabetes. The test reflects a patient's average blood glucose control over the previous 2 or 3 months and is a very accurate way to monitor overall diabetes control (Joslin Diabetes Center, 2016; Mayo Clinic, 2016). A person without diabetes would have a HbA1c level between 4% and 6%; and a common target level for patients with Type 2 diabetes is 7% or less (American Diabetes Association, 2016a; Joslin Diabetes Center, 2016; Mayo Clinic, 2016). HbA1c levels are directly correlated with blood sugar levels. Diet, exercise, medication adherence, and regular glucose testing all are factors that can contribute to blood sugar control that will also contribute to the HbA1c levels (Joslin Diabetes Center, 2016; UK Prospective Diabetes Study (UKPDS) Group, 1998).

The higher the HbA1c result, the more risk a person has of developing complications related to diabetes (American Diabetes Association, 2016a; Mayo Clinic, 2016). The importance of the HbA1c levels should not be minimized. For every percentage point decrease in HbA1c levels there is also a 35% reduction in the risk of microvascular complications, a 25% reduction in diabetes related deaths, and an 18% reduction in myocardial infarctions (UK Prospective Diabetes Study (UKPDS) Group, 1998). The risk of complications associated with diabetes is significantly reduced when the HbA1c values are less than 8%, ideally lower than 7% (Mayo Clinic, 2016; UK Prospective Diabetes Study (UKPDS) Group, 1998).

Self-care behaviors are an important aspect of disease management, specifically with Type 2 diabetes. The concept of self-care behaviors can encompass a variety of activities such as glucose monitoring, medication adherence, diet or exercise adherence, and other activities such as regularly checking one's feet for ulcers or signs of neuropathy (Toobert, Hampson, & Glasgow, 2000). Each of these individual activities is an important piece of the overall challenge of successful Type 2 diabetes management. Examining a patient's overall compliance with these

self-care activities can give a broader picture of how well a person can self-manage aspects of this disease. Wolpert and Anderson (2001) addressed behavioral change in diabetes care and stressed diabetes is a self-managed condition, models of care should be focused on promoting more self-care behaviors while stressing the importance of glycemic control from the patient's perspective.

### **Summary**

With Type 2 diabetes being a complex disease to manage, it would be unlikely that one facet of treatment would be the component that makes managing the disease successful. The CCM was designed with this complexity in mind (RW.ERROR - Unable to find reference:898; Austin et al., 2000; Bodenheimer, Wagner, & Grumbach, 2002a; Dancer & Courtney, 2010; Nutting et al., 2007; Robert Wood Johnson Foundation, 2016a). Each element of the CCM provides a unique piece of the necessary formula for successful management of chronic diseases, including Type 2 diabetes. Examining the effects of each of these elements related to outcomes such as HbA1c levels and self-care behaviors practices will be useful for designing future treatment plans for this patient population.

### **Purpose and Aims of Study**

This cross-sectional, descriptive, study will examine the effects of the components of the CCM on the outcomes of self-care behaviors and HbA1c levels for Type 2 diabetes patients cared for by nurse practitioners and physicians in the primary care setting. Specifically, this study will examine the effects of self-management support, conceptualized as patient perceptions of patient activation, participation in decision-making, and practitioner facilitation of patient involvement in care. This study will also examine the elements of the model together (community resources, self-management support, decision support, clinical information systems

and delivery system design for their combined and individual effect on patient self-care behaviors (Summary of Diabetes Self-Care Activities) and HbA1c levels. Current literature has not evaluated the relationship of these variables, as they are being conceptualized, on the specific diabetic patient outcomes of HbA1c levels and self-care behaviors, and any differences between health care providers.

The primary aims of this proposed study are to evaluate patient perceptions of patient activation, participation in decision-making, and facilitation of involvement in care (Self-Management Support) for their effect on self-care behaviors and HbA1c values. The combined elements of the CCM including decision support, community support, self-management support, delivery system design, and clinical information systems will also be assessed for their effect on self-care behaviors and HbA1c values. The secondary aim of this proposed study is to explore differences among these variables in patients receiving care from physicians compared to nurse practitioners.

### **Research Questions**

The research questions were the results of a thorough review of current literature examining the management of Type 2 diabetes. Numerous studies examined the desire of patients to participate in the decision-making process related to the treatment of Type 2 diabetes (RW.ERROR - Unable to find reference:285; Golin et al., 1996; Golin, DiMatteo, Leaks, Duan, & Gelberg, 2001; Heisler, Piette, Spencer, Keiffer, & Vijan, 2005; Jahng, Martin, Golin, & DiMatteo, 2005); however, no studies evaluated the extent the level of patient activation and patient participation in decision-making affect patient outcomes and any potential differences among practitioners. After examining literature, the following questions were formulated:

**Primary questions:**

1. Among Type 2 diabetic patients, do levels of patient activation, participation in decision-making for treatment planning, and facilitation of patient involvement in care affect HbA1c levels and patients' performance of self-care behaviors?
2. Based on the CCM, what are the effects of delivery system design and clinical information systems, together with patient perceptions of decision support, self-management support, and community resources on HbA1c levels and participation in self-care behaviors for patients with Type 2 diabetes?

**Secondary questions:**

1. Is there a difference in levels of patient activation, participation in decision-making, and facilitation of patient involvement in care when a nurse practitioner treats a patient compared to a physician?
2. Do patients who see nurse practitioners for management of Type 2 diabetes experience higher levels of engagement in self-care behaviors and more therapeutic HbA1c levels compared to patients who see a physician?

**Definition of Terms**

Rigorous research requires that the concepts being studied be defined in order to be operationalized. Based on a review of the current literature, these definitions have been developed for the variables presented in the study.

- Type 2 Diabetes – With Type 2, the body either does not produce enough insulin or the cells in the body are resistant to the insulin. If insulin is unable to carry sugar in the blood into the cells, then the cells become starved for energy. Over time, high blood glucose levels can cause damage to the eyes, kidneys, nerves, and/or heart (American Diabetes Association, 2016a).

- Patient – A patient is defined as someone who is sick with, or being treated for, an illness or injury. A patient is one who is receiving medical care (Patient. 2013, p. 1754). For this proposed study, the patient must have a diagnosis of Type 2 diabetes.
- Practitioner – A practitioner is one who has met the professional and legal requirements necessary to provide a health care service (Practitioner. 2013, p. 1884).
- Nurse Practitioner (NP) – A nurse practitioner is defined as licensed registered nurse who has advanced preparation (master’s or doctoral program) in the area of diagnosis and treatment of illnesses. Nurse practitioners may work in collaborative practice with physicians or independently in private practice or in nursing clinics. Depending on state laws, NPs may obtain prescriptive authority allowing them to prescriptions for medications. NPs must undergo national certification, periodic peer review, clinical outcome evaluations, and adhere to a code of ethical practices. NPs are licensed in all states and the District of Columbia, and practice under the rules and regulations of the state in which they are licensed. They provide care in clinics, hospitals, emergency rooms, urgent care sites, private practices, nursing homes, schools, colleges, and public health departments within rural, urban and suburban settings (Nurse practitioner. 2013, p. 1646; American Association of Nurse Practitioners, 2013).
- Primary Care Physician (PCP) – A primary care physician is a generalist physician who provides care to the undifferentiated patient at the point of first contact and takes continuing responsibility for providing the patient’s care. This physician assumes medical coordination of care with other physicians for the patient with multiple health concerns (Primary care physician. 2013, p. 1807; American Academy of Family Physicians, 2016).

- Decision-making – Decision-making is defined as the process of using adequate information to come to a conclusion and make choices (Decision-making. 2013, p. 627). For this study, decision-making refers to the decisions made related to treatment and management of Type 2 diabetes. Both practitioners and patients may be involved in decision-making.
- Participation in the decision-making process – Participation in the decision-making process is defined as the patient’s involvement and input related to decisions regarding treatment and management of Type 2 diabetes. Patients may be very active in voicing their opinions related to which options are most appropriate for their lifestyle, while other patients may defer to the practitioner to make the most appropriate choice based on their medical expertise (Decision-making. 2013; Merriam-Webster, 2013c). In this study, participation in the decision-making process will be operationalized using the Perceived Involvement in Care Scale. A wide range of participation may exist among patients.
- Shared decision-making – Shared decision-making is a process by which patients and providers consider outcome probabilities and patient preferences and reach a health care decision based on mutual agreement (Frosch & Kaplan, 1999, p. 285).
- Self-care behaviors – Self-care refers to actions that people initiate and perform on their own behalf in maintaining life, health, and well-being (Self-care. 2013, p. 2106). Diabetes self-care behaviors include a variety of activities, such as checking blood glucose levels, medication adherence, eating a particular diet, following an exercise regimen, checking feet regularly, smoking/alcohol habits (Toobert et al., 2000). Self-care behaviors will be operationalized using the Summary of Diabetes Self-Care Activities assessment.

- Chronic condition – A chronic condition is defined as any condition that requires ongoing adjustments by the affected person and interactions with the health care system (Robert Wood Johnson Foundation, 2016a).
- Chronic care – Chronic care is defined as long-term medical care (greater than 90 days) for individuals with a chronic physical or mental impairment (Merriam-Webster, 2013a).
- Decision support – In this setting, decision support is designed as the practice of sharing evidence-based guidelines and information with patients to encourage their participation in the decision-making process related to their treatment plans (Robert Wood Johnson Foundation, 2016c). Decision support will be operationalized using a subscale of the Patient Assessment of Care for Chronic Conditions (PACIC) questionnaire.
- Patient Activation – Patient activation is defined as developing experience with question formulation and building information-seeking skills that results in increased collaboration with the health care provider (Alegria et al., 2008, p. 247). Patient activation will be operationalized using the Patient Activation Measure (PAM) and the Patient Assessment of Care for Chronic Conditions (PACIC).
- Facilitation of Patient Involvement in Care – To facilitate is to make easier, help bring about (Merriam-Webster, 2013b). Behaviors, such as suggesting the patient ask questions, listening to the patient’s concerns, and providing as much information as possible to the patient, can facilitate the patient’s involvement in managing their health (Martin et al., 2001). Facilitation will be operationalized using the Facilitation of Patient Involvement Scale (FPI) and a subscale of the Perceived Involvement in Care Scale (PICS).



- Delivery System Design – The CCM defines delivery system design as defining roles and distributing tasks among team members, using plan interactions to support evidence-based care, providing clinical case management services for complex patients, ensuring regular follow-up care by the care team, and giving care that patients understand and fits with their cultural background (Robert Wood Johnson Foundation, 2016d). Delivery system design will be operationalized through participants self-reporting if follow-up appointments were requested by the practitioner and/or patients were referred to an endocrinologist, a dietician, optometrist/ophthalmologist (eye doctor), podiatrist (foot doctor) and/or a diabetes educator.
- Clinical Information Systems – The CCM defines clinical information systems as providing timely reminders for patients and providers, facilitating individual patient care planning, sharing information with patients and providers to coordinate care (Robert Wood Johnson Foundation, 2016b). Clinical information systems will be operationalized through the demographic form where patients will be asked to report if they discussed goals of treatment with their practitioner and if they were given any printed information from the practitioner related to goals of treatment or test results.
- Community Resources – The CCM defines this as encouraging patients to participate in effective community programs (Robert Wood Johnson Foundation, 2016g). Community resources will be operationalized using a subscale of the Patient Assessment of Care for Chronic Conditions (PACIC).
- Self-Management Support – The CCM defines self-management support as emphasizing the patient’s central role in managing their health, using effective self-management support strategies that include assessment, goal-setting, action planning, problem solving,

and follow-up, and organizing internal and community resources to provide ongoing self-management support to patients (Robert Wood Johnson Foundation, 2016f). Self-management support will be operationalized using two subscales of the Patient Assessment of Care for Chronic Conditions (PACIC) questionnaire.

- HbA1c level – The HbA1c level is determined from a HbA1c blood test. It can also be referred to as the glycated hemoglobin, glycosylated hemoglobin, and HbA1c. This blood test can determine both the presence of diabetes mellitus and the degree of glycemic control, which is how well a patient is managing his or her blood glucose levels. The HbA1c test reflects the average blood sugar level over the past 2-3 months. A normal HbA1c level for a person who does not have diabetes is from 4.5-6 percent. Someone with uncontrolled diabetes will have a level above 9 percent. For most patients with Type 2 diabetes, a level of 7 percent or less is considered representative of well-managed diabetes. In patients with diabetes mellitus, the HbA1c level will be normal or slightly elevated (7% or less) if blood glucose levels are optimally managed over an 8-12 week period. If glucose levels have not been controlled, the HbA1c levels will be elevated (greater than 7%). HbA1c levels are considered good indicators of long-term glycemic control (Hemoglobin, A1c. 2013, p. 1103; American Diabetes Association, 2016a; Mayo Clinic, 2016).

### **Assumptions**

The assumptions made by the researcher related to this study include:

1. The participants in this sample are representative of patients with Type 2 diabetes in this region, therefore the data will be generalizable to the regional area.
2. The patients will accurately portray themselves in their demographic data questionnaire.

3. The patients will accurately answer the five surveys: Patient Activation Measure Survey (PAM), Patient Assessment of Care for Chronic Conditions (PACIC), Summary of Diabetes Self-Care Activities, Facilitation of Patient Involvement Scale (FPI), and Perceived Involvement in Care Scale (PICS).

### **Limitations**

While every effort will be made to ensure a rigorous study, limitations are an inherent piece of all research studies. Possible foreseen limitations related to this study include:

1. The relatively small sample size relative to the overall number of patients with Type 2 diabetes nationally may limit the ability to generalize the results of this study to the entire population of patients with Type 2 diabetes.
2. Due to the concentrated area from which the participants of the study will be recruited, the ability to generalize the results beyond Western Pennsylvania might be limited.
3. The population of patients and providers for this study is being pooled from only one health system in the area, thus generalizability may be limited to this healthcare system.
4. Data on most variables except for HbA1c will be self-reported. Issues can arise related to self-report data when participants do not clearly understand the questions being asked. Directions for all questionnaires will be reviewed with each participant to reduce this limitation as much as possible. Another disadvantage of self-report data is the social-desirability bias. This occurs when participants answer the questions to portray themselves as socially acceptable, and answers may not always be truthful.
5. Another limitation related specifically to descriptive designs is that descriptive designs cannot establish causation; they can only describe effects on relationships between variables.

## Significance of the Study to Nursing

Throughout the past two decades, the number of people diagnosed with diabetes has risen 767%, with the majority of those affected residing in the United States and China (RW.ERROR - Unable to find reference:361). Currently, 20% of the populations in the Caribbean and Middle East are affected; this number is expected to double within the next twenty years (RW.ERROR - Unable to find reference:361). The cost of treating patients with diabetes is \$174 billion annually (US Department of Health and Human Services, 2014). The incidence of Type 2 diabetes is also increasing at an alarming rate with an estimated 48.3 million people being affected by Type 2 diabetes by 2050 (Venkat Narayna, Boyle, Geiss, Saadine, & Thompson, 2006). With this shocking rate of new diagnoses, it is necessary to evaluate treatment practices to ensure that these patients are receiving optimal care to promote optimal outcomes (Aljaseem, Peyrot, Wissow, & Rubin, 2001; Anderson & Robins, 1998; Venkat Narayna et al., 2006). Many patients with Type 2 diabetes are managed by primary care offices, with an increase in nurse practitioners managing these patients (American Diabetes Association, 2016a).

The current literature identifies issues related to management of Type 2 diabetes, acknowledging the involvement of nurse practitioners in addition to physicians; however, it is lacking in suggestions and recommendations for changes to be implemented to suit this patient population. Gaining an understanding of patient activation, participation in decision-making, and facilitation of patient involvement in care for the first primary research question could identify important information about the patient/provider relationship related to Type 2 diabetes management. Looking at delivery system design, clinical information systems, self-management support, and community resources can also identify meaningful data related to Type 2 diabetes from another perspective. The results from of the data analysis for each research question may

identify factors to promote improved management of Type 2 diabetes. These strategies can be used to plan and implement new guidelines related to the manner in which Type 2 diabetes is managed. Currently, there are no studies that have evaluated patient participation levels when different healthcare providers treat Type 2 diabetic patients, nor have there been any quantitative studies evaluating participation scores and their relationship to overall management outcomes. Understanding the effect of the self-management support element of the CCM conceptualized as patient activation, participation in decision making, and practitioner facilitation of patient involvement in care, along with the combined elements of the CCM together on patient self-care behaviors and HbA1c can be vital in the future care of Type 2 diabetic patients. Exploring any differences in these variables when patients are cared for by different healthcare providers, i.e., primary care physicians and nurse practitioners may also provide information to enhance patient outcomes.

### **Summary**

The number of patients with Type 2 diabetes continues to increase at an alarming rate. It is essential that continued research be focused on finding ways to include the patients in the treatment process and allow the patients to have a voice in the development of a treatment plan. In order for patients to have optimal outcomes related to the treatment of Type 2 diabetes, the variables in this study, guided by the CCM, need to be examined to reveal factors that may influence the complex treatment of this chronic disease. The proposed research questions are designed to examine the important elements from the CCM to identify how the elements, together, have an impact on patient outcomes, specifically HbA1c levels and self-care behavior practices. By examining specific variables related to these elements, new information may be discovered to improve the way care is delivered for patients with Type 2 diabetes, thereby

improving patient outcomes. Practitioners may become aware of how these variables, including differences among physicians and nurse practitioners, impact patients with Type 2 diabetes. Assessing the impact of these variables on HbA1c levels and self-care behavior practices will provide additional information to improve the care and outcomes of patients with Type 2 diabetes.

## **Chapter 2**

### **Review of Literature**

This chapter discusses the current literature as it relates to the research questions and concepts presented in this study. The direct elements of the Chronic Care Model (CCM) include the community, the health system, self-management support, delivery system design, decision support, and clinical information systems. These elements combined with productive interactions between informed, activated patients and prepared, proactive practice team members are designed to promote improved outcomes in patients with chronic conditions. Variables that will be examined in this proposed study include patient activation, patient participation in decision-making, patient activation, and facilitation of patient involvement. Delivery system design, clinical information systems, and decision support systems will also be assessed. Variations in practice among types of practitioners and the use of or referral to available community resources will be evaluated, in addition to the outcome variables of HbA1c (HbA1c) levels and self-care behavior practices. Appropriate literature will be presented on each of these variables that will be assessed in the proposed study. The information presented in this chapter will outline the historical background of the concepts, why they are important in the management of Type 2 diabetes, and how this study will attempt to fill in any voids, or gaps, in the current literature.

This chapter will be outlined as followed, in concordance with the CCM:

- I. Theoretical Framework, The CCM
- II. Literature Relevant to Research Questions, Underlying Concepts, and CCM Elements
  - a. The Health System: Delivery System Design, Clinical Information Systems, and Decision Support

- i. Delivery System Design
  - ii. Clinical Information Systems
  - iii. Decision Support
  - iv. Literature Examining Delivery System Design, Clinical Information Systems, and Decision Support
  - v. Summary
- b. The Community: Community Resources and Self-Management
  - i. Community Resources
  - ii. Self-Management Support
  - iii. Summary
- c. Informed, Activated Patients: Patient Activation and Participation in Decision-Making
  - i. Patient Activation
  - ii. Participation in Decision-Making
  - iii. Summary
- d. Prepared, Proactive Practice Team: Facilitation of Patient Involvement in Care and Differences among Types of Practitioners
  - i. Facilitation of Patient Involvement in Care
    - 1. Facilitation and Decision-Making Examined Together
  - ii. Variations in Care Among Physicians and Nurse Practitioners
  - iii. Summary
- e. Improved Outcomes: HbA1c Levels and Self-Care Behavior Practices
  - i. HbA1c Levels



## ii. Self-Care Behavior Practices

### 1. Summary

## III. Summary

### **Theoretical Framework**

#### **The Chronic Care Model**

The Chronic Care Model (CCM) defines a “chronic condition” as “any condition that requires ongoing adjustments by the affected person and interactions with the health care system (Robert Wood Johnson Foundation, 2016a).” It is estimated that more than 145 million people, essentially half of all Americans, are dealing with a chronic condition (Robert Wood Johnson Foundation, 2016a) such as diabetes, requiring ongoing adjustments and interactions with the health care system.

The CCM was developed at the MacColl Center for Health Care Innovation at the Group Health Research Institute in the mid-1990s. The CCM recognizes the crucial elements of the health care system that encourage “high-quality chronic disease care (Robert Wood Johnson Foundation, 2016e).” The elements include “the community, the health system, self-management support, delivery system design, decision support, and clinical information systems (Robert Wood Johnson Foundation, 2016e).” In 2003, the model was slightly revised and gained five additional themes. These themes are “patient safety, cultural competency, care coordination, community policies, and case management (Robert Wood Johnson Foundation, 2016e).” The model synthesizes self-management support, delivery system design, decision support, and clinical information systems with productive interactions between informed, activated patients, and prepared, proactive practice team members for improved patient outcomes. The overall goal

of applying this model is to have healthier patients, more satisfied providers, and cost savings (Robert Wood Johnson Foundation, 2016e).

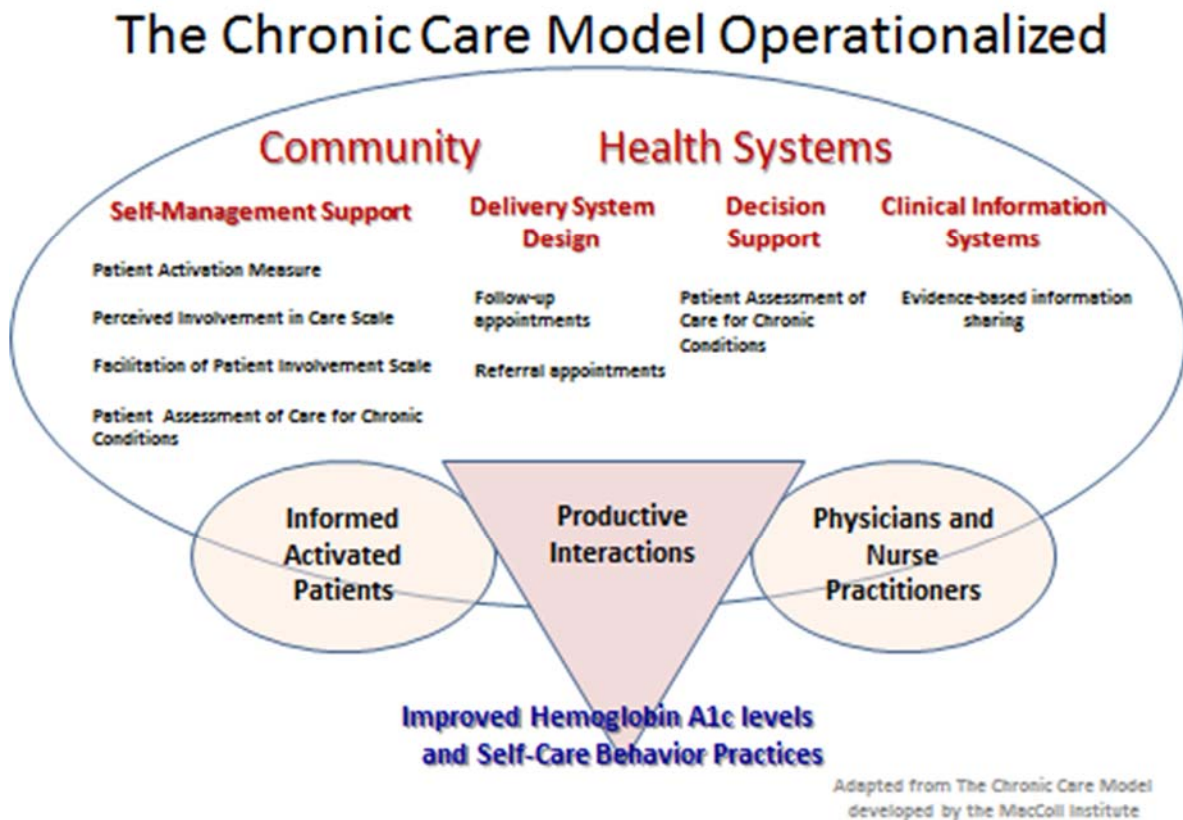
The CCM has been used in research studies, including studies that focused on the management of Type 2 diabetes. A study evaluating use of the CCM in practices treating patients with Type 2 diabetes found that when the model was implemented as part of routine care, patients had significantly lower values for HbA1c levels and lipid ratios (Nutting et al., 2007). Another study also found that utilizing CCM based-care resulted in significantly improved HbA1c levels, non-HDL cholesterol levels, and rates of self-monitoring blood glucose levels (Piatt et al., 2006). A third study evaluated 15,687 patient outcomes over the course of one year after implementing the CCM in primary care clinics (Siminerio et al., 2004).

Over the course of a year, 60% of patients achieved a HbA1c level of <7% and 81.1% of patients were less than 8% (Siminerio et al., 2004). In a rural primary care setting, researchers found that after implementation of the CCM, patients had overall improvements in diabetes knowledge, patient empowerment, HbA1c levels, and HDL cholesterol levels (Siminerio, Piatt, & Zgibor, 2005). Other studies also found positive outcomes with the implementation of the CCM related to the management of chronic obstructive pulmonary disease, depression, asthma, and congestive heart failure (RW.ERROR - Unable to find reference:898; Bodenheimer, Wagner, & Grumbach, 2002b; Pearson et al., 2005; Solberg et al., 2006; Wagner, Austin, Davis, Hindmarsh, & et al, 2001).

For the proposed study, the CCM provides a strong theoretical framework because of the overall focus on chronic disease management and specific elements of the model are either being examined or directly relate to the variables being examined. The areas of the model that will be focused on are the health system, including delivery system design, health care practitioners

(NPs and physicians), decision support, and clinical information systems. Referral of community resources, especially those related to self-management support will also be examined. Patient activation, participation in decision-making and taking part in self-care behaviors, along with practitioner facilitation of patient involvement are also important aspects of the CCM that will be evaluated in the proposed study. The focus of this research study is to examine patient activation, facilitation of patient involvement by practitioners, patient participation in the decision-making process, and self-care behavior practices; along with decision support, clinical information systems, delivery system design, self-management support, and community resources related to the management of Type 2 diabetic patients. The model elements serve as a foundation for this study.

Figure 2. The Chronic Care Model Operationalized



## **Literature Relevant to Research Questions, Underlying Concepts, and Chronic Care Model Elements**

### **The Health System: Delivery System Design, Clinical Information Systems, and Decision Support**

Delivery system design refers to the structure of the medical practice, including defined roles for care team members, the use of electronic health records, and planned patient visits (Austin et al., 2000; Barr et al., 2003; Bodenheimer et al., 2002b; Boville et al., 2007). Clinical information systems are computerized information systems, such as electronic health records, that have the ability to provide reminders for practitioners related to standardized care guidelines and performance quality indicators (Boville et al., 2007). Decision support refers to the practice of sharing evidence-based guidelines and information with patients to encourage their participation in the decision-making process related to their treatment plans (Boville et al., 2007; Robert Wood Johnson Foundation, 2016c). These evidence-based guidelines can be integrated into daily practice through the reminders and alerts provided by the clinical information system (Boville et al., 2007).

Delivery system design, clinical information systems, and decision support are an intertwined set of variables that are all individual elements of the CCM under the Health Systems umbrella, directly relating to the organization of health care for patients with chronic diseases (Robert Wood Johnson Foundation, 2016a). These variables are practitioner centered, focusing on how care is delivered to the patients. Characteristics of these variables include evidence-based care, ensuring follow-up care, culturally appropriate care, sharing evidence-based guidelines and information to encourage patient participation in care, integrating specialist expertise in care, using appropriate decision support and reminder tools, facilitating individual

care planning, and sharing of information among patients and provider (Robert Wood Johnson Foundation, 2016b; Robert Wood Johnson Foundation, 2016c; Robert Wood Johnson Foundation, 2016d).

**Delivery system design.** Delivery system design is especially important for patients with Type 2 diabetes because these patients require continued management and occasional involvement from other practitioners or specialists. This does not simply refer to adding more tasks into an already busy system, rather streamlining processes and having defined roles for care team members to improve the delivery of care to patients (Austin et al., 2000; Barr et al., 2003). The use of decision support tools is an important part of delivery system design to improve self-management support and provide appropriate follow-up care (Austin et al., 2000; Barr et al., 2003; Bodenheimer et al., 2002b). Having organized and well managed care is important to improve outcomes within this patient population (Dancer & Courtney, 2010). Team-based care has been shown to improve outcomes of patients with diabetes, including a dietician and certified diabetes educator as part of the treatment plan (National Institutes of Health and the Centers for Disease Control and Prevention, 2011).

**Clinical information systems.** A component of an organized delivery system design involves the use of clinical information systems. The clinical information system should be a readily available database relating to each individual patient, such as an electronic health record. This type of database can remind practitioners to order specific tests or address specific issues for each patient, based on the information in their individual record. This type of system should also include performance summaries of various aspects of care, such as HbA1c levels over time (Glasgow et al., 2001). Having an electronic based system can also provide easy access for other practitioners or specialists who are treating the patient to access information related to other

patient consultations or treatments that have been carried out by other members of the care team. This type of documentation and easily accessible electronic information is especially important in patients with Type 2 diabetes because of the complexity of care required (Dancer & Courtney, 2010; Siminerio et al., 2004).

The use of clinical information systems can prompt practitioners and support decisions related to planned, preventative care (Barr et al., 2003; Glasgow et al., 2001; Lewis & Dixon, 2004). Information within the systems should be regularly updated to provide the most current evidence-based recommendations which can directly contribute to the care provided for patients needing chronic management (Glasgow et al., 2001). The use of status summaries, which are provided through the clinical information system showing a summary of the patient, including trends in lab values and current medication lists, are available and be extremely useful for tracking patient progress and preventative care they have received (Solberg et al., 1997).

**Decision support.** Decision support systems (DSS) are computer-based programs that can be used to support complex decision making and problem solving in healthcare and other disciplines (Shim et al., 2002). Decision support systems were developed in the early 1970s, based upon theoretical studies of organizational decision-making at the Carnegie Institute of Technology in the late 1950s and technical development at Massachusetts Institute of Technology during the 1960s (RW.ERROR - Unable to find reference:1047). Typical DSS characteristics include database management with access to internal and external information, modeling functions, and interface designs to allow for queries, reporting, and graphing (Shim et al., 2002).

Decision support systems and the use of evidence based guidelines can be tied to the use of electronic health records. The use of clinical information systems and electronic decision

support tools has been shown to improve practitioner performance. However, research related to patient outcomes and use of decision support systems has been insufficient and the data that has been analyzed has been inconsistent (Crosson et al., 2012; Frijling et al., 2002; Garg et al., 2005; Hunt et al., 1998; Jaspers et al., 2011; Keyhani et al., 2008; Lau et al., 2012; McCoy et al., 2012; O'Connor et al., 2011; Poon et al., 2010; Romano & Stafford, 2011; Smith et al., 2008). The proposed study will fill in the gap in the literature by examining the use of decision support systems in conjunction with other variables that directly relate to the care and management of patients with Type 2 diabetes in order to evaluate the impact of the decision support system when combined with other aspects of care delivery.

**Literature examining delivery system design, clinical information systems, and decision support.** A study tested the CCM components in a clinic treating patients with diabetes, using the outcomes of HbA1c levels and low-density lipoprotein (LDL) cholesterol. Three leaders from each clinic that participated in the study completed a survey assessing components of the CCM in their clinics. These survey scores were correlated with the outcome measures for the patients with diabetes. Delivery system design scores were positively correlated with improvements in HbA1c levels and LCL cholesterol test rates at the clinics ( $r = 0.49-0.57, p < .05$ ). Self-management support and clinical information systems were associated with outcomes but were not found to be statistically significant (Sperl-Hillen et al., 2004). A study by Poon (2010) examined the relationship between the use of electronic health records (EHR) and quality of care. Using a statewide survey of physicians in Massachusetts, questions were asked regarding practice organizations, populations served, physician demographics, and use of EHR features including laboratory test results, radiology test results, laboratory order entry, radiology order entry, electronic visit notes, reminders for care activities, electronic

problem list, electronic medication lists, and electronic prescription transmission. Of the 507 respondents, only 144 (28.4%) used an EHR. Examining the overall quality of care when using an EHR, improvements in quality of care were found related to women's health ( $p = .18$ ), depression, ( $p = .34$ ), colon cancer screening ( $p = .09$ ), cancer prevention ( $p = .08$ ), and well child care ( $p = .78$ ). In areas of diabetes ( $p = .47$ ) and asthma ( $p = .85$ ), physicians who were not using an EHR, had higher quality scores than those using the EHR. These overall results among medical subpopulations did not yield any significant relationships among quality of care and use of the EHR; however, further research is necessary to clarify the relationship between EHRs and outcomes for patients with Type 2 diabetes (Poon et al., 2010).

A systematic review of the impact of electronic health records (EHR) in Canada examined the impact on prescribing support, disease management, clinical documentation, work practice, preventative care, and patient-physician interaction. Forty-three studies were selected for this review; 27 were published between 2005 and 2009. Overall, 22 of the 43 studies showed positive impacts on patient care. The greatest improvements were noted related to preventative care (66.7%), work practice (64.3%), disease management (57.1%), and productivity (63.6%). Clinical documentation (16.7%) and user satisfaction (18.2%) had the least improvement (Lau et al., 2012).

Keyhani and colleagues (2008) used previously collected data from National Ambulatory Medical Care Survey (NAMCS, 2005) and the National Hospital Ambulatory Medical Care Survey (NHAMCS, 2005) to examine the use of an EHR on blood pressure control and receipt of appropriate therapy for chronic conditions. The authors found no significant effects of using an EHR and appropriate therapy for chronic conditions, except in the case of inhaled steroids for asthma therapy (adjusted OR 2.86%, 95% CI, 1.12-7.32). There were no significant effects of



using an EHR for blood pressure control except for the use of angiotensin converting enzyme inhibitors or angiotensin receptor blockers in patients with diabetes and hypertension (OR 2.58, 95% CI, 1.22-5.42 (Keyhani et al., 2008). This study also reflects the need for further research related to patient outcomes and the use of EHRs, along with evaluation of the CCM, as the results of this particular study directly contrast the premise of the model.

A different study analyzed survey data related to the use of electronic health records (EHR) and clinical decision support systems (CDSS) using a more recent set of data from the National Ambulatory Medical Care Survey (NAMCS, 2005-2007) and the National Hospital Ambulatory Medical Care Survey (NHAMCS, 2005-2007). Information from 243,478 different patient visits was evaluated for 20 different quality indicators. Among all indicators, only diet counseling in high-risk adults showed statistically significant results related to the incorporation of this practice when using an EHR or CDSS (28% vs. 20%, adjusted OR 1.65, 95% CI, 1.21-2.26;  $p = .002$ ). There were no significant improvements among the remaining 19 indicators based on the use of an EHR or CDSS, compared to those not using these types of electronic systems (Romano & Stafford, 2011).

Garg and colleagues (2005) performed a review of one hundred studies related to clinical decision support systems (CDSS) to identify characteristics of various CDSS that predicted benefits. In 97 of the studies assessing practitioner performance, 62 studies (64%) showed positive improvements related to the use of diagnostic systems, reminder systems, disease management systems, and drug dosage/prescription systems. The improvements in practitioner performance were also associated with CDSSs that provided automatic prompts rather than requiring users to activate system prompts on their own. A 73% improvement in practitioner performance was found when the CDSSs had automatic prompts compared to only 47%

improvement when the CDSSs required users to activate systems prompts ( $p = .02$ ). Patient outcomes were assessed in 52 of the 100 studies, however only 7 (13%) of these studies reported improvements related to patient specific outcomes, none of which were related to the management of Type 2 diabetes (Garg et al., 2005). This further enforces the need for research related to outcomes that relate directly to the patient population that is targeted in this proposed study.

A more focused study on decision support systems and care of patients with diabetes examined a telemedicine intervention for improving care within the context of the CCM (Smith et al., 2008). A group of 97 primary care physicians and 639 patients participated in an interventional study using an author-designed, disease-specific, web-form recommendation for each patient encounter. The physicians reported using 49% of the generated summaries they received via email. There were no significant effects found for the intervention group related to the process of diabetes care ( $p = .41$ ), HbA1c levels ( $p = .95$ ), low density lipoprotein cholesterol ( $p = .19$ ), blood pressure levels (systolic,  $p = .15$ ; diastolic,  $p = .85$ ) or the estimated 10-year risk of coronary artery disease ( $p = .93$ ), nor were there any significant cost differences among the intervention and control group ( $p = .02$ ) (Smith et al., 2008).

Another literature review was synthesized to evaluate the impact of CDSS on practitioner performance and patient outcomes. A total of 17 systematic reviews (SR) were included in this analysis, all published between 1994 and 2009. Twelve of the 17 SRs found strong evidence that CDSS significantly impact practitioner performance, mainly noting benefits of reminder systems for preventative care. Sixteen of the 17 SRs examined the use of CDSS and patient outcomes. Three of the 16 SRs found strong evidence of positive impacts on patient

outcomes related to appropriate drug dosing and preventative care reminders (Jaspers et al., 2011).

A study that included 11 clinics, 41 primary care physicians, and 2,556 patients with diabetes focused on the impact of an EHR based decision support system (DSS) called the Diabetes Wizard on HbA1c levels, blood pressure, and low-density lipoprotein (LDL) cholesterol levels. This program generated recommendations based on algorithms and recommendations based on individual patient data related to specific changes in medication, changes in treatment for patients with contraindications to current treatment, overdue laboratory tests, and changes in follow-up intervals based on the patient's current state of diabetes control. Patients in the intervention group had significantly greater improvements in HbA1c levels (intervention effect -.26%, 95% CI, -.06% to -.47,  $p = .01$ ). There were no significant impacts on blood pressure (SPB <130mm Hg, intervention effect 5.1%,  $p = .03$ ; DBP <80mm Hg, intervention effect = 3.9%,  $p = .07$ ) or LDL cholesterol levels (mean LDL levels, intervention effect 1.37%,  $p = .62$ ) (O'Connor et al., 2011).

Other authors analyzed data from 16 EHR-using facilities and 26 non-EHR-using facilities to assess quality of diabetes care. The use of the EHR was not associated with better adherence to guidelines or more rapid improvement in adherence. Facilities not using an EHR were more likely to meet the targeted outcomes for HbA1c levels, LDL cholesterol, and blood pressure at the 2-year follow up assessment (OR = 1.76, 95% CI, 1.12-2.51) (Crosson et al., 2012). While this study shows that targets were more likely to be met when not using an EHR, research will need to continue and build upon the previous study with the increasing use of EHRs. The proposed study will continue to examine the use of EHRs from a different perspective to include use of reminders related to patient outcomes.

**Summary.** There is an abundance of literature relating to delivery system design, clinical information systems, and decision support. The proposed study will examine how these variables impact care provided to patients with Type 2 diabetes and if they have an impact on the specific patient outcomes of HbA1c levels and self-care behaviors practices. Patients with Type 2 diabetes may see a variety of practitioners for various aspects of care; and use of CISs and/or DSSs by their primary care practitioner may impact the quality of care for patients related to control of their blood sugars. Examining how care is delivered using aspects of a CIS and/or DSS will give insight into whether these techniques of care are beneficial in helping this patient population manage their disease.

### **The Community: Community Resources and Self-Management Support**

**Community resources.** Effective management of chronic diseases, like Type 2 diabetes, requires that the delivery system design also be linked to community resources. Awareness of cultural and ethnic backgrounds of patients and their ties to the community can be useful in determining potential community resources that can be helpful to patients. There may be disease-specific support groups within neighborhoods that may be more appropriate for patients, as they can be engaged in their community and a setting in which they are comfortable (Austin et al., 2000). The success of delivery system designs can be improved by establishing links to the community resources to support patients in their self-management endeavors. Resources relevant to diabetes management such as peer groups, exercise classes, or home nursing care within local communities can be valuable to patients, especially those who have limited access to transportation and vulnerable populations such as the elderly, children, low-income, and underserved areas (Glasgow et al., 2001).

Literature related to preventative services has identified the importance of community resources to promote, support, and maintain healthy behaviors (Curry & McBride, 1994; Irvin, Bowers, Dunn, & Wang, 1999; Starfield, Power, & Weiner, 1994). Community services are available in a variety of forms including mobile screening vans, voluntary agencies, community centers, and senior centers (Glasgow et al., 2001). Practitioner awareness of and referral of patients to appropriate community resources or other care team members can help to increase the patient's success at self-management of Type 2 diabetes (Barr et al., 2003).

Appropriate follow-up care is not only part of delivery system design, but also part of community resources within the CCM (Glasgow et al., 2001; Lewis & Dixon, 2004). Appropriate care that is formulated within the ideals of delivery system design needs to use the appropriate community resources to be successful (Austin et al., 2000; Lewis & Dixon, 2004). Utilizing not only other care team members such as certified diabetes educators, dietitians, and/or medical specialists such as an endocrinologist, but also using resources within the community such as support groups, community exercise programs, and mobile health clinics are vital at promoting independence and successful outcomes for patients with Type 2 diabetes (Barr et al., 2003; Glasgow et al., 2001; Lewis & Dixon, 2004).

Examining the referral to and use of community resources for patients with Type 2 diabetes is an important variable related to the management and support for patients with Type 2 diabetes. Community resources can be invaluable to patients, especially those with transportation difficulties. Becoming aware of how community resources are referred and utilized will help with the future development of diabetes treatment standards. Ensuring that these available community resources are utilized will benefit patients by allowing them to work within their own communities to manage Type 2 diabetes.

**Self-management support.** The CCM is different than traditional models and approaches to management of chronic diseases because self-management training and counseling are a focus (Siminerio et al., 2004). Benefits related to Diabetes Self-Management Education have been recognized by the American Diabetes Association and are considered an integral piece of diabetes care to strength the ability of patients to self-manage (Siminerio et al., 2006; Siminerio et al., 2004; Wagner, 1998). Self-management is considered to be a primary goal of diabetes education interventions because the cost and complications associated with diabetes are often preventable when blood sugar levels are well controlled (Stuckey et al., 2009). Self-management support prepares patients to take an active role in the management of Type 2 diabetes (Glasgow et al., 2001). Successful self-management and education programs help the patient to better understand the goals, priorities, barriers, and potential problems that can arise when dealing with Type 2 diabetes (Glasgow & Anderson, 1999; Glasgow et al., 2001; Von Korff & Gruman, 1997). The use of patient education brochures, referrals to other care team members, phone support hotlines, group and/or one-on-one counseling, and referrals to diabetes education classes can all aid in increasing self-management support for patients with Type 2 diabetes (RW.ERROR - Unable to find reference:1044; Solberg et al., 2006).

According to the National Standards for Diabetes Self-Management Education (Funnell et al., 2009), patients should have a personalized follow-up plan that should be developed by the patient and educator. Patient outcomes and goals of treatment, as well as a plan for ongoing self-management support, should be communicated to the primary care provider. In addition to a diabetes educator, patients may benefit from working with a nurse case manager for self-management support. The case manager can provide patient reminders for follow-up care, needed tests, answering medication questions, providing supplemental education, working with

the patient to modify behaviors and set goals, providing psychosocial support, and supplying the patient with information about beneficial community recourses (Funnell et al., 2009).

Another study among 463 adults with Type 2 diabetes and elevated BMI examined psychosocial and social-environmental variables that impact diabetes self-management and diabetes control. Participants completed self-report surveys, a baseline consultation, along with blood work for HbA1c (HbA1c) levels and lipid profiles. The findings indicated that self-efficacy, problem solving, and social-environmental support were independently associated with diet and exercise habits. Improvements in lipid levels and HbA1c levels were contributed to medication adherence ( $p = .001$ ,  $p < .0001$ , respectively), while healthy eating ( $p = .0003$ ), and exercise habits ( $p = .0004$ ) were directly related to BMI. The authors concluded that self-management support interventions should be aimed at promoting self-efficacy, problem solving, and social-environment support to improve outcomes in patients with Type 2 diabetes (King et al., 2010a).

**Summary.** Self-management support is a key element of the CCM (Robert Wood Johnson Foundation, 2016e), yet there is little literature available directly examining different strategies for self-management support and the impact of self-management support on patients with Type 2 diabetes. The proposed study will have a unique perspective on self-management support by examining referrals for patients to other practitioners or programs and the patients' perspectives related to self-management support. Examining this variable from both perspectives will give insight to the most beneficial ways of providing patients with this necessary support.

### **Informed, Activated Patients: Patient Activation and Participation in Decision-Making**

**Patient activation.** Patient activation can be defined as “developing experience with question formulation and building information-seeking skills that results in increased

collaboration with the health care provider (Alegria et al., 2008, p. 247).” Hibbard, Stockard, Mahoney, and Tusler (2004) described the process for conceptualizing and operationalizing what it means for a patient to be “activated,” and found that this process involves four stages. The four stages of activation include “believing the patient role is important, having the confidence and knowledge necessary to take action, actually taking action to maintain and improve one’s health, and staying the course, even under stress (Hibbard et al., 2004, p. 1016).” Research has found that patients who are more engaged, informed, activated, and confident are more likely to perform self-care behaviors to promote their health (Lorig et al., 1999; Mosen et al., 2007; Remmers et al., 2009; Von Korff & Gruman, 1997). Patients who are found to have higher levels of activation also have better outcomes related to quality of life, physical and mental function, maintaining an exercise regimen, regularly checking glucose levels, and maintaining an appropriate blood pressure level (Hibbard et al., 2004; Hibbard, Mahoney, Stock, & Tusler, 2007; Mosen et al., 2007).

The role of trust in the patient-physician relationship was examined related to levels of patient activation. Data were collected by surveying 2224 participants from different patient populations including those with diabetes, those with elevated lipids but without coronary artery disease, and a group of low risk patients. The researchers found a positive association between patient-physician trust and patient activation ( $\beta = 0.235, p < 0.05$ ) (Becker & Roblin, 2008).

Whether patient activation is a changeable personal characteristic and whether changes in the level of patient activation correlate with changes in health behavior were examined in a study with 479 participants who were divided into intervention and control groups. Survey data were collected at the initiation of the study, then again at six weeks and six months. The intervention group participated in a weekly discussion workshop comprised of patients with various chronic



diseases. The survey data collected was related to self-management behaviors, disease specific self-management behaviors (hypertension, diabetes, and arthritis), depression, the health related quality of life (HRQoL) measure, the PAM, and the Short Marlowe-Crowne Social Desirability Scale. The data from the intervention group was nearly equal to the control group with results showing that patients who were able to increase their activation level were also more likely to increase self-management behaviors, such as taking medications as directed, checking glucose levels as directed, checking feet for cracks or blisters, reading food labels, and reading about side effects related to medications (Hibbard et al., 2007).

A different study was conducted to examine whether a patient activation intervention resulted in patients becoming more active during consultations with practitioners and improved HbA1c levels in patients with Type 2 diabetes over a one year period. The 197 participants were divided into the activation intervention (generating 3-5 care-related questions to ask the practitioner) educational intervention groups. Raters reviewed the audiotaped consultations to assess patients' active involvement by using the Active Involvement Scale (AIS), a 7-point Likert-type scale ranging from 1(not true at all) to 7 (very true). The results of the study showed that prior to the intervention, rated active involvement was significantly correlated with rated active involvement after the intervention ( $r = .66, p < .001$ ). Rated active involvement was significantly correlated with the number of questions asked ( $r = .39, p < .001, n = 151$ ) and with percentage of time speaking ( $r = .67, p < .001, n = 151$ ). There was a significant effect for increasing rated active involvement ( $\beta = .65, F(1,148) = 110.48, p < .01$ ) and a significant effect for the activation intervention compared to the passive education ( $\beta = .13, F(1,148) = 4.54, p < .05$ ). There was also a significant effect for patients in the activation group asking more questions ( $\beta = .32, F(1,122) = 23.53, p < .01$ ) and speaking a greater percentage of time ( $\beta = .18,$

$F(1,122) = 6.80, p < .01$ ) than the patients in the passive education group. The findings did indicate that, among the total participants, patients with higher rated activation had greater decreases in HbA1c values over the 12 month period ( $\beta = -.21, F(1,148), p < .01$ ). Important findings in this study noted that patient activation did increase rated active involvement in consultations and greater active involvement predicted improvements in HbA1c values (Williams et al., 2005).

In a different study, Patient Activation Measure (PAM) scores were correlated with self-management behaviors, attitudes, and knowledge related to diabetes in a predominately minority and underinsured population of 287 participants. Remarkably, the majority of patients (62.2%) scored in the highest level of activation, which was much higher than previous studies using the PAM. Previous studies found that only 14% to 22% of participants typically have scores in the highest level (Ellins & Coulter, 2005; Greene, Hibbard, & Tusler, 2005; Hibbard, Mahoney, Stockard, & Tusler, 2005; Rask et al., 2009). The results also showed that patients with higher PAM scores were more likely to perform foot checks ( $p = .009$ ), receive eye care ( $p = .009$ ), exercise regularly ( $p = .021$ ), and have overall less difficulty managing diabetes ( $p = .001$ ). However, there was not a correlation between higher PAM scores and HbA1c knowledge (Rask et al., 2009).

A study by Mosen and colleagues (2007) examined PAM scores in adults with chronic conditions. A total of 6673 patients, including those with asthma, diabetes, heart failure, coronary artery disease, chronic pain, and a group that had both coronary artery disease and diabetes, responded to the surveys. The results showed that patients with higher PAM scores were significantly more likely to perform self-management behaviors, adhere to medications, use appropriate self-management service, report higher patient satisfaction scores and higher quality

of life scores, and also had higher physical and mental function scores compared to participants with lower PAM scores (Mosen et al., 2007).

A retrospective study used secondary data to examine the relationship between PAM scores and future diabetes related health outcomes. The PAM scores were predictive for HbA1c testing ( $p < .008$ ), low density lipoprotein cholesterol testing ( $p < .005$ ), and HbA1c control ( $p < .01$ ). Higher PAM scores were found to have a positive association to an increased likelihood that patients had HbA1c and low density lipoprotein cholesterol testing and better control of their blood sugars, as evidenced by HbA1c results. The PAM scores were not found to have a significant relationship with lipid lowering drug use and low-density lipoprotein cholesterol control (Remmers et al., 2009).

A more current study examined the levels of patient activation and relationships with physicians in chronically ill patients (Alexander, Hearld, Mittler, & Harvey, 2012). A cross-sectional, multivariate analysis was performed from data collected through 8,140 digital surveys of chronically ill patients, relating to experiences with their physicians, accessibility and use of health information about physicians, demographic information, socioeconomic status, health status, and health service utilization. The Patient Activation Measure and the Patient-Physician Relationship Scales were used in data collection. Results of the analysis found that patients who reported higher quality interpersonal exchanges with their physicians ( $\beta = 9.81, p < .001$ ), reported that their physicians treated them more fairly and respectfully ( $\beta = 5.55, p < .001$ ), and had frequent communication by physicians outside of office visits ( $\beta = 4.13, p < .001$ ) had higher levels of patient activation. Treatment goal setting related to patient activation levels was not found to be statistically significant ( $\beta = .91, p < .10$ ) (Alexander et al., 2012).

African Americans ( $\beta = -2.38, p < .001$ ) and Hispanic patients ( $\beta = -.43, p < .001$ ) were found to have significantly lower patient activation levels in general compared to Caucasians. Those who had English as a second language were significantly more likely to have lower patient activation levels than those who spoke English as a first language ( $\beta = -2.54, p < .001$ ). Those who were employed ( $\beta = 3.11, p < .001$ ) and those with an income level greater than \$75,000/year ( $\beta = 2.22, p < .001$ ) had higher levels of patient activation than those who were unemployed or had an income less than \$25,000/year. Patient activation was found to increase as a patient gets older, but began to decline after the age of 53. The health status control variables of self-assessed health status ( $\beta = 1.75, p < .001$ ) and number of chronic conditions ( $\beta = 1.68, p < .001$ ) were positively associated with patient activation levels. There was a negative association between patients with a regular physician and patient activation ( $\beta = -2.71, p < .001$ ), meaning that those patients who regularly saw one physician had higher levels of patient activation (Alexander et al., 2012).

The studies presented related to patient activation examine a variety of variables in various combinations related to patient activation. Studies have demonstrated the potential connection of patient activation to improved self-management of Type 2 diabetes (Hibbard & Tusler, 2007; Mosen et al., 2007; Remmers et al., 2009; Rost, Flavin, Cole, & McGill, 1991) however examining patient activation in conjunction with the other facets that are involved in the management of Type 2 diabetes is lacking. The data related to activation levels and/or PAM scores and HbA1c levels is inconsistent among the literature (Alexander et al., 2012; Mosen et al., 2007; Rask et al., 2009; Remmers et al., 2009; Rost et al., 1991; Williams et al., 2005). Examining patient activation in conjunction with the other variables presented in this study will provide a more comprehensive picture of how patient activation benefits patients with

Type 2 diabetes related to the multi-faceted, overall management that is required with this type of disease; as well as further clarify the relationship between activation and HbA1c levels.

**Participation in decision-making.** Cahill (RW.ERROR - Unable to find reference:252) referred to the term “patient participation” as “over-used and ambiguous” (p. 561) in an in-depth concept analysis. The term “patient participation” is currently a commonly used phrase that is employed when discussing decision-making, dignity, and quality of life (RW.ERROR - Unable to find reference:252). The early conceptualization of a shared decision-making relationship between the patient and practitioner was identified by Szasz and Hollender (RW.ERROR - Unable to find reference:794). The initial framework from which the patient/practitioner shared decision-making process stemmed was developed by Arnstein (RW.ERROR - Unable to find reference:795) in her framework related to American citizen participation and citizen power. Arnstein discussed the difference between the ritual of participating and the act of participating that resulted in change or affected the outcome of a process related to citizen’s participating in government. Arnstein’s definitions and ladder of participation have been used throughout other areas to describe and define participation in other activities or situations. In the 1970s there was pressure to promote patient participation related to the belief that patients had a right and responsibility to be involved in their health care, which was endorsed and supported by the World Health Organization (WHO) (RW.ERROR - Unable to find reference:792).

Patient participation not only encompasses the decision-making process, it extends into all aspects of care including, compliance of treatment plans, self-medication, medication adherence, patient education, information sharing, and taking part in physical care (RW.ERROR - Unable to find reference:801; RW.ERROR - Unable to find reference:285; RW.ERROR - Unable to find reference:804; RW.ERROR - Unable to find reference:321; RW.ERROR -

Unable to find reference:802; Golin et al., 1996; Wolpert & Anderson, 2001). McEwen et al. (RW.ERROR - Unable to find reference:791) assert that patient participation has many benefits, including increased patient responsibility with a commitment to health and health promoting behaviors. Other authors report that increased patient participation enables more effective self-management of diseases (RW.ERROR - Unable to find reference:796; RW.ERROR - Unable to find reference:285; Golin et al., 1996; Heisler et al., 2002). Patient participation in the decision-making process is vital to promoting and encouraging self-management of diseases, especially among patients who require a significant amount of disease self-management, as is the case with Type 2 diabetes. Because of the increased incidence and prevalence of Type 2 diabetes, it is important that practitioners learn how to engage and educate patients to make informed decisions about treatment plans and disease management, giving patients the best chance to manage their diabetes and improve their quality of life.

Charles, Gafni, and Whelan (RW.ERROR - Unable to find reference:379) acknowledge that the concept of shared decision-making between physicians and patients has been increasingly advocated as the idyllic model of treatment. The authors further discuss the meaning of shared decision-making, recognizing that even when using the paternalistic model, in which the patient passively agrees to the physician's treatment of choice, there is still a required type of partnership between the patient and physician (RW.ERROR - Unable to find reference:379). The shared decision-making model requires that the patient and physician share all stages of the decision-making process, meaning that both the patient and physician have treatment options in mind and both decide on a final action together (RW.ERROR - Unable to find reference:379).

Patient participation in the decision-making process is consistently missing in regards to medical decisions, thus increasing the potential for noncompliance with diabetes treatment plans (RW.ERROR - Unable to find reference:285). A study by Golin et al. (1996) examining if patients wanted to be involved in the decision making process found that 71.9% of patients wanted the doctor and patient to make decisions together, equally. Including the patient in the decision-making process can decrease the perceived burden of treatment and increase adherence to treatment plans (Vijan, Hayward, Ronis, & Hofer, 2005). An example would be discussing the transition of a patient from oral medications to insulin injections. Discussing this transition in a manner than allows the patient to voice concerns, while also allowing the practitioner to provide information to minimize fears can be helpful. Practitioners can present the transition to insulin injections in a less “threatening manner”, such as a trying insulin as a “temporary trial” (Vijan et al., 2005, p. 481).

A diabetes-specific scale to assess the patient’s desire to participate in the medical decision making process (DPMD) was developed and tested for internal consistency reliability, stability, and validity among 65 patients with Type 2 diabetes. The tool had high internal consistency reliability (Cronbach’s alpha = .90,  $r = 0.71$ ) and demonstrated good validity (Pearson  $r = 0.23$ ,  $p = .07$ ). The results of the initial testing of this tool found that patients who received diabetes education by attending a group education session with a diabetes educator had a greater desire to participate in the medical decision making process than those without education (Golin et al., 2001).

In a survey of 2,000 patients, individuals were asked to evaluate physicians’ participatory decision-making style, rate the physicians’ communication styles, and report understanding of the effects of self-care on self-management of the diabetes. Higher ratings on provider

participatory decision-making style and provider communication were associated with higher patient self-management assessments ( $p < .01$  in all models). Thus, the authors concluded that participatory decision-making and provider communication were likely to enhance self-management by increasing patient understanding and self-confidence (Heisler et al., 2002).

**Summary.** Patient participation in the decision-making process is discussed in the literature in a variety of ways. There are varying data related to the amount of participation that a patient desires and what the ultimate effects of the levels of participation have on patient outcomes. Literature has demonstrated a desire among patients to participate in the decision-making process related to medical decisions regarding treatment (RW.ERROR - Unable to find reference:381; Golin et al., 2001). It has also been determined that increased patient participation in the decision-making process can have positive effects related to a patient's ability to self-manage a disease (RW.ERROR - Unable to find reference:324). Research is lacking which examines levels of patient participation related to patient outcomes, specifically in patients with Type 2 diabetes and there is also a lack in research related to patient participation in decision-making related to the type of practitioner that patients see. Examining patient participation in decision-making with a specific outcome, such as a HbA1c level, can provide a unique insight into the importance of patient participation in the decision-making process for the treatment and management of Type 2 diabetes. Also examining which practitioners have higher levels of patient participation in decision-making and better patient outcomes can impact which type of practitioner a patient may choose see.



## **Prepared, Proactive Practice Team: Facilitation of Patient Involvement in Care and Differences among Types of Practitioners**

**Facilitation of patient involvement in care.** Facilitating patient involvement in care requires that there is open communication between the practitioner and the patient, that the practitioner provides information to the patient, and that the practitioner allows the patient to express his or her concerns, views, and opinions related to treatment (Martin et al., 2001). Research has shown that when patients recognize that their health care provider has facilitated their involvement in care, patients in a variety of settings tend to be more satisfied with care and better adhere to treatment plans related to the specific diseases or health concerns for which they are being treated (Martin et al., 2001). Health care practitioners can actively facilitate, or encourage, patients to be involved in their own healthcare by using behaviors such as suggesting the patient ask questions, listening to the patient's concerns, and providing as much information as possible to the patient (Martin et al., 2001). Health care practitioners can also facilitate the patient's involvement in decision making by offering the patient choices among treatment options; and, by facilitating the patient's involvement in care, the patients can then maintain a sense of control related to disease management and have a sense of responsibility to care for oneself (RW.ERROR - Unable to find reference:368).

In addition to the benefits already noted, facilitation of involvement in care has been related to higher levels of trust in the practitioner and self-efficacy, measured in this particular study using Wake Forest Physician Trust Scale (WFPTS) and the Diabetes Management Self-efficacy scale (DMSES) (RW.ERROR - Unable to find reference:869). A cross-section study examined 268 patients and the relationship between literacy, trust, self-efficacy, and participation in medical decision-making in patients with Type 2 diabetes. Literacy levels were assessed

using the Rapid Estimate of Adult Literacy in Medicine (REALM); and the Spoken Knowledge in Low Literacy in Diabetes Scale (SKILLD) was used to assess diabetes knowledge which does not require a certain level of literacy to be used accurately. There was no relationship found between literacy and trust, self-efficacy, or facilitation of patient involvement. Self-efficacy ( $p < .001$ ,  $p < .001$ ), trust in the practitioner ( $p < .003$ ,  $p < .02$ ), and facilitation of patient involvement in care ( $p < .003$ ,  $p < .008$ ) were related to diabetes-specific mental and social quality of life outcomes and facilitation of patient involvement in care was strongly related to self-efficacy ( $p < .001$ ) and trust ( $p < .001$ ) (RW.ERROR - Unable to find reference:869).

Gotler and colleagues (RW.ERROR - Unable to find reference:868) examined the prevalence of physician facilitation of patient involvement in decision-making (PDM facilitation) by observing 3,435 patient consultations with family physicians in a community practice. Research nurses directly observed the consultations assessing for physician facilitation of patient involvement, using a measure of 20 physician practice style behaviors that been tested and showed good interrater reliability and time use during the consultation. At the conclusion of each visit, the nurse completed a post observation checklist, measuring specific visit characteristics. The results indicated that PDM facilitation occurred in 25% of the observed consultations. Rates of PDM facilitation varied considerably among individual physicians, ranging from 0% to 79%. The results also showed that patient satisfaction was not associated with PDM facilitation in this particular study (RW.ERROR - Unable to find reference:868).

A study examined physician facilitation of patient involvement in care and physician behaviors related to the patient's perception that the physician encouraged and facilitated their involvement in care (N=128). The results showed that there was congruence among the patient perceptions and observer perceptions related to the physician facilitation of patient involvement

in care ( $r = .238, p < .01$ ). The behavior most closely associated with the patient's perception of the physician's facilitation of involvement in care was asking open-ended questions ( $\beta = .49, p < .001$ ). Consistently responding to patient questions ( $\beta = .22, p < .01$ ) and offering fewer, not more, alternatives for treatment options ( $\beta = .21, p < .01$ ) were also associated with higher perceptions related to facilitation of patient involvement (Martin, Jahng, Golin, & DiMatteo, 2003).

Facilitation of patient involvement in care has been examined in a variety of areas, including patients with Type 2 diabetes. However, by moving beyond the initial acknowledgement of whether or not practitioners facilitate care and by incorporating other factors such as the level of patient activation and participation in decision-making, a more complete picture can be drawn related to facilitation of patient involvement in care and how other variables can change based on practitioner facilitation. Examining only whether practitioner-facilitated involvement in care effects outcomes is not encompassing of the multifarious process involved in the management of Type 2 diabetes. There is also a significant gap in the literature related to facilitation of patient involvement in care and the effect it has on HbA1c levels and self-care behaviors. This proposed study will explore the effect of facilitation of involvement, participation in decision-making, and patient activation on participation in self-care behaviors and HbA1c values to examine a complete picture of Type 2 diabetes care and management, in addition to also examining the differences in facilitation of patient involvement in care among physicians and nurse practitioners. This proposed study will also begin to fill the gap related to facilitation of patient involvement in care and diabetes specific outcomes, such as HbA1c levels and self-care behavior practices.

*Facilitation and decision-making examined together.* Facilitation of patient involvement in care and patient involvement in decision-making overlap in many studies (RW.ERROR - Unable to find reference:868; RW.ERROR - Unable to find reference:946; Martin et al., 2003). Participation in decision-making is often considered to be part of the concept of facilitation of patient involvement in care. Facilitation of involvement can take place in a variety of ways. Greenfield, Kaplan, and Ware (RW.ERROR - Unable to find reference:946) acknowledge that there are two main lines of research related to facilitation of patient involvement in care. The first focuses on the patient's willingness and ability to participate in medical decision-making. The second line focuses on physician-patient interactions related to outcomes such as satisfaction, knowledge, and compliance. After completing the study related to facilitating involvement in care by coaching patients to ask questions and negotiate medical decisions with their practitioners, the authors suggest that further research should continue to examine how both lines of research affect each other and patient outcomes (RW.ERROR - Unable to find reference:946). The proposed study will examine both the amount of patient participation in the decision-making process and the practitioner's facilitation of patient involvement in care. Examining this relationship among Type 2 diabetic patients will help close the gap in the literature related to these variables.

**Variations in care among physicians and nurse practitioners.** The advanced practice role of nurse practitioners (NPs) began in 1956 (Mundinger, 2002). In order to provide primary care to homebound patients, the nurse practitioner program was designed by Lee Ford, who was a nurse with a doctoral degree, and a physician named Henry Silver (Mundinger, 2002). Mundinger (2002) described nurse practitioner care, saying that nurse practitioners approach care in a unique fashion. Characteristics of a patient they treat include one who is more informed

about care, more empowered with self-care, and more confident that all health issues are being addressed regularly. This type of approach is called “differentiated practice (Mundinger, 2002, p. 799).” While many physicians approach patient care in a comprehensive fashion, according to Mundinger (2002), nurse practitioners are the only clinicians trained specifically in this manner. The nurse practitioner has a crucial role in the care of patients with chronic diseases (Dancer & Courtney, 2010). As the role of the NP continues to expand with increased autonomy, reimbursements rates for NPs have increased, and the overhead costs for employing NPs are lower than employing physicians, NPs are in a unique position to increase their presence in managing care for patients with chronic illness, including Type 2 diabetes (Boville et al., 2007; Mundinger et al., 2000; Mundinger, 2002).

Varied data exist related to satisfaction and patient outcomes of NPs and physicians. While there tends to be a general consensus that patients are more satisfied with care provided by NPs, data related to patient outcomes tends to be more inconsistent (Chang et al., 2007; Fain & Melkus, 1994; Kinnersley, Anderson, Parry, Clement, & et al, 2000; Roblin et al., 2004; Rudy, Davidson, Daly, Clochesy, & et al, 1998; Salisbury & Tattersell, 1998; ter Bogt et al., 2011; Venning, Durie, Roland, Roberts, & Leese, 2000). One study discovered that in patients with Type 2 diabetes, physician care was preferred over NP care and a few other studies found patient satisfaction and/or patient outcomes in NP groups to be very similar to those seeing physicians (Horrocks et al., 2002; Lenz, Mundinger, Hopkins, Lin, & Smolowitz, 2002; Mundinger et al., 2000; Roblin et al., 2004; Rudy et al., 1998; Salisbury & Tattersell, 1998; ter Bogt et al., 2011; Venning et al., 2000). There is data to show that nurses and NPs can improve patient outcomes through various interventions and programs in conjunction with physicians in patients with diabetes, however little data exists to show a significant difference in patient outcomes for

patients strictly seeing NPs instead of physicians (Chang et al., 2007; Hoffman, Tasota, Zullo, Scharfenberg, & Donahoe, 2005; Litaker et al., 2003; Renders et al., 2001; Taylor et al., 2003; ter Bogt et al., 2011). In general, the data related to the variations in care from NPs and physicians do not have a clear advantage of one practitioner over another. The studies have shown positive, negative, and neutral results related to measured outcomes for patients who see NPs compared to patients who see physicians.

A health system in Ohio used the CCM to guide the development of a new model that incorporated NPs into the delivery of care for patients with chronic illnesses (Boville et al., 2007). The goal of this project was to promote interdisciplinary models of care for patients with chronic illnesses and to promote training of this interdisciplinary system in other academic medical centers. The role of the nurse practitioner was carried out through planned patient visits, which included medication assessments and algorithms for care with the main goals being to ensure the patients received all recommended screenings and assessments per disease guidelines and to improve patient outcomes through medication changes (if needed) and assisting the patient with goal setting for self-management. Team consultations with NPs, primary care physicians, medical residents, and various other, as-needed, care team members were conducted to present patient cases and use group problem solving strategies. Success of this model has been noted, with improved clinical outcomes in glycemic control, lipid management, and blood pressure control (Boville et al., 2007).

A systematic review of whether NPs could provide care at the first point of contact as effectively as physicians in a primary care setting found 11 trials and 23 observational studies that met all inclusion criteria. Overall, patients were more satisfied with NPs (standardized mean difference 0.27, 95% CI 0.07 to 0.47); however, no differences in health status were found.

Health status was assessed using different measures including physical function, emotional function, social function, and a satisfaction questionnaire incorporating a health status measure. Nurse practitioners were found to have longer consultations (weighted mean difference 3.67 minutes, 95% CI 2.05 to 5.29). Quality of care by NPs was found to be better in a variety of ways, such as identifying physical abnormalities more often, providing more information to patients, and offering more advice related to self-care, management of illnesses, and having more complete medical records and higher communication scores than the physicians (Horrocks et al., 2002).

An examination of the cost effectiveness among physicians and NPs in a primary care setting among 1292 patients (651 from physicians and 641 from NPs) looked at the consultation process, patient satisfaction, health status, return visits over a two week period, and costs. Results indicated that NPs had consultations that were significantly longer (11.57 v 7.28 min, adjusted difference 4.20, 95% CI 2.98 to 5.41), carried out more tests (8.7% v 5.6% of patients, OR= 1.66, 95% CI 1.04 to 2.66), and asked patients to return more frequently than physicians did (37.2% v 24.8%, OR= 1.93, 95% CI 1.36 to 2.73). Patients were more satisfied with care provided by NPs (mean score 4.40 v 4.24, adjusted difference 0.18, 95% CI 0.092 to 0.257). There was no significant difference in costs among NPs and physicians. Based on these results, if NPs could decrease their consultation time while maintaining the benefits of their care, NPs could become more cost effective than general practice physicians in primary care settings (Venning et al., 2000).

A study by Mundinger et al. (2000) examined patient outcomes among physicians and NPs for primary care visits and follow-ups related to emergency room or urgent care visits. The study was conducted over a two-year period, interviewing 1316 patients immediately following

the consultation and then again at six months and one year after the initial appointments to gather various data. There were no significant differences found in the patients' health status between the NP group and the physician group at the six month interview ( $p = .92$ ). Patients with hypertension were found to have statistically significantly decreased diastolic values in the NP group (82 v 85 mm Hg,  $p = .04$ ). There were no differences in satisfaction among groups after the initial consultations; however, at the six month interview ( $p = .88$ ), scores for physicians were significantly higher than NPs related to "provider attributes" specifically related to patient satisfaction (4.2 v 4.1 on a scale where 5 = excellent,  $p = .05$ ) (Mundinger et al., 2000).

Condosta (2012) examined if care by NPs in a free diabetic clinic exceeded that of the physicians. Outcome measures included HbA1c levels, LDL and HDL levels, ophthalmology and podiatry referrals, foot inspection, and microfilament-sensation testing. The results showed that NP care had higher odds (yet statistically insignificant) of foot inspection (adjusted OR 5.98,  $p = .01$ ), podiatry referral (adjusted OR = 1.90,  $p = .04$ ), and filament sensation testing (adjusted OR 1.60,  $p = .0002$ ). There was no indication that patients of NPs had better LDL levels, HbA1c levels, and ophthalmology referrals (Condosta, 2012).

The differences among NP and physicians care were examined in patients seeking "same day" primary care consultations. Outcome measures included patient satisfaction, resolution of symptoms and concerns, care provided, information provided, and patients' intentions for seeking care in the future. The findings indicated that in adult consultations, patients were more satisfied with the care received from the NPs (e.g. practice 1 OR -8.79 (95% CI -13.59 to -3.98); practice 5 -5.92 (-15.70 to 3.86); practice 10 -5.90 (-12.11 to .31). Resolution of symptoms and concerns and care provided were similar between the groups (OR 1.23 (95% CI .87 to 1.73)). Patients seeing NPs did report receiving significantly more information related to their illness



(cause of illness: OR .58(95% CI .44 to .76); relief of symptoms: OR .32(95% CI .24 to .43); duration of illness: OR .34(95% CI .14 to .84) to 2.38(.79 to 7.14); how to reduce recurrence: OR .19(95% CI .09 to .38) to OR 1.57(95% CI .46 to 5.23); what to do if problem persists: OR .61(95% CI .41 to .90) and all NP consultations except for one practice were significantly longer than those with an physician (physician median range of 6 minutes with a range of 4-8 minutes; NP median range of 10 minutes with a range of 7-14 minutes) (Kinnersley et al., 2000).

Patient satisfaction among physicians and NPs was examined in a managed care setting by surveying 41,209 patients from 1997 through 2000. Findings indicated that patients were significantly more satisfied with NP consultations than physician consultations ( $p < 0.05$ ). Patient satisfaction with access to care did not differ significantly by practitioner. Only in consultations specifically related to diabetes management were patients more satisfied with the care provided by the physician than the NP for practitioner interaction ( $p < 0.05$ ), care access ( $p < 0.01$ ), and overall experience ( $p < 0.05$ ) (Roblin et al., 2004).

Another study examined NPs and physicians specifically related to quality of care for patients with diabetes among practices with NPs, PAs, or physicians and to assess if the type of practitioner contributed to difference in care. A total of 846 patients from 46 different family medicine practices participated in chart audits related to diabetes care and adherence to American Diabetes Association (ADA) guidelines. The findings indicated that practices employing NPs had overall better adherence to ADA guidelines, however the reasons for these differences were not clear. The authors were not hypothesizing that the NPs specifically had better adherence to ADA guidelines, simply that practices employing NPs had overall better compliance with ADA guidelines among all practitioners than practices who did not have any

NPs on staff (Ohman-Strickland et al., 2008) ; however, this finding suggests that NPs played a role in the overall better compliance.

A third study related to Type 2 diabetes examined care processes and patient outcomes among NP and physician patients. The findings indicated that NPs were more likely to document diabetes education, height, urinalyses results, and HbA1c values. There were no differences among NPs and physicians when documenting medications, drug/alcohol/tobacco use, depression, weight, blood pressure, foot exams, cardiovascular exams, blood glucose testing, creatinine testing, and referrals to ophthalmologists. There were no differences found in patient outcomes (HbA1c values, SF-36 results, and improvements in diabetes specific symptoms including blurred vision, drowsiness, polyuria, and nocturia) between the two groups (Lenz et al., 2002).

**Summary.** The variations among physicians and NPs are an important part of examining outcomes related to Type 2 diabetes. Understanding the differences between NPs and physicians and how those differences relate to patients, goals of treatment, and outcomes can influence management styles when caring for patients with Type 2 diabetes. The inconsistency in the literature related to outcomes and aspects of practice among physicians and NPs is also an important gap in knowledge that will be addressed in the proposed study. HbA1c values and self-care behavior practices among patients from each type of practitioner will be evaluated, in addition to looking at referral and follow-up practices. Physicians and NPs may have patterns of practice related to the other variables being examined in this study. Looking at these variables and outcomes for patients among the physician and NP groups may also provide new insights related to patterns of practice that benefit this specific patient population.

## **Improved Outcomes: HbA1c levels and Self-Care Behavior Practices**

**HbA1c levels.** The HbA1c test, also known as glycated hemoglobin, glycosylated hemoglobin, glycohemoglobin, A1c, or HbA1c, is a way to measure blood glucose management over a two- to three-month period. This blood test should be done every three to six months for patients with diabetes. The test reflects a patient's average blood glucose control over the previous two or three months and is a very accurate way to monitor overall diabetes control (Joslin Diabetes Center, 2016; Mayo Clinic, 2016).

A person without diabetes would have a HbA1c level between 4% and 6% (Joslin Diabetes Center, 2016). A common recommended target level is 7% or less for patients with diabetes (American Diabetes Association, 2013; Joslin Diabetes Center, 2016; Mayo Clinic, 2016). A level of 7% would correlate with an estimated average glucose (eAG) of 154mg/dL (American Diabetes Association, 2016c). Based on these recommendations, patients should strive to achieve an eAG of 154 or less; or an HbA1c level of 7% or less. The higher the HbA1c result, the more risk a person has of developing complications related to diabetes (Mayo Clinic, 2016). The importance of the HbA1c levels should not be minimized. For every percentage point decrease in HbA1c levels, there is also a 35% reduction in the risk of microvascular complication for patients with Type 2 diabetes, a 25% reduction in diabetes related deaths, and an 18% reduction in myocardial infarctions (UK Prospective Diabetes Study (UKPDS) Group, 1998). The risk of complications associated with diabetes is significantly reduced when the HbA1c values are less than 8%, ideally lower than 7% (Mayo Clinic, 2016; UK Prospective Diabetes Study (UKPDS) Group, 1998). HbA1c levels are directly correlated with blood sugar levels. Therefore, higher blood sugar levels, no matter what the higher levels are caused by, will result in higher HbA1c levels. Diet, exercise, medication adherence, and regular glucose testing

all are factors that can contribute to blood sugar control that will also contribute to the HbA1c levels (Joslin Diabetes Center, 2016; UK Prospective Diabetes Study (UKPDS) Group, 1998).

The proposed study will contribute to the limited literature that has examined all areas of the CCM to provide a comprehensive picture of how a patient's actions and involvement in care can directly affect HbA1c levels. Using HbA1c levels as an outcome measure is a reliable way to examine blood glucose control that can provide a long-term picture of a patient's ability to manage their diabetes.

**Self-care behavior practices.** Self-care refers to a significant set of activities that are important to patient-centered chronic illness management (Song & Lipman, 2008). Effective management of diabetes requires complex, continual, and demanding self-care behaviors including recognizing signs and symptoms of the disease, diet control, exercise, blood glucose monitoring, managing physical and emotional distress, foot care, smoking cessation, limiting alcohol consumption, medication regimens, and utilizing family support and community resources (American Diabetes Association, 2016a; Arar, Hunt, & Larme, 1998; National Institutes of Health and the Centers for Disease Control and Prevention, 2011; Song & Lipman, 2008). Managing Type 2 diabetes has proven to be very challenging because of the difficulty and complexity involved in making the necessary life-style changes. Vigilant self-care for patients with Type 2 diabetes is particularly important because it can help to delay the progression of the disease and onset of complications (Song & Lipman, 2008). There is much literature discussing patient involvement in the medical decision-making process, self-care behaviors, and goals of self-management related to diabetes treatment plans.

Effective self-management is necessary to improve outcomes, specifically HbA1c levels, for patients with Type 2 diabetes (Funnell et al., 2009). Self-care behaviors, such as checking

blood glucose levels, medication adherence, eating a particular diet, following an exercise regimen, checking feet regularly, smoking cessation, and reducing alcohol intake are necessary to prevent morbidity and mortality in patients with Type 2 diabetes (Toobert et al., 2000; Wang & Fenske, 1996; Weinger, Butler, Welch, & La Greca, 2005). Incorporating self-care behaviors related to the management of Type 2 diabetes is key to living a long, healthy life and decreasing the risk of developing complications (Aljaseem et al., 2001). Patients with Type 2 diabetes are expected to make complex, life-long changes in everyday behaviors in order to manage this disease; these patients cannot simply take a pill to manage the disease (RW.ERROR - Unable to find reference:884; McNabb, 1997). Diabetes requires lifestyle management in addition to medication adherence.

Patients have reported that learning to manage self-care behaviors and incorporate these changes into their lifestyles is more difficult than accepting the initial diagnosis of Type 2 diabetes (Hurley & Shea, 1992). Self-management and the incorporation of self-care behaviors are conceptually different than many other health behaviors because these changes are more complex, restrictive, and sometimes expensive (Jones et al., 2003). Diet and exercise have been found to be the most difficult self-care behaviors for patients to incorporate in their management of Type 2 diabetes (Goodall & Halford, 1991).

A study by Sousa and colleagues (2005) examined whether self-care management and affects blood sugar control and addressed the relationship between self-efficacy and self-care agency. A cross-sectional study using previously collected data and a convenience sample of 141 adults with type 1 or Type 2 diabetes and used the Demographic Questions of the Diabetes Care Profile, Appraisal of Self-Care Agency scale, Insulin Management Diabetes Self-Efficacy Scale (IMDSES), and the Insulin Management Diabetes Self-Care Scale to examine their

association with HbA1c levels. Diabetes self-care management was a significant predictor of blood sugar control ( $\beta = -.18, t(136) = -2.219, p < .05$ ). Self-efficacy was found to strongly affect diabetes self-care management ( $\beta = .61, t(136) = 9.197, p < .001$ ). However, upon further analysis, diabetes self-care management did not strongly affect blood sugar control ( $\beta = -.12, p > .05$ ), when controlling for demographics, self-rated health, and self-care agency (Sousa et al., 2005).

A study with 1,032 patients from Veterans' Affairs facilities examined patients' own assessments of self-management with blood sugar control and high-quality diabetes care. Higher evaluations of self-management were significantly associated with lower HbA1c levels ( $\beta = -.013, p < .001$ ). Participants in the 95<sup>th</sup> percentile for self-management had mean HbA1c levels of 7.3 (95% CI, 6.4-8.3). Those in the 5<sup>th</sup> percentile had mean HbA1c levels of 8.3 (95% CI, 7.4-9.2). The analysis revealed that for every 10-point increase in patient evaluations of their self-management practices the odds of receiving HbA1c tests increased by 15% (4-27%), receiving an eye examination increased by 16% (7-27%), and receiving a nephropathy screening increased by 13% (2-26%) (Heisler, Smith, Hayward, Krein, & Kerr, 2003).

A study examining the burden of Type 2 diabetes found that adherence to self-management goals was independently correlated with a patient's views about the burdens of treatment (Vijan et al., 2005). Including the patient in the decision-making process can decrease the perceived burden of treatment and increase adherence to treatment plans (Vijan et al., 2005). Physicians cannot assume that patients will be compliant to a specific treatment plan; rather, the patients will often tailor the treatment plan to better fit into their personal lifestyles.

Management of Type 2 diabetes requires behavioral changes on the part of the patient to meet the goals of therapy (RW.ERROR - Unable to find reference:321; Wolpert & Anderson,

2001). Wolpert and Anderson (2001) stressed that because diabetes is a self-managed condition, models of care should be focused on promoting more self-care behaviors while stressing the importance of glycemic control from the patient's perspective. Researchers have acknowledged that while the long-term benefits of tight glycemic control are well published, this desired control is rarely achieved in the general clinical practice arena. In order for practitioners to be to achieve desired outcomes with their patients, the importance of blood sugar control must be evaluated from the patient's perspective, and the patient's goals must be incorporated into treatment (Wolpert & Anderson, 2001).

The effectiveness of self-management training in 72 patients with Type 2 diabetes was examined, noting positive effects of self-management training on knowledge, frequency and accuracy of self-monitoring of blood glucose, self-reported dietary habits, and glycemic control. Educational interventions were found to be more effective than didactic interventions in relation to glycemic control, weight control, and lipid profile results. The authors summarized that self-management training was effective in the short term for patients with Type 2 diabetes (RW.ERROR - Unable to find reference:324).

A study by Toljamo and Hentinen (2001) examined self-care behaviors, metabolic control, and social support in 213 patients with diabetes. Of the total sample, 36% of participants had a HbA1c level under 7.5%, and 12% of participants had a HbA1c level above 10%. Participants living alone had a mean HbA1c value of 8.7%, compared to those living with a family member or partner (mean HbA1c level 8.0%,  $p < .05$ ). The authors discovered four different categories relating to self-care behavior practices: flexible self-care (46%), strictly regimen-adherent self-care (16%), self-planned self-care (19%), and neglect of self-care (19%). Participants with poorer metabolic control were found to be smokers, living alone, and a higher

than average risk of neglect of self-care, with mean HbA1c values of 9.1% ( $F = 11.8, p < .001$ ) compared to those who adhered to self-care (Toljamo & Hentinen, 2001).

A study by Daly and colleagues (2009) examined patient self-care behaviors, barriers associated with problem behaviors and diabetes control. A randomly selected sample of 458 patients completed a mail survey consisting of 141 questions adopted from a variety of previously validated instruments. Cost ( $p = .005$ ) was found to be the most common barrier related to self-care practices. Respondents who viewed Type 2 diabetes as a serious problem ( $p = .006$ ) and those who had depression ( $p = .007$ ) were strongly associated with higher HbA1c levels. Lower HbA1c levels were associated with participants who were married ( $p = .026$ ) and reported greater adherence satisfaction with taking medications and checking blood glucose levels ( $p < .001$  for all) (Daly et al., 2009).

Another study examined relationship between diabetes treatment barriers and self-efficacy related to self-care behaviors. The study used a self-report questionnaire focusing on diet, exercise, medication practices, blood glucose testing, and insulin and diet adjustments in patients with Type 2 diabetes. The patients reported barriers related to carrying out diet and exercise but less difficulty with blood glucose testing and medication adherence (Aljasem et al., 2001).

A literature analysis was completed to examine patient decision-making and non-routine behaviors in their personal working concept of self-care (Song, 2010). Articles chosen were published between 1999 and 2009 and targeted adult populations with diabetes mellitus. The authors then set out to address how existing studies examine health outcomes for patients with diabetes, how negative health outcomes can be minimized, and the results of the current literature on the relationship between self-care in patients with diabetes and health outcomes.



The health risks for patients with diabetes include microvascular (blindness and kidney disease) and macrovascular (cardiovascular disease and coronary heart disease) complications, nontraumatic extremity amputations, pregnancy complications, and death related to flu and pneumonia. The current literature demonstrated that glycemic control helps to prevent both microvascular and macrovascular complications in patients with diabetes (Song, 2010).

Typical research related to self-care behaviors involves monitoring for signs/symptoms of diabetes, managing diet, exercise, testing blood glucose levels, medication compliance, regular foot checks, smoking cessation, and limiting alcohol consumption. Newer research is beginning to examine the role of patient decision-making in response to individual disease process responses and the need for additional non-routine behaviors to self-manage. The literature and research is beginning to recognize the importance of other factors on self-care behaviors including personal experiences, values, and culture (Song, 2010).

Another systematic literature review summarized existing knowledge regarding barriers to Type 2 diabetes management from both the patient and practitioner perspectives using literature published between 1990 and 2009. The author summarizes that patients' adherence, attitudes, beliefs and knowledge related to diabetes can affect the way individuals manage their disease. Other factors such as culture, language, health beliefs, financial resources, co-morbidities, and social support also impact individual self-management. Practitioners' attitudes, beliefs, and knowledge can affect how they choose to treat patients with Type 2 diabetes. Practitioners may further influence patient perceptions through effective communication and by identifying barriers with the patients that directly affect them. Awareness of these factors can aid in the development of treatment plans and goals of treatment to enhance the success that a patient has at self-managing Type 2 diabetes (Nam, Chesla, Stotts, Kroon, & Janson, 2011).

**Summary.** The literature related to self-care behaviors in patients with Type 2 diabetes is vast. However, most of the literature examines why patients do or do not adhere to recommendations related to self-care behaviors. Multiple studies have examined patient activation and self-care behaviors (Hibbard & Tusler, 2007; Mosen et al., 2007; Rask et al., 2009; Remmers et al., 2009). While all of the studies noted that there was some positive impact on self-care behaviors in patients with higher activation levels, there were also limitations and areas for further research. Three of the studies noted that having a cross-sectional design was a limitation (Mosen et al., 2007; Rask et al., 2009; Remmers et al., 2009). Mosen et al (2007) also noted that from their research, it could not be concluded if patient activation leads to increased self-management, or if those patients who engage in self-management behaviors increased their activation levels. The proposed study will have a unique perspective in that it will examine the effects of levels of patient activation, participation in decision-making, and facilitation of involvement in care on self-care behaviors and HbA1c levels. Examining variables such as patient activation together with and participation in decision-making and facilitation of involvement in care will provide information as to whether these factors affect a patient's ability to follow through with self-care recommendations.

### **Summary**

The variables in this proposed study can impact self-management of chronic disease and achieving desired outcomes related to chronic diseases, including Type 2 diabetes. Higher levels of activation and participation in decision-making have been shown to increase self-management behaviors such as adhering to self-care behaviors and having improvements in HbA1c levels (Golin et al., 1996; Hibbard et al., 2004; Hibbard et al., 2007; Lorig et al., 1999; Mosen et al., 2007; M. L. Parchman, Zeber, & Palmer, 2010; Remmers et al., 2009; Von Korff &

Gruman, 1997). Parchman, Zeber, and Palmer (2010) found that participation in decision-making was associated with patient activation levels, which then increased the medication adherence among patients with Type 2 diabetes. The literature suggests that the amount of patient participation in the decision-making process related to the treatment plan can have a direct effect on adherence to self-care behaviors related to management of diabetes (RW.ERROR - Unable to find reference:364; RW.ERROR - Unable to find reference:285; RW.ERROR - Unable to find reference:365; RW.ERROR - Unable to find reference:366; RW.ERROR - Unable to find reference:368; RW.ERROR - Unable to find reference:369; Golin et al., 1996; Golin et al., 2001; Heisler et al., 2005; Jahng et al., 2005; Montori, Gafni, & Charles, 2006; Muhlhauser & Bergert, 2000; Pooley, Gerrard, Hollis, Morton, & Astbury, 2001). Brashers, Haas, and Neidig (RW.ERROR - Unable to find reference:871) found that patients who were more assertive, or more activated, were more likely to receive more information from their physicians and received more treatment options. Facilitation of patient involvement in care has been associated with greater patient satisfaction with care, better patient adherence to treatment plans, higher levels of patient trust in practitioners, and increased self-efficacy (RW.ERROR - Unable to find reference:869; Martin et al., 2001). While focusing on treatment from a pathophysiological standpoint is important, it is equally important to include patients in deciding on the goals related to self-management of the disease, such as diet and exercise (Arar et al., 1998). Practitioners should explain rationales behind treatment plans, become aware of the patient's perception related to treatment, and address any concerns related to how the treatment plans will be incorporated into the patient's lifestyle (Wilson et al., 1986).

Delivery system design, clinical information systems, decision support, self-management support, and community resources are also important aspects related to the management of Type

2 diabetes. The use of clinical information systems and electronic decision support tools has been shown to improve practitioner performance. However, research related to patient outcomes and use of decision support systems has been insufficient and the data that has been analyzed has been inconsistent (Crosson et al., 2012; Frijling et al., 2002; Garg et al., 2005; Hunt et al., 1998; Jaspers et al., 2011; Keyhani et al., 2008; Lau et al., 2012; McCoy et al., 2012; O'Connor et al., 2011; Poon et al., 2010; Romano & Stafford, 2011; Smith et al., 2008).

Studies specifically examining patients with Type 2 diabetes found conflicting results related to blood glucose control, HbA1c monitoring, HbA1c values, overall quality of care, and adherence to evidence-based guidelines (RW.ERROR - Unable to find reference:1040; Crosson et al., 2012; O'Connor et al., 2011). Effective management of chronic diseases, like Type 2 diabetes, requires that the delivery system design also be linked to community resources. The success of delivery system designs can be improved by establishing links to the community resources to support patients in their self-management endeavors (Austin et al., 2000; Barr et al., 2003; Bodenheimer et al., 2002b; Dancer & Courtney, 2010; National Institutes of Health and the Centers for Disease Control and Prevention, 2011; Robert Wood Johnson Foundation, 2016b; Robert Wood Johnson Foundation, 2016c; Robert Wood Johnson Foundation, 2016d).

Self-care behaviors and self-management support are integral parts of managing Type 2 diabetes in order to delay the progression of the disease, reduce the risk of complications, and promote optimal quality of life (Aljasem et al., 2001; Song & Lipman, 2008; Stuckey et al., 2009). Increasing patient participation in the decision-making process and providing self-management support has been shown to directly affect patients' likelihood of adhering to self-care behaviors (RW.ERROR - Unable to find reference:379; RW.ERROR - Unable to find reference:285; RW.ERROR - Unable to find reference:365; RW.ERROR - Unable to find

reference:366; RW.ERROR - Unable to find reference:368; RW.ERROR - Unable to find reference:369; Golin et al., 1996; Golin et al., 2001; Heisler et al., 2005; Jahng et al., 2005; Montori et al., 2006; Muhlhauser & Bergert, 2000; Pooley et al., 2001). Ensuring that the available community resources are appropriately referred to and utilized by patients is also important related to the self-management of Type 2 diabetes. Examining follow-up care and referral procedures is important in order to assess whether patients with less desirable HbA1c values are being adequately treated and given appropriate resources for support. Finding successful techniques for teaching patients the importance of self-care behaviors and supporting them beyond the consultation office is important to increase the patient's ability to effectively manage blood sugars on a daily basis. Because of the personal choices that patients may make, the importance of self-care should be stressed to the patient in order to promote as much successful self-management as possible (RW.ERROR - Unable to find reference:285).

Further examining the differences among practitioners is important with the ever evolving and expanding role of the nurse practitioner. NPs are continuing to increase their presence in the treatment of chronically ill patients, including those with Type 2 diabetes (Boville et al., 2007; Munding, 2002). Continuing the research examining outcomes for patients seeing NPs compared to Physicians is important to ensure that patients are receiving optimal care and achieving the desired outcomes related blood glucose management, as measured in HbA1c values. Examining the patient outcomes of HbA1c values and self-care behavior practices among these two groups, in addition to examining referrals and use of generated prompts in the EHRs, will help to fill the current gaps in the literature.

Examining all of these variables together can provide a more comprehensive view of diabetes management through the eyes of the patient. If patient activation, facilitation of patient

involvement, and participation in decision-making are all lacking, there is a potential that there will be mismatched goals between the patient and practitioner related to diabetes management, which can ultimately lead to overall poor management of diabetes (Heisler et al., 2002; Hibbard & Tusler, 2007; Martin et al., 2003; Mosen et al., 2007; Rask et al., 2009; Vermeire, Van Royen, Coenen, Wens, & Denekens, 2003; Wolpert & Anderson, 2001). Also, if delivery system designs, clinical information systems, decision support tools are not being utilized as appropriately designed, there is a potential to miss important aspects of care for patients requirement continual, complex management as those patients with Type 2 diabetes. The gaps in the literature show a need for all of the variables and outcome measures presented in this chapter to be examined together to obtain a better understanding of the complexities involved in the management of Type 2 diabetes. Current literature as presented data showing that diabetes has been found to be poorly controlled throughout the United States (Li et al., 2004) and the CCM has been shown to be a beneficial framework for providing care to patients with Type 2 diabetes (Bodenheimer et al., 2002a; Dancer & Courtney, 2010; National Institutes of Health and the Centers for Disease Control and Prevention, 2011; Nutting et al., 2007; Parchman, Michael L,MD, MPH, Pugh, Wang, & Romero, Raquel L,MD, MPH, 2007; Robert Wood Johnson Foundation, 2016a; Siminerio et al., 2006; Siminerio et al., 2004; Smith et al., 2008). Therefore, the results of this proposed study that was developed using a successful model for managing chronic diseases can offer information to improve outcomes and provide a comprehensive picture of current Type 2 diabetes patients to see where future research efforts need to be focused.

## **Chapter 3**

### **Methods**

While a variety of literature has examined multiple combinations of the variables in this study, no study to date has examined the variables in the comprehensive fashion presented here based upon the CCM. Also, no study has examined the patient participation in decision-making related to HbA1c values. Participants for this study are patients who have a medical diagnosis of Type 2 diabetes prior to taking part in this study. The tools that will be used for data collection will be completed by the participants, a review of the medical record will be completed by the primary investigator (PI), and a blood draw will be collected from each participant to obtain the HbA1c level within two months prior to or following the consultation. The methodology presented in this chapter will describe the procedures for this study to recruit participants and gather the data to examine the variables of patient activation, facilitation of patient involvement, participation in decision-making, decision support, delivery system design, clinical information systems, community resources, self-management support, and differences between physicians and nurse practitioners in relation to HbA1c values and self-care behaviors as outcomes.

### **Research Questions**

The research questions were the results of a thorough review of current literature examining the management of Type 2 diabetes presented in chapter two.

Primary questions:

1. Among Type 2 diabetic patients, do levels of patient activation, participation in decision-making for treatment planning, and facilitation of patient involvement in care affect HbA1c levels and patients' performance of self-care behaviors?

2. Based on the CCM, what are the effects of delivery system design and clinical information systems, together with patient perceptions of decision support, self-management support, and community resources on HbA1c levels and participation in self-care behaviors for patients with Type 2 diabetes?

Secondary questions:

3. Is there a difference in levels of patient activation, participation in decision-making, and facilitation of patient involvement in care when a nurse practitioner treats a patient compared to a physician?
4. Do patients who see nurse practitioners for management of Type 2 diabetes experience higher levels of engagement in self-care behaviors and more therapeutic HbA1c levels compared to patients who see a physician?

## **Research Procedures**

### **Design**

This cross-sectional, descriptive study will examine patient activation, facilitation of patient involvement, participation in the decision-making process, decision support, delivery system design, clinical information systems, referral to community resources, and self-management support related to the management of Type 2 diabetes for patients seen by nurse practitioners and physicians in the primary care setting. This study will examine the effects of patient activation (Patient Activation Measure), participation in decision-making (Perceived Involvement in Care Scale), and practitioner facilitation of patient involvement (Facilitation of Patient Involvement Scale and Perceived Involvement in Care Scale) and how these variables impact self-care behavior practices (Summary of Diabetes Self-Care Activities) and HbA1c levels on patients with Type 2 diabetes. Delivery system design (Patient Assessment of Care for



Chronic Conditions and demographic form), clinical information systems (demographic form), decision support (Patient Assessment of Care for Chronic Conditions), self-management support (Patient Assessment of Care for Chronic Conditions and demographic form), and referral to community resources (Patient Assessment of Care for Chronic Conditions and demographic form) will also be assessed for their impacts on the same outcomes, self-care behaviors (Summary of Diabetes Self-Care Activities) and HbA1c levels. Secondary aims are to examine the variables for patients seen by a nurse practitioner compared to a physician. Patients will complete instruments for the independent variables and the outcome of patient self-care behaviors at one time point after consultation with a physician or NP, and HbA1c values will be examined within two months prior to or immediately following the scheduled consultation.

### **Setting**

Data collection for this study will be completed in five primary care offices throughout a health system in Western Pennsylvania. Literature has shown that many Type 2 diabetes patients are managed through their primary care provider at least in the early stages of treatment (Prijetel, 2011). There are a total of seven NPs and 18 physicians among the five locations.

### **Participants and Sampling**

Participants of this study will be required to be diagnosed with Type 2 diabetes and be 18 years of age or older. Patients must be seeing a physician or nurse practitioner for treatment. Patients using medication such as oral agents and/or insulin will be included, and medication usage will be categorized as 1) oral agents, 2) insulin, 3) combination oral/insulin, and 4) no medication, and controlled for in the data analysis. Participants must be able to speak, read, and write in English. Patients with dementia and mental illness will be excluded if they are unable to make independent decisions, have a surrogate decision maker, a designated care giver.

Patients at the designated primary care offices with Type 2 diabetes will be made aware that they can have the option of learning about a research study that they may qualify to participate in when they are called by phone from the office administration to be reminded of their upcoming appointment. Flyers will be hung in the waiting rooms and exam rooms in the participating primary care offices providing a study overview and contact information for the principle investigator (PI). The PI will contact the administration teams at the offices three times per week to obtain the number of patients who will be coming to the office with a diagnosis of Type 2 diabetes. No identifying information will be given at that time. If patients with a diagnosis of Type 2 diabetes are scheduled for an appointment, the PI will be available at the primary care offices for potential meetings with those patients regarding enrollment in the study after an office staff person has introduced the study to the patient, and they agree to speak to the PI. Patients must sign a consent form to participate in the study, which includes giving permission for the PI to access the patient's medical records to obtain a HbA1c value. The care providers will also need to sign a confidentiality statement of their agreement to participate in the study and to keep the patients participating in the study confidential.

The PI will gain approval and support for the study from the primary care providers and will be given written information related to the recruitment of potential participants and inclusion/exclusion criteria prior to the initiation of the study. Patients who are interested in participating in the study will meet with the PI at the conclusion of the consultation with their care provider in order to be formally enrolled in the study. At this time, potential participants will be assessed by the PI using an eligibility checklist. Once the potential participants are deemed eligible, the PI will discuss the processes of the proposed study, review the consent form, and answer any questions they may have. The participant will then be asked to sign a consent form

to participate in the study. After a consent form is signed, the participants will be given a packet of questionnaires to complete. The packet will include a copy of the Patient Activation Measure, Facilitation of Patient Involvement Scale, Perceived Involvement in Care Scale, Patient Assessment of Care for Chronic Conditions and the Summary of Diabetes Self-Care Activities, and a demographics form. The patients may complete the questionnaires immediately after their consultation with their practitioner or they may take the packet home and will also be given a stamped, addressed envelope to send the questionnaires to the PI. If the patients wish to take the packet home, the PI will request a contact phone number to follow-up with participants if the packets are not returned within one month of the office visit. If the questionnaires are not returned within this time frame, the PI will follow up with the participants via a telephone call. If the questionnaires are still not returned within another week, the PI will follow up with one additional telephone call.

**Power analysis.** In a multiple regression analysis, a standard formula of  $N > 50 + 8k$  is used to determine sample size, with  $N$  being the sample size and  $k$  being the number of predictors. A minimal sample size of 91 patients ( $k = 5$ ) will be necessary to achieve statistical significance based on the number of variables. However, using Cohen's guidelines of effect size, an a priori power analysis could be performed to ensure the sample size is large enough to have a power of .80. In this case,  $R^2 = .10$  (small to moderate effect) would be used to determine a sample size of 112 participants would be necessary to ensure the study had a power of .80 (Polit, 2010c).

### **Instruments Used for Data Collection for Independent Variables**

**Demographic form.** Participants will be asked to complete a 17-item, researcher developed demographics tool that will take approximately 3-4 minutes to complete. In addition

to describing the population of this proposed study, the tool will also be used to assess delivery system design and use of clinical information systems. The tool will require the patient to circle the correct response, with a few handwritten responses required. The tool will request information including name, age, sex, race/ethnicity, level of education completed, marital status, and employment status. The patient will also be asked what type of practitioner they are seeing on the day of the consultation (NP or physician). The patient will be asked the length of time the patient has had a relationship with his or her practitioner, the number of visits to the primary care provider in the previous 12 months related to diabetes care, the number of visits to care team members or community services in the previous 12 months that related to diabetes care, and length of time since initial diagnosis of Type 2 diabetes. The patient will also be asked to identify if they have seen only physicians or NPs, or if the patient has seen both physicians and NPs within the previous 12 months and how frequently they have seen each.

To assess delivery system design, use of clinical information systems, self-management support and referral to community services, the patients will be asked yes or no to whether they were asked to make a follow-up appointment, yes or no to whether they were referred to any other practitioners or services. If referred to other practitioners or services, the patients will be asked to circle which other services they were referred to (i.e.: endocrinologist, dietician, foot specialist, eye doctor, certified diabetes educator) and/or write on the form any other services they were referred to that are not listed. The patients will also be asked if they discussed goals of treatment with their practitioner and if they were given any printed information from the practitioner related to goals of treatment or test results.

**Patient Activation Measure (PAM).** The PAM will be used to measure *patient activation*. The PAM is a 22-item questionnaire to be completed by the participant. There are

four subscales that include: Believes Action Role Important (2 items), Confidence and Knowledge to Take Action (10 items), Taking Action (6 items), and Staying the Course Under Stress (4 items). Scores range from 1 (disagree strongly) to 4 (agree strongly), allowing for total scores to range from 13-52. Higher scores are associated with higher levels of patient activation. The PAM should take approximately 5-7 minutes to complete. The PAM was purchased for doctoral dissertation use through the Insignia Health Website (Insignia Health LLC, 2012). The PAM was developed in four stages by Hibbard, Stockard, Mahoney, and Tusler (2004). The first stage involved conceptually defining activation through a literature review, consultations with experts using the “consensus method,” and focus groups with individuals who have chronic diseases. The domains identified in this stage related to the importance of self-management, collaboration with health care providers, maintaining function/preventing declines in health status, and having access to appropriate and high quality care (Hibbard et al., 2004).

The second stage involved a preliminary scale development using the domains that were identified during the first stage. Rasch psychometric methods were used to develop the scale and test the psychometric properties. Rasch measurement can be used to create interval-like, one-dimensional, probabilistic Guttman-like scales from ordinal data, and the analysis indicated the PAM worked in this manner. In the case of the PAM, a person’s score on the scale, indicates how activated the person is. The Rasch Person reliability for the 21-item measure was between .85 and .87. The Cronbach’s alpha was .87. A test-retest reliability assessment was measured by the standard error of measurement (SEM) for each person’s estimated activation at each testing. A confidence interval (CI) of 95% was calculated for each participant. Of the 30 participants, 28 retested within the bounds of the 95% CI. Criterion validity was assessed using interviews of the five highest scorers and five lowest scorers from the initial study. Using transcribed semi-

structured interviews and three independent judges, the interviews were categorized by the judges as being from a person of “high” or “low” activation. The judges’ classifications matched the participants activation level as measured on the PAM in 83% of the classifications (25 out of 30 were correct). Cohen’s kappa for measured activation and the individual judge’s classification were .80, .90, and .90 ( $p < .001$  for all kappas) (Hibbard et al., 2004).

The third stage involved exploring the idea of extending the range of measure to see if this measure could be used on patients who did not have any chronic diseases. A 22-item PAM was used based on the Rasch rating scale model for this stage. The authors did find that the scale could translate to patients without chronic diseases. Reliability statistics for those with and without chronic conditions were comparable (Hibbard et al., 2004).

The fourth stage used a national probability sample to assess the measure against different subsamples throughout the population and to assess the construct validity. There was a high-level reliability of the PAM across the national sample with infit values ranging from .71 to .144. The 22-item PAM was tested for construct and criterion validity. The authors tested the PAM (activation) with the SF 8 (self-reported health status) and found that those with higher activation reported significantly better health ( $r = .38, p < .001$ ) and had significantly lower rates of doctor office visits, emergency room visits, and hospital stays ( $r = -.07, p < .01$ ) (Hibbard et al., 2004).

**Facilitation of Patient Involvement (FPI) Scale.** The FPI scale will be used to measure *facilitation of patient involvement in care*. The FPI scale is a 9-item questionnaire that is completed by the participant and estimated to take two to four minutes to complete. Each item is scored using a range of 1 (none of the time) to 6 (all of the time), with overall scores ranging from 9-54. Higher scores are related to increased patient perception of facilitation of

involvement of the patient by the practitioner. The FPI was developed by Martin, DiMatteo, and Lepper (2001) as a self-report scale for patients to be used to assess perceptions of physicians' facilitative behaviors. The authors developed a preliminary 18-item tool that was reviewed by a group of seventeen psychologists for feedback on face validity, content overlap, and ambiguity. After review, 9 items were removed, 7 of the remaining 9 items were modified for clarity and specificity. The response format is similar to that of a Likert scale. Respondents are asked to circle the response that best indicates their answer (Martin et al., 2001). Permission to use the FPI scale was granted by Dr. Leslie Martin via email.

Cronbach's alpha was used to establish internal consistency reliability with a cutoff point of .85. Pearson's  $r$  was used to assess test-retest reliability with a cutoff point of .80. The authors conducted five separate studies to assess consistency reliability and test-retest reliability. The Cronbach's alpha values to establish internal consistency reliability were .93 (N=236), .90 (N=338), .91 (N=333), .93 (N=44), and .89 (N=84). All values were above the predetermined cutoff value of .85. The test-retest results were .89 (N=44), and .85 (N=84), both also above the predetermined cutoff value of .80 (Martin et al., 2001).

Construct validity was tested using patient age, gender, level of education (discriminant), physician gender, patient's preferred communication style, and information seeking (convergent). The authors tested the hypothesis that individuals will seek medical information and communicate more effectively if the physicians behave in a manner that facilitates their involvement. Validity was determined when communication style and self-reported adherence both positively correlated with FPI scores. The results for communication style were  $r = .28$  (N=338,  $p < .001$ ),  $r = .38$  (N=333,  $p < .001$ ),  $r = .35$  (N=44,  $p < .10$ ), and  $r = .46$  (N=84,  $p < .05$ ).

The results for self-reported adherence were  $r=.31$  ( $N=338$ ,  $p < .001$ ),  $r=.32$  ( $N=333$ ,  $p < .001$ ),  $r=.32$  ( $N=44$ ,  $p < .10$ ), and  $r= .42$  ( $N=84$ ,  $p < .05$ ) (Martin et al., 2001).

**Perceived Involvement in Care Scale (PICS).** The PICS will be used to measure *facilitation of patient involvement* and *patient participation in decision-making*. The PICS is a 13-item questionnaire that will be completed by the patient in 2-5 minutes. The PICS includes three subscale that are Provider Facilitation Scale (5 items), Patient Information Scale (4 items), and Patient Decision-Making Scale (4 items). The patient answers *agree* (1 point) or *disagree* (0 points) to each question for a minimum score of 0 and a maximum score of 13. Higher scores are associated with an increased patient perception that their practitioner is involving them in in the decision-making process (Lerman et al., 1990). Permission to use a copy of the PICS was granted by Dr. Lerman through email.

The PICS was developed by Lerman and colleagues (1990) and can be used to assess patients' perceptions of physician and patient behaviors that occur during routine medical visits, regarding patient attitudes towards illness and the management of illness. The initial questionnaire was comprised of 25 agree/disagree questions. Scoring was determined by awarding one point for every *agree* answer and 0 points for every *disagree* answer. After item analysis was completed, the final PICS version was finalized with 13 agree/disagree questions. Internal consistency was measured using Cronbach's alpha with a result of .73 ( $N=131$ ). Factor analysis resulted in three relatively independent factors labeled provider facilitation (PF), patient-physician information exchange (PI), and patient decision-making (PDM) (Lerman et al., 1990).

**Patient Assessment of Care for Chronic Conditions (PACIC).** The PACIC will measure *decision support*, *patient activation*, *delivery system design*, *referral to community resources*, and *self-management support*. The PACIC is a 20-item, self-report questionnaire that



will be completed by the patient in two to five minutes. Each item is scored on a 5-point scale ranging from 1 (no or never) to 5 (yes or always). The 20 items are arranged into 5 subscales including Patient Activation (3 items), Delivery System Design/Decision Support (3 items), and Follow-up/Coordination (5 items), Goal Setting (5 items) and Problem-solving/Contextual Counseling (4 items) subscales; these latter two scales assess self-management support. Higher scores are associated with increased decision support. The PACIC should take approximately two to five minutes to complete (Glasgow et al., 2005). The PACIC is available in the public domain and can be found on the Improving Chronic Illness Care website (Robert Wood Johnson Foundation, 2016h).

The PACIC was developed by Glasgow and colleagues (2005). Internal consistency for the PACIC was evaluated using coefficient alpha. A confirmatory factor analysis was used to evaluate item loading with almost all of the items highly loaded on the proposed scales. Only three items had factor loadings less than .70. Ten of the twenty items had factor loadings of .80 or greater. Item reliability was greater than .50 for 75% of the items, which the authors deemed to be acceptable. Overall test-retest reliability was .58 and individual scale reliabilities ranged from .47 to .68. Validity for the PACIC was correlated moderately to strong (.42-.60) with four of the convergent validity measures and  $r = .32$  (Glasgow et al., 2005).

### **Instruments Used for Data Collection for Dependent Variables**

**Summary of Diabetes Self-Care Activities (SDSCA).** The SDSCA will measure the dependent variable *self-care behaviors*. The SDSCA is an 11-question, self-report measure related to the frequency of patients completing various self-management activities over the preceding seven days. The SDSCA is divided into five subscales that include Diet (4 items), Exercise (2 items), Blood Sugar Testing (2 items), Foot Care (3 items), and Smoking Habits (1

item). The SDSCA can be completed in 5-7 minutes. The self-management behaviors assessed include diet, exercise, glucose testing, medication adherence, foot care, and smoking habits. The first 10 items are related to how frequently in the previous seven days a patient performed these activities. Each item can be scored 0-7 to correspond with the number of days patients report engaging in these activities. Item 11 is a question regarding smoking habits with in the last seven days. The patient will answer yes or no. If yes, the patient is asked to report how many cigarettes are smoked on an average day. For items 1-10, the number of days per week (0-7) for each question is used as the score. For the general diet score, the mean number of days for items one and two is the score. For the specific diet score, the mean number of days for items three and four are the score, however the score for item four is to be reversed, (0=7 days, 1=6 days, etc.). The exercise score is the mean number of days for items five and six. The blood glucose testing score is the mean number of days for items seven and eight. The foot care score is the mean number of days for items 9 and 10. The smoking status score is “0” for “nonsmoker” or “1” for “smoker.” Higher scores correspond to participating in self-care behaviors more frequently, with the exception of the scoring for item 11 (Toobert & Glasgow, 1994; Toobert et al., 2000) The SDSCA was available in the public domain and permission for use was also provided by Dr. Toobert.

The SDSCA was developed by Toobert and Glasgow (1994). Three different studies were conducted to perform a factor analysis and test the validity and reliability of the SDSCA on various sample populations (Toobert & Glasgow, 1994). Factor analysis was used to assess the overall structure of the tool. Three factors were assessed including self-care/adherence, exercise, and glucose testing. All items loaded highly on their intended factor in all three studies. Based on the results of the factor analysis, the SDSCA questionnaire was broken down into three

subscales of diet, exercise, and glucose testing. The average inter-item correlations within each SDSCA subscale exceeded .50. For test-retest reliability the 127 participants in the first study we retested six months later, with results ranging from .43 to .58 (Toobert & Glasgow, 1994).

Face, content, concurrent, and predictive validity were also assessed. The content of the SDSCA was collected by a group of experts assembled by the RAND Corporation in an effort to study self-care activities in people with diabetes. The authors note that the SDSCA has face validity because it “inquires only about diabetes-related information and specifically about the areas of the diabetes regimen for which most patients have daily recommended activities (Toobert & Glasgow, 1994, p. 363).” Concurrent validity was assessed through analysis using correlations of SDSCA subscale scores with relevant self-monitoring, behavior inventories, interviews, and/or reflective meter measures. For all of the subscales, concurrent validity was determined through statistically significant correlations. The predictive validity was not determined, as the authors attempted to predict HbA1c values using the SDSCA subscales, however no significant associations were found. The authors determined that based on the data collected, the SDSCA is a valid and reliable tool for assessing self-care practices among patients with diabetes (Toobert & Glasgow, 1994).

**HbA1c values.** The HbA1c value is a result from HbA1c blood test. It can also be referred to as the glycated hemoglobin, glycosylated hemoglobin, and HbA1c. This blood test can determine both the presence of diabetes mellitus and the degree of glycemic control, which is how well a patient is managing his or her blood glucose levels. The HbA1c test reflects the average blood sugar level over the past 2-3 months. A normal HbA1c level for a person who does not have diabetes is from 4.5-6 percent. Someone with uncontrolled diabetes will have a level above 9 percent. For most patients with Type 2 diabetes, a level of 7 percent or less is

considered representative of well-managed diabetes (American Diabetes Association, 2013). In patients with diabetes mellitus, the HbA1c level will be normal or slightly elevated (7% or less) if blood glucose levels are optimally managed over an 8-12 week period. If glucose levels have not been controlled, the HbA1c levels will be elevated (greater than 7%). HbA1c levels are considered good indicators of long-term glycemic control (Joslin Diabetes Center, 2016; Mayo Clinic, 2016).

If not drawn within the two months prior to the consultation, the care provider will give the patient a new laboratory order for a HbA1c test. The patient will need to go to an appropriate laboratory, as designated by their insurance, to have their HbA1c level drawn within the next two months, in addition to any other lab work that is ordered by their care provider. The patient will register at the laboratory and the phlebotomist will draw blood from the patient to collect the HbA1c level. The blood samples will be analyzed and reported back to the care provider, according to laboratory policy. The HbA1c level will need to be drawn either within two months following the consultation, or if there has been a value drawn within the previous two months prior to the consultation, that value can be used. HbA1c results will also be accepted from rapid test machine that may or may not be available at the primary care offices.

### **Procedures for Data Collection**

Only data related to the variables of this study will be collected from the patient. All information related to the patient will be obtained directly from the patient with the exception of HbA1c values. The HbA1c values will be obtained via the electronic health record, only after a consent form has been signed by the patient. The PI has extensive training using the electronic health record program that will be used to obtain the HbA1c values. The PI will complete a HIPPA agreement with the health system and will be granted access to the HbA1c values for the

purpose of this study. All written data pertaining to the patients will be kept in a locked file cabinet at the PI's home of which only the PI will access. The written data obtained from the patients will be de-identified and entered into a password protected, computerized database. Each participant will be given a random identification number as part of the data collection process. Only the PI will know the patient identification codes. Patient names with corresponding code numbers will be kept on a master list that will be stored in a locked file that is separate from the data. Hard copies of the demographics forms and questionnaires will be number coded to allow the PI to identify the data appropriately. No patient identifiers will be entered into the computer database. Only the identification numbers will be entered into the database. There will be no identifying information on the patient questionnaires.

All raw data will be checked for errors by the PI by reviewing each individual form to ensure the responses are within the limits of the appropriate responses, as designated by the directions provided for each instrument used in this proposed study. The PI will then enter the data in to the database and check the entered data against the written data for accuracy.

### **Data Analysis**

The SPSS software package version 20.0 will be used to analyze the data. The data will first be screened to ensure accuracy of the values and assess for any missing values. Univariate normality will be assessed among each of the variables. Histograms, skewness, kurtosis, means, SDs, and frequencies will be evaluated for each of the variables. Outliers will be identified by examining standardized residuals. Mahalanobis distance (D2) can also be used to evaluate outliers by comparing individual values to a standardized value table. The underlying assumptions for each statistical analysis will then be examined.

For ease of understanding, the types of data for each tool are as follows. The PAM scores range from 0-100, meaning they are ratio data. The PACIC scores are based on a Likert-type scale. Therefore the data is interval. The SDSCA scores are based on the total number of days reported by the patient, meaning this is ratio because there can be zero days reported. The FPI scale scoring is also a Likert-type scale. This data is interval. The PICS tool is scored using “0” if the patient disagrees with the statement or “1” if the patient agrees, and a total score out of 13 is derived. This type of scoring requires the data to be interval. The HbA1c levels are measured on a ratio scale. Values can range anywhere from 0 and beyond. A level of 7 or less is considered optimal for a person with Type 2 diabetes. Levels in excess of 7 are associated with poor control (Joslin Diabetes Center, 2016; Mayo Clinic, 2016). Type of care provider will have to be coded for each respective group, NP or physician, making this nominal data. Referrals will be coded yes or no, making this nominal data.

**Research Question 1.** *Among Type 2 diabetic patients, do levels of patient activation, participation in decision-making for treatment planning, and facilitation of patient involvement in care affect HbA1c levels and patients’ performance of self-care behaviors?* A multiple regression will be used to analyze the data with an alpha set at .05. Assumptions for multiple regression will first be assessed. The first assumption requires ratio or interval level data for the dependent variable. Both HbA1c levels and SDSCA scores are ratio level data. The PAM, PICS, and FPI scores are all either ratio or interval level data, and do not require any special coding as part of the analysis. The second assumption is that the data is randomly and independently sampled. Participation in this research study is strictly on a volunteer basis and at a variety of different primary care offices, therefore the data is randomly and independently sampled. The fourth assumption is related to homoscedasticity of the data, which is for each value of X, the

variability of Y scores must be about the same, and vice versa. The assumption of equal variances will be examined by examining the standardized residual plots against the standardized predicted values. The shape should be approximately rectangular to satisfy the assumption. The next assumption is that variables being correlated are assumed to have an underlying distribution that is bivariate normal, meaning scores on variable X are assumed to be normally distributed for each value of variable Y, and vice versa. This assumption will be tested by examining scatter plots for each of variables against HbA1c levels and against SDSCA scores. Data needs to appear linear to satisfy assumption. Correlations among variables will also need to be assessed to ensure that none of the pairs are too highly correlated. Tolerance will be evaluated for each predictor variable. Tolerance values fall between 0 and 1.0, with higher values being more desirable (Polit, 2010c).

Using the SPSS output, inferences will be made from the data. After controlling for the type of medication used by the patient and the length of time each patient has been diagnosed as having Type 2 diabetes, the R<sup>2</sup> in the model summary will indicate the percentage of variability in HbA1c scores and percentage of variability in SDSCA scores that can be accounted for based on the PAM, PICS, and FPI scores. To evaluate the overall fit of the model, the F values and *p* values from the ANOVA table will be examined. A *p* value < .05 would indicate significant findings. The b-weights and standard errors of the predictor variables will be evaluated. Larger standard error values are considered to be unreliable. The standardized  $\beta$  value will represent the correlation between PAM, PICS, and FPI scores and SDSCA and HbA1c levels, while controlling for other variables, with the statistical significance (*p* < .05) based on the *t* distribution. These values will be presented in the tables as each predictor variable is entered into the model. The 95% confidence interval (CI) will also be evaluated; this is the 95%

likelihood that the  $\beta$  value for PAM, PICS, and FPI scores in the population fall between the lower and upper portion of the 95% CI. The zero-order, part, and partial correlations for each predictor variable will also be evaluated. Zero-order correlations will look at the bivariate correlations. Partial correlations will give values while controlling for other variables. Semi-partial correlations will look at the unique contributions of each variable. All of these will be examined to determine the specific ways the variables affect the SDSCA scores and HbA1c levels in patients with Type 2 diabetes. Using Cohen's guidelines of effect size, an a priori power analysis could be performed. In this case,  $R^2 = .10$  (small to moderate effect) would be used to determine a sample size of 112 participants would be necessary to ensure the study had a power of .80 (Polit, 2010c). If the results of the multiple regression analysis are insignificant, post hoc testing can be performed using the calculated  $R^2$  to test if the sample size is too small or to verify that there truly is no relationship between the variables (Polit, 2010c).

**Research question 2.** *Based on the CCM, what are the effects of Delivery System Design and Clinical Information Systems, together with patient perceptions of Decision Support, Self-Management Support, and Community Resources on HbA1c levels and participation in self-care behaviors for patients with Type 2 diabetes?* A multiple regression will be used to analyze the data with an alpha set at .05. Assumptions for multiple regression will first be assessed. The first assumption requires ratio or interval level data for the dependent variable. Both HbA1c levels and SDSCA scores are ratio level data. The PACIC subscale scores for decision support, self-management support, and community resources are interval data. The data related to the patient referrals (REF), whether patient goals were discussed (PG), and if any printouts (PO) were given to the patient related to goals of treatment or test results for patient care will need to be dummy coded for appropriate use in the multiple regression analysis. The REF responses will be either



yes or no. Yes will be coded “1” and No will be coded “0”. The discussion of goals will also be a yes/no response and will be coded “1” for Yes and “0” for No. Whether the patient received any printouts from the care providers will also be dummy coded “1” for Yes and “0” for No. The second assumption is that the data is randomly and independently sampled. Participation in this research study is strictly on a volunteer basis and at a variety of different primary care offices, therefore the data is randomly and independently sampled. The fourth assumption is related to homoscedasticity of the data, which is for each value of X, the variability of Y scores must be about the same, and vice versa. The assumption of equal variances will be examined by examining the standardized residual plots against the standardized predicted values. The shape should be approximately rectangular to satisfy the assumption. The next assumption is that variables being correlated are assumed to have an underlying distribution that is bivariate normal, meaning scores on variable X are assumed to be normally distributed for each value of variable Y, and vice versa. This assumption will be tested by examining scatter plots for each of variables against HbA1c levels and against SDSCA scores. Data needs to appear linear to satisfy assumption. Correlations among variables will also need to be assessed to ensure that none of the pairs are too highly correlated. Tolerance will be evaluated for each predictor variable. Tolerance values fall between 0 and 1.0, with higher values being more desirable (Polit, 2010c).

Using the SPSS output, inferences will be made from the data. After controlling for the type of medication used by the patient and the length of time each patient has been diagnosed as having Type 2 diabetes, the R<sup>2</sup> in the model summary will indicate the percentage of variability in HbA1c scores and percentage of variability in SDSCA scores that can be accounted for based on the PACIC scores and the presence of chart documented referrals (REF), discussion of patient goals (PG), and whether any printouts were given to the patient (PO) (which will be dummy

coded, 0-No, 1-Yes for REF, PG, and PO). To evaluate the overall fit of the model, the F values and  $p$  values from the ANOVA table will be examined. A  $p$  value  $<.05$  would indicate significant findings. The b-weights and standard errors of the predictor variables will be evaluated. Larger standard error values are considered to be unreliable. The standardized  $\beta$  value will represent the correlation between PACIC scores, REF, PG, PO and SDSCA and HbA1c levels, while controlling for other variables, with the statistical significance ( $p<.05$ ) based on the t distribution. These values will be presented in the tables as each predictor variable is entered into the model. The 95% confidence interval (CI) will also be evaluated; this is the 95% likelihood that the  $\beta$  value for PACIC scores, REF, PG, and PO in the population fall between the lower and upper portion of the 95% CI. The zero-order, part, and partial correlations for each predictor variable will also be evaluated. Zero-order correlations will look at the bivariate correlations. Partial correlations will give values while controlling for other variables. Semi-partial correlations will look at the unique contributions of each variable. All of these will be examined to determine the specific ways the variables affect the SDSCA scores and HbA1c levels in patients with Type 2 diabetes. Using Cohen's guidelines of effect size, an a priori power analysis could be performed. In this case,  $R^2 = .10$  (small to moderate effect) would be used to determine a sample size of 112 participants would be necessary to ensure the study had a power of .80 (Polit, 2010c). If the results of the multiple regression analysis are insignificant, post hoc testing can be performed using the calculated  $R^2$  to test if the sample size is too small or to verify that there truly is no relationship between the variables (Polit, 2010c).

**Research question 3.** *Is there a difference in levels of patient activation, participation in decision-making, and facilitation of patient involvement in care when a nurse practitioner treats a patient compared to a physician?* To answer this question, an ANCOVA analysis will be

completed. There will be three ANCOVA models. The first model will use PAM scores as the dependent variable, the second model will use the PICS scores as the dependent variable, and the third model will use the FPI scores as the dependent variable.

The data will first be screened to ensure the assumptions for ANCOVA are met. The first and second assumptions are related to data level. Covariates are usually continuous interval or ratio level variables. The covariate of length of time for patients since being diagnosed as having Type 2 diabetes is ratio data. The PAM scores are ratio data. The PICS and FPI scores are interval data. The type of care provider, being a nurse practitioner or a physician, will be coded as nominal data because the independent variable in ANCOVA is always nominal (Polit, 2010a).

The third assumption requires that there is random selection of subjects. The selection of participants will be on a volunteer basis and random to ensure this assumption is met. The fourth assumption requires that the dependent variable be normally distributed. A visual examination of histograms will ensure that this assumption is not violated (Polit, 2010a).

The fifth assumption is that there is homogeneity of variance. This will be examined using Levene's test for equality of variance. A non-significant Levene's test indicates the variance between the groups is most likely equal. The sixth assumption is that the relationship between the dependent variable and covariates is linear. Scatterplots will be evaluated, assessing for any curvilinearity. If a covariate is found to have curvilinear relationship with the dependent variable, the variable could be transformed as appropriate. The seventh assumption is that relationships between all pairs of covariates are linear. Scatterplots will again be examined to assure this assumption is not violated. The eighth and final assumption is that there is homogeneity of regression across groups. The covariate should have the same relationship with the dependent variable in every group. Regression lines will be examined and should be parallel

to each other to prevent any violation of this assumption and any increased risk of type II errors. The assumption of homogeneity of regression across groups can also be tested in SPSS using an interaction term in the analysis. If the interaction term is statistically significant, ANCOVA should not be used. The researcher will also be mindful of cases of multicollinearity. Independent variables and covariates that are too highly correlated (.85 or greater) will not be included in the analysis (Polit, 2010a).

The ANCOVA table for each model from the SPSS output will be evaluated. After controlling for the length of time each patient has been diagnosed as having Type 2 diabetes, the researcher will be looking for F values that are statistically significant ( $p < .05$ ) in order to reject the null hypothesis that the adjusted group means are equal. Parameter estimates will also be examined, including b weights, standard errors, t statistics, and significant levels for each component in both models. CIs around the b weights will also be examined. If 0.00 is included in the CI range, then the results are not significant. The partial  $\eta^2$  will be evaluated for net effect size in each respective model. The partial  $\eta^2$  will indicate the percentage of variance accounted for by PAM, PICS, and FPI scores. Adjusted means will be examined along with the 95% CI's around them. Post hoc tests for pairwise comparisons using the Bonferroni multiple comparison procedure, which adjusts for the inflated risk of a Type I error with multiple comparisons will be evaluated (Polit, 2010a).

**Research question 4.** *Do patients who see nurse practitioners for management of Type 2 diabetes experience higher levels of engagement in self-care behaviors and more therapeutic HbA1c levels compared to patients who see a physician?* To answer this question, an ANCOVA analysis will be completed. There will be two ANCOVA models. The first model will use

HbA1c levels as the dependent variable and the second model will use the SDSCA scores as the dependent variable.

The data will first be screened to ensure the assumptions for ANCOVA are met. The first and second assumptions are related to data level. Covariates are usually continuous interval or ratio level variables. The covariates of type of medication used by the patient is categorical data and the length of time each patient has been diagnosed as having Type 2 diabetes is continuous interval data. The HbA1c levels and the SDSCA scores will be ratio data. The type of care provider, being a nurse practitioner or a physician, will be coded as nominal data because the independent variable in ANCOVA is always nominal (Polit, 2010a).

The third assumption requires that there is random selection of subjects. The selection of participants will be on a volunteer basis and random to ensure this assumption is met. The fourth assumption requires that the dependent variable be normally distributed. A visual examination of histograms will ensure that this assumption is not violated (Polit, 2010a).

The fifth assumption is that there is homogeneity of variance. This will be examined using Levene's test for equality of variance. A non-significant Levene's test indicates the variance between the groups is most likely equal. The sixth assumption is that the relationship between the dependent variable and covariates is linear. Scatterplots will be evaluated, assessing for any curvilinearity. If a covariate is found to have curvilinear relationship with the dependent variable, it is best to eliminate it from the analysis. The seventh assumption is that relationships between all pairs of covariates are linear. Scatterplots will again be examined to assure this assumption is not violated. The eighth and final assumption is that there is homogeneity of regression across groups. The covariate should have the same relationship with the dependent variable in every group. Regression lines will be examined and should be parallel to each other

to prevent any violation of this assumption and any increased risk of type II errors. The assumption of homogeneity of regression across groups can also be tested in SPSS using an interaction term in the analysis. If the interaction term is statistically significant, ANCOVA should not be used. The researcher will also be mindful of cases of multicollinearity. Independent variables and covariates that are too highly correlated (.85 or greater) will not be included in the analysis (Polit, 2010a).

The ANCOVA table for each model from the SPSS output will be evaluated. The researcher will be looking for F values that are statistically significant ( $p < .05$ ) in order to reject the null hypothesis that the adjusted group means are equal. Parameter estimates will also be examined, including b weights, standard errors, t statistics, and significant levels for each component in both models. CIs around the b weights will also be examined. If 0.00 is included in the CI range, then the results are not significant. The partial  $\eta^2$  will be evaluated for net effect size in each respective model. Adjusted means will be examined along with the 95% CI's around them. Post hoc tests for pairwise comparisons using the Bonferroni multiple comparison procedure, which adjusts for the inflated risk of a Type I error with multiple comparisons will be evaluated (Polit, 2010a).

### **Human Participants and Ethics Precautions**

The study will be reviewed and approved by Duquesne University Institutional Review Board (IRB) and the Allegheny-Singer Research Institute at Allegheny General Hospital, the research review body for primary care practices of Allegheny Health Network. Office staff or care providers who will have knowledge of the study and a direct relationship with potential participants will obtain verbal consent from the potential participants to permit the Primary Investigator (PI) to discuss the study with those patients. Once a verbal consent is to approach

the patient about participation, the PI will explain the study in detail and answer any questions from the potential participant before beginning any data collection. Participants will only be approached by the PI after verbal consent has been obtained. After the study is thoroughly explained, the consent form is reviewed with each participant, and the participant verbally agrees to proceed with the study, a written consent will be then obtained from the participant. After obtaining written consent, a packet of five questionnaires and a demographics form will be given to the participant. The questionnaires and demographics form will be explained to the participants by the PI to clarify any questions or confusion that the participants may have. The participants can complete the form and questionnaires immediately following the office visit, they can return the forms at the following visit, or they can complete the packet at home and mail the information directly to the PI (each packet will contain a stamped, addressed envelope for the convenience of the participant). The participants will be reminded to get their prescribed laboratory work, which will include a HbA1c level, if they have not had this lab work drawn prior to the consultation visit at which they were enrolled in the study.

The consent form will be reviewed with the participants and a copy of the consent will be given to each participant. All participants will be made aware that the risk of participating in the study is minimal. The patients will be receiving no extra treatment or invasive procedures, other than the normal recommended blood tests they would be getting as part of their usual care regardless of whether they participated in the study. The participants will be made aware that a small amount of time (at most 30 minutes) is required to complete the necessary questionnaires. Participants will be informed that their electronic health record will be accessed by the PI to obtain the HbA1c level results. No other information in the EHR will be accessed. A consent form will be signed, allowing the PI to gain access to the electronic health record. There will be

a minimal risk of breach of confidentiality related to the written information and access of the electronic health records. The information will be stored in a secure manner and the PI will be the sole possessor of the data. Collected data will only be shared with limited personnel and no patient identifiers will ever be shared. Each participant will be given a random identification number as part of the data collection process. Only the PI will know the patient codes. Hard copies of the demographics forms and questionnaires will be number coded to allow the PI to identify the data appropriately. No patient identifiers will be entered into the database, which will be stored on a password-protected computer. Only the identification numbers will be entered into the database. Patient names with corresponding code numbers will be kept on a master list that will be stored in a locked file that is separate from the data. Hard copies of the questionnaires will be kept in a locked file cabinet that only the PI will have access to, and will be kept separate from the master list containing patient names and numeric codes.

In order to reduce as much risk as possible, several precautions will be taken to ensure the participants' confidentiality is not breached. No unique identifiers related to the patient will be obtained, such as address, phone number (except in the case of patients taking packet of questionnaires home to return via mail), social security number, insurance information, medical record number, etc. The PIs electronic database will be secure and password protected. The paper and electronic data will be destroyed as soon as possible after academic requirements have been fulfilled and research findings have been disseminated.

The participants in this study will not gain any immediate benefit by taking part in this study. The potential benefits that could be derived from this proposed study for future Type 2 diabetic patients are related to the types of care providers that patients may benefit from seeing. Additional possible benefits are related to how care providers encourage, or facilitate, the



involvement of patients in care and decision-making related to the management of Type 2 diabetes. The results of this proposed study could have an effect on the approaches that are taken, by both care providers and patients, when working to manage blood sugars in patients dealing with Type 2 diabetes. The risks encountered are not greater than those encountered in everyday life.

### **Conclusion**

This chapter provides the details of how this proposed study will be carried out and what instruments will be used to collect data. The instruments have been thoroughly evaluated and analyzed in the literature, allowing for confidence when using these instruments in the proposed study. The proposed data analysis process will provide a thorough and accurate analysis of the information collected from the participants in this proposed study. The results of this proposed study could be beneficial to future patients dealing with Type 2 diabetes, including benefits by selecting a type of care provider, and may provide information that can promote more patient involvement and collaborative approaches to the management of Type 2 diabetes.

## Chapter 4

### Data Analysis and Results

#### Background and Significance of this Study

Type 2 diabetes is currently a significant epidemic in the United States (US), and was the seventh leading cause of death based on US death certificates (Centers for Disease Control and Prevention, 2015). The Centers for Disease Control and Prevention estimates that one out of three people will develop type 2 diabetes, and current statistics report that 25.6 million people ages 20 and older currently have type 2 diabetes (Centers for Disease Control and Prevention, 2015; National Institutes of Health and the Centers for Disease Control and Prevention, 2011). In 2012, there were 1.7 million people with new diagnoses of type 2 diabetes, and it is projected that by the year 2050, one out of every three individuals will develop type 2 diabetes (Centers for Disease Control and Prevention, 2015; Venkat Narayna et al., 2006). The total estimated costs, both direct and indirect, related to diabetes in 2013 was \$254 billion, and those with diabetes have medical costs that are 2.3 times higher than those without diabetes (Centers for Disease Control and Prevention, 2015). Evidence shows that diabetes is poorly controlled throughout the United States (Fisher, Thorpe, McEvoy Devellis, & DeVellis, 2007; Lynch & Egede, 2011). Despite all of the research that has demonstrated the importance of optimal control of diabetes, there are still many people who do not receive adequate care, education, and support in managing their diabetes (Barnard et al., 2012; Rossi et al., 2015).

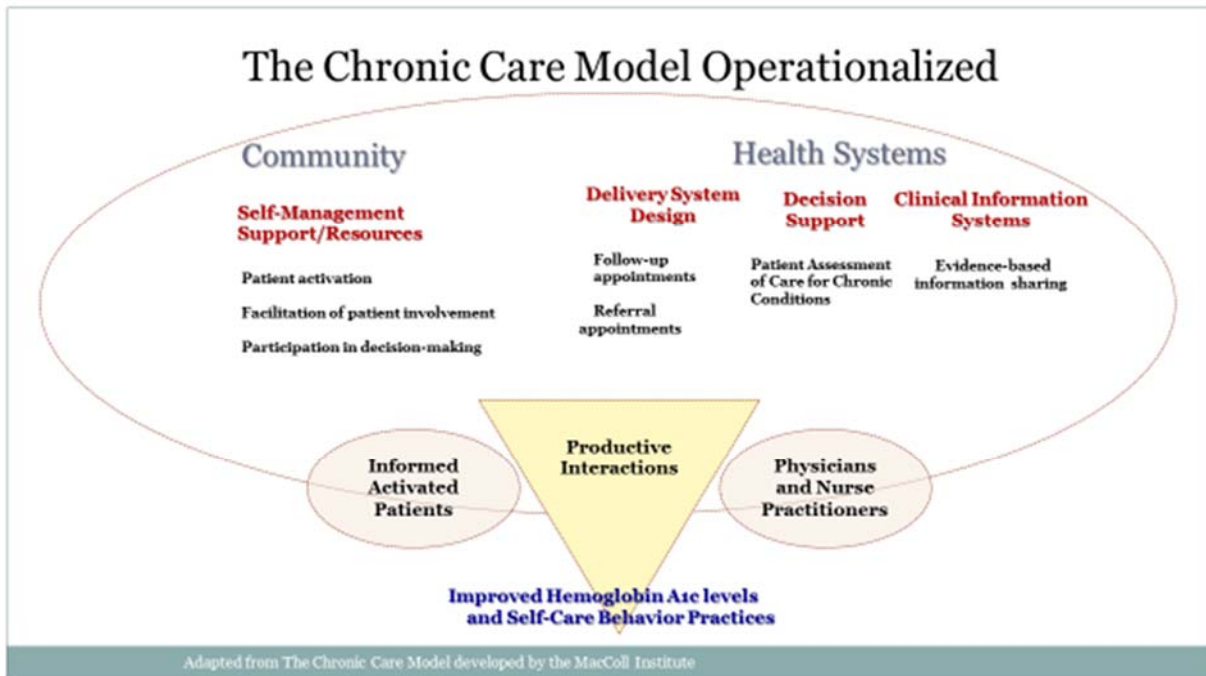
Because Type 2 diabetes is a chronic disease, the Chronic Care Model (CCM) was used as a guide for this study. The CCM was developed at the MacColl Center for Health Care Innovation at the Group Health Research Institute in the mid-1990s and recognizes the crucial elements of the health care system that encourage “high-quality chronic disease care.” These

elements include “the community, the health system, self-management support, delivery system design, decision support, clinical information systems, patient safety, cultural competency, care coordination, community policies, and case management” (Robert Wood Johnson Foundation, 2016a; Robert Wood Johnson Foundation, 2016e). The model synthesizes self-management support, delivery system design, decision support, and clinical information systems with productive interactions between informed, activated patients, and prepared, proactive practice team members for improved patient outcomes. The overall goal of applying this model is to have healthier patients, more satisfied health care providers, and cost saving. The CCM has been used in research studies, including studies that focused on the management of Type 2 diabetes and has shown to be a beneficial framework for providing care to patients with Type 2 diabetes (Bodenheimer et al., 2002b; Dancer & Courtney, 2010; Frei et al., 2014; Koh, Brach, Harris, & Parchman, 2013; National Institutes of Health and the Centers for Disease Control and Prevention, 2011; Parchman, Michael L,MD, MPH et al., 2007; Peterson, Blackburn, Phillips, & Puffer, 2014; Robert Wood Johnson Foundation, 2016a; Siminerio et al., 2006; Stellefson, Dipnarine, & Stopka, 2013). Studies evaluating the incorporation of the CCM into care for patients with Type 2 diabetes found improved HbA1c levels, improved lipid ratios, improved blood pressure, higher rates of smoking cessation, and higher rates of self-monitoring of blood glucose levels (Frei et al., 2014; Koh et al., 2013; Nutting et al., 2007; Peterson et al., 2014; Piatt et al., 2006; Siminerio et al., 2005; Stellefson et al., 2013).

The CCM is different from traditional models and approaches to management of chronic diseases because the main foci are self-management training, counseling, and tracking patient care (Stellefson et al., 2013). Self-management support and counseling prepares patients to take an active role in the management of Type 2 diabetes (Glasgow et al., 2001; Stellefson et al.,

2013). By having a system that tracks patient appointments, laboratory studies, and upcoming recommendations for patient care, the continuity of care becomes more effective and has an increased likelihood of improved patient outcomes (Stellefson et al., 2013).

Figure 3. The Chronic Care Model Operationalized



There are two overarching umbrellas that make up the CCM (figure 3), the health system and the community. Under the health system umbrella, delivery system design, clinical information systems, and decision support are an intertwined set of variables that directly relate to the organization of health care for patients with chronic diseases (Robert Wood Johnson Foundation, 2016a). These variables are health care providers centered, focusing on how care is delivered to the patients, and include evidence-based care, ensuring follow-up care, culturally appropriate care, sharing evidence-based guidelines and information to encourage patient participation in care, integrating specialist expertise in care, using appropriate decision support and reminder tools, facilitating individual care planning, and sharing of information among

patients and provider (Robert Wood Johnson Foundation, 2016a; Robert Wood Johnson Foundation, 2016d; Robert Wood Johnson Foundation, 2016e; Robert Wood Johnson Foundation, 2016f; Robert Wood Johnson Foundation, 2016g).

Under the community umbrella, there is community resources and self-management support. Self-management focuses on the concept of the patient having the prominent role in managing their personal health (Robert Wood Johnson Foundation, 2016g). Self-management support refers to the activities that help to prepare the patient to manage their health such as checking blood glucose levels, medication adherence, eating a particular diet, following an exercise regimen, checking feet regularly, smoking cessation, and reducing alcohol intake, which are necessary to improve outcomes, specifically HbA1c levels among patients with Type 2 diabetes (Funnell et al., 2009; Robert Wood Johnson Foundation, 2016f; Toobert et al., 2000; Wang & Fenske, 1996; Weinger et al., 2005). According to the National Standards for Diabetes Self-Management Education (Funnell et al., 2009), patients should have a personalized follow-up plan that should be developed by the patient and educator addressing desired outcomes and goals of treatment, as well as a plan for ongoing self-management support and reminders for follow-up care. Benefits related to Diabetes Self-Management Education have been recognized by the American Diabetes Association and are considered an integral piece of diabetes care to strengthen the ability of patients to self-manage (Siminerio et al., 2006; Siminerio et al., 2004; Stellefson et al., 2013; Wagner, 1998). Successful self-management and education programs help the patient to better understand the goals, priorities, barriers, and potential problems that can arise when dealing with Type 2 diabetes, especially because the cost and complications associated with diabetes are often preventable when blood sugar levels are well controlled

(Glasgow & Anderson, 1999; Glasgow et al., 2001; Glasgow, Toobert, & Gillette, 2001; Koh et al., 2013; Stuckey et al., 2009; Von Korff & Gruman, 1997).

The CCM builds on the Community and Health System elements, combining them with productive interactions between patients and health care providers (Robert Wood Johnson Foundation, 2016e). Combining these elements together, is what ultimately leads to improved outcomes for patients with type 2 diabetes (Robert Wood Johnson Foundation, 2016e).

Informed, activated patients are those patients who have the ability and desire to actively engage in their health care and participate in the decision-making related to their treatment (Hibbard & Greene, 2013). Prepared, proactive care providers actively engage in a shared decision making process, and facilitate the patient's involvement in their care (Hibbard & Greene, 2013).

Many patients with type 2 diabetes are managed by primary care offices, with an increase in nurse practitioners managing the care of these patients (American Diabetes Association, 2013a). Varied data exist comparing patient outcomes for nurse practitioners and physicians (Chang et al., 2007; Fain & Melkus, 1994; Kinnersley et al., 2000; Roblin et al., 2004; Rudy et al., 1998; Salisbury & Tattersell, 1998; ter Bogt et al., 2011; Venning et al., 2000). The literature is inconsistent related to patient provider preferences (Horrocks et al., 2002; Lenz et al., 2002; Munding et al., 2000; Roblin et al., 2004; Rudy et al., 1998; Salisbury & Tattersell, 1998; ter Bogt et al., 2011; Venning et al., 2000). In patients with diabetes, there are data to show that nurses and nurse practitioners can improve patient outcomes through various interventions and programs in conjunction with physicians; however, little data exist to show a significant difference in patient outcomes for patients strictly seeing nurse practitioners rather than physicians (Chang et al., 2007; Hoffman et al., 2005; Litaker et al., 2003; Renders et al., 2001; Taylor et al., 2003; ter Bogt et al., 2011). In general, the data related to the variations in care

from nurse practitioners and physicians do not show a clear advantage of one health care provider over another. The studies have shown positive, negative, and neutral results related to measured outcomes for patients who see nurse practitioners rather than physicians (Eisenstat, Ulman, Siegel, & Carlson, 2013; C. Everett et al., 2013; C. M. Everett et al., 2013; Fain & Melkus, 1994; Horrocks et al., 2002; Kinnersley et al., 2000; Lenz et al., 2002; Litaker et al., 2003; Mundinger et al., 2000; Ohman-Strickland et al., 2008; Roblin et al., 2004; Rudy et al., 1998; Salisbury & Tattersell, 1998; Stanik-Hutt et al., 2013; Venning et al., 2000). Further exploring patient outcomes when comparing health care providers (physicians and nurse practitioners) was a main goal of this study.

Health care providers' actions and approaches to patient care may impact health outcomes for patients with type 2 diabetes. Health care providers can shift their focus from personal perceptions and managing lab values to actively facilitating, or encouraging, patients to be involved in their own healthcare (Freeman & Loewe, 2000; Martin et al., 2001). Provider behavior can facilitate the patient's involvement in managing their health (Martin et al., 2001). When health care providers take into account the patients' perspectives to provide a more personal approach to management, patients recognize that their health care provider has facilitated their involvement in care, thus leaving patients more satisfied with care and more adherent to treatment plans (Martin et al., 2001; Vijan et al., 2005).

Guided by the CCM, the focus of this research study was to examine the elements of the CCM, which include community resources, self-management support, delivery system design, decision support, clinical information systems, along with patient activation, facilitation of patient involvement by health care providers, and patient participation in the decision-making process, for their effect on patient hemoglobin A1c levels and participation in self-care

behaviors. This study also explored if type of health care provider caring for the patient impacted components of the CCM or type 2 diabetes-specific outcome measures. The results of this study can offer information to improve patient outcomes by providing a comprehensive picture of the needs of patients with type 2 diabetes based on the CCM.

### **Research Questions**

1. Based on the Chronic Care Model, what are the effects of delivery system design and clinical information systems, together with patient perceptions of decision support, self-management support, and community resources on hemoglobin A1c levels and participation in self-care behaviors for patients with type 2 diabetes?
2. Among Type 2 diabetic patients, do levels of patient activation, participation in decision-making for treatment planning, and facilitation of patient involvement in care affect HbA1c levels and patients' performance of self-care behaviors?
3. Do patients who see nurse practitioners for management of type 2 diabetes experience higher levels of engagement in self-care behaviors and more therapeutic HbA1c levels compared to patients who see a physician?
4. Is there a difference in levels of patient activation, participation in decision-making, and facilitation of patient involvement in care when a nurse practitioner treats a patient compared to a physician?

### **Methods**

#### **Research Design and Procedures**

Using the comprehensive structure of the CCM, this cross-sectional, descriptive study examined patient activation, facilitation of patient involvement, participation in the decision-making process, decision support, delivery system design, clinical information systems, referral



to community resources, and self-management support for their effect on self-care behaviors and HbA1c levels among patients with Type 2 diabetes seen by nurse practitioners and physicians in the primary care setting. Patients completed six instruments to measure demographic variables, the independent variables, and the outcome of patient self-care behaviors at one time point after a routine consultation with their physician or nurse practitioner. HbA1c values were examined within six months prior to or two months following the data collection visit.

Data collection for this study was completed in five primary care offices throughout Western Pennsylvania and Eastern Ohio. Two of the offices cared for underserved members of the community and did not require health insurance for provision of services. The study was approved by a university Institutional Review Board, and all participants signed a consent form to participate in the study, which included completing six questionnaires and giving permission for the nurse in the office to provide the researcher with their HbA1c value.

### **Instruments- Independent Variables**

Instruments used to collect data related to the independent variables include a demographic form, Patient Activation Measure, Facilitation of Patient Involvement Scale, Perceived Involvement in Care Scale, and Patient Assessment of Care for Chronic Conditions. The dependent variables were measured using the Summary of Diabetes Self-Care Activities Scale and a Hemoglobin A1c level.

**Demographic Form.** Participants completed a 17-item, researcher developed demographics tool. In addition to describing the sample of this proposed study, the tool was used to assess delivery system design and the use of clinical information systems. *Delivery system design* was assessed by asking patients to report about follow-up appointments, referrals to other health care providers/specialists, and they length of time they have had a relationship with their

health care provider. *Clinical information systems* was assessed with questions related to follow-up appointments, discussion of goals during the appointment, and receipt of any printouts related to the patient's summary of care at the visit.

**Patient Activation and the Patient Activation Measure (PAM).** Patient activation can be defined as the “patient’s willingness and ability to take independent actions to manage their health and care” (Hibbard & Greene, 2013). A variety of studies have examined patient activation using the Patient Activation Measure (PAM) and found that patients who have higher PAM scores are more likely to participate in preventative health care and healthy self-care behaviors (Becker & Roblin, 2008; Fowles et al., 2009; Greene & Hibbard, 2012; Hibbard et al., 2004; Hibbard et al., 2005; Hibbard et al., 2007; Mosen et al., 2007). Along with increased participation in preventative care and health behaviors, studies have also shown a link between increased patient activation and improved patient outcomes, more specifically, improvements in Hemoglobin A1c, blood pressure, and cholesterol levels (Greene & Hibbard, 2012; Hibbard & Greene, 2013; Remmers et al., 2009). Research also suggests that patients who have higher levels of patient activation are more satisfied with the care they receive from their provider, and also have lower costs associated with their health care, such as less hospitalizations and emergency department visits than those with lower activation scores (Greene & Hibbard, 2012; Hibbard & Greene, 2013; Remmers et al., 2009).

The PAM is a 13-item questionnaire and was the instrument used to measure the level of patient activation. Each question is answered by the patient using a scale of agreement/disagreement (0-4). The scores range from Not Applicable (0), Disagree Strongly, Disagree, Agree, and Strongly Agree (4). Higher PAM scores correlate with higher levels of patient activation. The Rasch Person reliability for the 13-item measure was between .85 and

.87; the Cronbach's alpha was .87 (Hibbard et al., 2004). The Cronbach's alpha for this study was .876.

**Facilitation of Patient Involvement and the Facilitation of Patient Involvement (FPI) Scale.** Wolpert and Anderson (2001) stressed that diabetes is a self-managed condition, models of care should be focused on promoting more self-care behaviors while stressing the importance of glycemic control from the patient's perspective. While the benefits of tight glycemic control are well-established, this is rarely achieved in the general clinical practice arena (Wolpert & Anderson, 2001). In order for health care providers to help their patients achieve well-controlled glucose levels, the importance of blood sugar control must be evaluated from the patient's perspective, and the patient's goals must be incorporated into treatment (Wolpert & Anderson, 2001). Moreover, providers and patients have been noted to agree on treatment options when patients have more education related to diabetes, stronger beliefs in the efficacy of the prescribed treatment program, and share the decision making process with the physician (Heisler et al., 2003).

Facilitation of patient involvement was measured by the FPI scale, a 9-item self-report questionnaire that measures to what degree patients perceive that their health care provider encourages them to be involved in their own healthcare (Martin et al., 2001). Each item is scored using a range of 1 (none of the time) to 6 (all of the time), with total scores ranging from 9-54. Higher scores indicate increased patient perception of facilitation of involvement of the patient by the health care provider. The Cronbach's alpha values to establish internal consistency reliability ranged from .89 to .93, and test-retest results were  $r = .89$  (N=44), and  $r = .85$  (N=84). (Martin et al., 2001). The Cronbach's alpha for this study was .303.

### **Participation in Decision-Making and the Involvement in Care Scale (PICS).**

Participation in decision making refers to a patient-centered process by which patient and the health care provider share information related to decisions that needs to be made (Barry & Edgman-Levitan, 2012; Branda et al., 2013; Wilkinson, Whitehead, & Ritchie, 2014). The healthcare provider presents the benefits and risks of possible choices and the patient presents their personal values and feelings related to the options (Barry & Edgman-Levitan, 2012; Branda et al., 2013; Wilkinson et al., 2014). A meta-aggregation study examined factors that influence the ability of patients to successfully self-manage type 2 diabetes (Wilkinson et al., 2014). Patients were found to be more successful at self-management when their health care providers showed consideration for the patient's "feelings, rights, wishes, or traditions" (Wilkinson et al., 2014), and acknowledgement that both parties had valuable opinions. It was also found that patients who reported higher ratings on health care provider participatory decision-making and health care provider communication were also found to have higher ratings on self-management assessments (Heisler et al., 2003; Heisler et al., 2002; Heisler et al., 2003).

The PICS measured patient involvement in care and is a 13-item questionnaire that assesses patients' attitudes related to the management of their chronic illness (Lerman et al., 1990). Each question is answered with Agree (1) or Disagree (0). Higher scores are associated with an increased patient perception that their health care provider is involving them in the decision-making process. Internal consistency was measured using Cronbach's alpha with a result of  $\alpha=.73$  (N=131) (Lerman et al., 1990). Cronbach alpha for this study was .76.

**Patient Assessment of Care for Chronic Conditions (PACIC).** The PACIC is a 20-item, self-report questionnaire that measures various aspects of the CCM. The 20 items are arranged into 5 subscales including Patient Activation (3 items), Delivery System

Design/Decision Support (3 items), Follow-up/Coordination (5 items), Goal Setting (5 items) and Problem-solving/Contextual Counseling (4 items) subscales; these latter two scales assess self-management support (Robert Wood Johnson Foundation, 2016h). Each item is answered on a scale of 1-5 by the patient choosing how often the items occurred during the course of the relationship with their health care provider. Responses range from None of the time (1), A little of the time, Some of the time, Most of the time, and Always (5). Higher scores are associated with the patient's perception that their care is congruent with the goals of the Chronic Care Model. Internal consistency for the PACIC was evaluated using coefficient alpha ( $\alpha=.93$ ). Overall test-retest reliability was  $r=.58$ , and individual scale reliabilities ranged from  $r=.47$  to  $.68$  ( $n=52-57$ ). Validity for the PACIC was correlated moderately to strongly ( $r=.42-.60$ ) with four of the convergent validity measures (Glasgow et al., 2005). Cronbach alpha for this study was  $.948$ .

**Type of Health Care Provider.** The nurse practitioner has a crucial role in the care of patients with chronic diseases (Dancer & Courtney, 2010). Varied data exist related to satisfaction and patient outcomes of nurse practitioners and physicians. In general, many studies that examine generalized patient populations present data that shows patients are more satisfied with care and outcomes are improved when being treated by nurse practitioners (Chang et al., 2007; Condosta, 2012; Eisenstat et al., 2013; C. Everett et al., 2013; C. M. Everett et al., 2013; Fain & Melkus, 1994; Kinnersley et al., 2000; Roblin et al., 2004; Rudy et al., 1998; Salisbury & Tattersell, 1998; Stanik-Hutt et al., 2013; ter Bogt et al., 2011; Venning et al., 2000).

Identifying significant differences in patient outcomes and how those differences relate to goals of treatment, may influence management styles among physicians and nurse practitioners when caring for patients with Type 2 diabetes. HbA1c values and self-care behavior practices among

patients from each type of health care provider (physicians and nurse practitioners) were evaluated, in addition to looking at referral and follow-up practices.

### **Instruments- Dependent Variables**

#### **Self-Care Behaviors and the Summary of Diabetes Self-Care Activities (SDSCA).**

Self-care refers to a significant set of activities that are important to patient-centered chronic illness management (Song & Lipman, 2008). Effective management of diabetes requires complex, continual, and demanding self-care behaviors including recognizing signs and symptoms of the disease, diet control, exercise, blood glucose monitoring, managing physical and emotional distress, foot care, smoking cessation, limiting alcohol consumption, medication regimens, and utilizing family support and community resources (American Diabetes Association, 2016a; Nam et al., 2011; National Institutes of Health and the Centers for Disease Control and Prevention, 2011; Song & Lipman, 2008; Wolpert & Anderson, 2001). Managing Type 2 diabetes has proven to be very challenging because of the difficulty and complexity involved in making the necessary life-style changes. Vigilant self-care for patients with Type 2 diabetes is particularly important because it can help to delay the progression of the disease and onset of complications and increases the likelihood that the patient will live a longer, healthier life (Aljaseem et al., 2001; Booth, Lowis, Dean, Hunter, & McKinley, 2013; Haas et al., 2013; King et al., 2010b; Nam et al., 2011; Nouwen et al., 2011; Powers et al., 2015; Rise, Pellerud, Rygg, & Steinsbekk, 2013; Song, 2010; Song & Lipman, 2008; Svenningsson, Marklund, Attvall, & Gedda, 2011; Wilkinson et al., 2014).

The SDSCA is an 11-question, self-report measure about the frequency in which patients completed various self-management activities over the preceding seven days. For example, the patient reports how many days in the last week they followed a specific diet, checked their blood

sugar as directed, and exercised. Based on the results of a factor analysis, three subscales were derived: diet, exercise, and glucose testing (Toobert & Glasgow, 1994). Two scores are obtained from the diet subscale, the general diet score (GDS) and the specific diet score (SDS). For the general diet score (GDS), which looks at the patient's overall diet, the mean number of days for items one and two is the score. For the specific diet score (SDS), which looks at the frequency of which patients eat specific food groups, the mean number of days for items three and four are the score. The exercise score, which captures how many days per week the patient participates in exercise, is the mean number of days for items five and six. The blood glucose testing score, which captures how many days a patient checks their blood sugar in relation to how many times per day they are ordered by their health care provider to do so, is the mean number of days for items seven and eight. The foot care score is the mean number of days for items 9 and 10. The smoking status score is "0" for "nonsmoker" or "1" for "smoker." The number of days per week one may smoke is not assessed. Higher scores correspond to participating in self-care behaviors more frequently (Toobert & Glasgow, 1994; Toobert et al., 2000). The mean scores are added together, along with the inverse scores related to smoking, for a total score. The average inter-item correlations within each SDSCA subscale exceeded .50; for test-retest reliability, results ranged from .43 to .58 (Toobert & Glasgow, 1994). The Cronbach Alpha for this study is .690, and .70 is considered an acceptable value (Polit, 2010b) .

**Hemoglobin A1c Values.** The Hemoglobin A1c test, also known as glycated hemoglobin, glycosylated hemoglobin, glycohemoglobin, A1c, or HbA1c, is a way to measure longer-term blood glucose management and reflects a patient's average blood glucose control over the previous 2 or 3 months (Joslin Diabetes Center, 2016; Mayo Clinic, 2016). A common recommended target level is 7% or less for patients with diabetes (American Diabetes

Association, 2013; Joslin Diabetes Center, 2016; Mayo Clinic, 2016). The importance of the HbA1c levels should not be minimized. The risk of complications associated with diabetes is significantly reduced when the HbA1c values are less than 8%, ideally lower than 7% (Mayo Clinic, 2016; UK Prospective Diabetes Study (UKPDS) Group, 1998). In this study, the HbA1c levels were checked via routine bloodwork results from a lab or by a rapid check machine that uses a finger stick blood sample that was available in some offices. Patients using medications for glucose control, such as oral agents and/or insulin were included in the sample, and medication usage was categorized as 1) oral agents, 2) insulin, 3) combination oral/insulin, and 4) no medication.

### **Sample Selection and Size**

Participants of this study were diagnosed with type 2 diabetes, 18 years of age or older, and currently seeing a physician or nurse practitioner within a primary care setting for the care and management of their type 2 diabetes. A total of 83 patients consented to participate in this study. Eighty-two participants completed all required questionnaires. Forty patients were being seen by a physician, and forty-three patients were being seen by a nurse practitioner. To compensate them for their time, the participants received a \$15.00 gift card to Giant Eagle or Wal-Mart upon completion of the questionnaires.

In a multiple regression analysis, a standard formula of  $N > 50 + 8k$  is used to determine sample size, with  $N$  being the sample size and  $k$  being the number of predictors. A minimal sample size of 91 patients ( $k = 5$ ) will be necessary to achieve statistical significance based on the number of variables. However, using Cohen's guidelines of effect size, an a priori power analysis could be performed to ensure the sample size is large enough to have a power of .80. In



this case,  $R^2 = .10$  (small to moderate effect) would be used to determine a sample size of 112 participants would be necessary to ensure the study had a power of .80 (Polit, 2010c).

### **Collection of Data**

When the patients arrived at their scheduled office visit, they were asked by the staff if they would be interested in participating in a brief study for patients with type 2 diabetes. If the patients were interested, they were then directed to meet with the primary investigator who was present in the waiting room. After obtaining written consent, a packet of six questionnaires was given to the participants. The questionnaires and demographics form were explained to the participants by the researcher, and any questions that the participants had were answered. Each participant completed all questionnaires immediately following their office visit with their health care provider either in the exam room or in the waiting room. All of the participants had Hemoglobin A1c values tested within the last 6 months, either at an outside lab, or on the day of the visit via a rapid test machine. Those values were on file in the patients' charts. An office nurse provided the primary investigator with the value for each patient who participated in the study. All data were de-identified, and participants were each assigned a random identification number.

### **Data Analysis**

The SPSS (IBM, SPSS, Inc, Chicago, Illinois, USA, Version 24) software package was used to analyze the data. The data were entered into the database by the primary investigator. Descriptive statistics including, age, sex, race, education, marital status, employment, and length of diagnosis were used to examine and describe the sample. The data were screened to ensure accuracy of the values and assess for any missing values. Univariate normality was assessed among each of the variables. Histograms, skewness, kurtosis, means, SDs, and frequencies were

evaluated for each of the variables. An alpha was set at .05 for all analyses. Variables that were controlled for in all models include type of health care provider, length of time under the care of that health care provider, length of time since diagnosis, sex, age, marital status, education, race, and employment status. In the models that examined HbA1c values as an outcome, medication usage was also controlled for. On the demographics form, patients designated whether they were not on any medication, oral medication, insulin, or both oral medication and insulin. These responses were coded into the data and used as covariates in the analysis.

The types of data for each tool are as follows. The PAM scores are ratio-level data and range from 0-100. The PACIC scores are based on a Likert-type scale, making them interval level. The SDSCA scores are ratio-level data and based on the total number of days reported by the patient. The average score for each SDSCA subscale and the inverse score of their smoking response are added together for a total score. The FPI scale uses a Likert-type scale, producing interval-level data. The PICS tool is scored using “0” if the patient disagrees with the statement or “1” if the patient agrees, and a total score out of 13 is derived. This type of scoring requires the data to be interval. The HbA1c levels are measured on a ratio scale. Type of health care provider was coded for each respective group, nurse practitioner or physician, making this nominal data. Referrals were coded yes or no, making this nominal data.

**Research question 1.** *Based on the CCM, what are the effects of Delivery System Design and Clinical Information Systems, together with patient perceptions of Decision Support, Self-Management Support, and Community Resources on HbA1c levels and participation in self-care behaviors for patients with Type 2 diabetes?* Multiple regression models were used to analyze the data. Assumptions for multiple linear regression were assessed and met. The first assumption required ratio or interval level data for the dependent variable (Polit, 2010c). The first model

used the PACIC as the independent variable and the HbA1c values as the dependent variable. The other five models used the PACIC as the independent variable and each of the self-care behaviors measured by the SDSCA (GDS, SDS, exercise, blood glucose testing, and foot care) as the dependent variables. A logistic regression model was used when analyzing smoking (yes/no) as a dependent variable.

**Research Question 2.** *Among Type 2 diabetic patients, do levels of patient activation (PAM), participation in decision-making for treatment planning (PICS), and facilitation of patient involvement in care (FPI) affect HbA1c levels and patients' performance of self-care behaviors?* Multiple linear regression models were used to analyze the data. Assumptions for multiple regression were assessed. The first assumption, requiring ratio or interval level data for the dependent variable, was met with both HbA1c levels and SDSCA scores. The second assumption that the data were randomly and independently sampled was met. The fourth assumption, related to homoscedasticity of the data, was examined and met. The assumption of equal variances was examined and met. The next assumption is that variables being correlated are assumed to have an underlying distribution that is bivariate normal, meaning scores on variable X are assumed to be normally distributed for each value of variable Y, and vice versa. This assumption was tested by examining scatter plots for each of variables against HbA1c levels and against SDSCA scores and determined to be met (Polit, 2010c).

Each of the models analyzed used scores from a different tool (PAM, PICS, or FPI) as the independent variable. Each of the three tools had a total of 6 models per tool to analyze all of the dependent variables. The dependent variables included HbA1c levels and the five self-care scores (GDS, SDS, exercise, blood glucose testing, and foot care) from the SDSCA. As with

RQ1, a logistic regression model was used when analyzing smoking (yes/no) as an outcome variable.

**Research question 3.** *Do patients who see nurse practitioners for management of Type 2 diabetes experience higher levels of engagement in self-care behaviors and more therapeutic HbA1c levels compared to patients who see a physician?* To answer this question, an ANCOVA analysis was completed. There were a total of six ANCOVA models. The first model used HbA1c levels as the dependent variable, and the other five models used the SDSCA scores as the dependent variables. A logistic regression model was again used when analyzing smoking (yes/no) as an outcome variable.

The data was screened to ensure the assumptions for ANCOVA were met. The first and second assumptions were related to data level. The covariates of type of medication used by the patient is categorical data and the length of time each patient has been diagnosed as having Type 2 diabetes is continuous ratio-level data. The HbA1c levels and the SDSCA scores are also ratio data. The type of health care provider, being a nurse practitioner or a physician, was coded as nominal data because the independent variable in ANCOVA is always nominal (Polit, 2010a).

The third assumption required that there was random selection of subjects, and participation was on a volunteer basis. The fourth assumption required that the dependent variable be normally distributed (Polit, 2010a). This was verified by examining the scatterplots. The fifth assumption uses the Shapiro-Wilk test to verify that there is homogeneity of variance. The sixth assumption is that the relationship between the dependent variable and covariates is linear. This was verified the using the Levene's test. The seventh assumption is that relationships between all pairs of covariates were linear, which was verified by examining the scatterplots.

The eighth of homoscedasticity and ninth assumption of homogeneity of regression across groups were also tested and met.

The assumptions for logistic regression were verified for the analysis related to the dichotomous dependent variable of smoking. The first assumption requires that the dependent variable be measured on a dichotomous scale. The second assumption requires that one more of the independent variables be on a continuous or categorical scale. The third assumption requires that there be independent observations and the dependent variable be mutually exclusive and have exhaustive categories. The fourth assumption requires that there be a linear relationship between any continuous independent variables and the logit transformation of the dependent variable (Polit, 2010d).

**Research question 4.** *Is there a difference in levels of patient activation, participation in decision-making, and facilitation of patient involvement in care when a nurse practitioner treats a patient compared to a physician?* To answer this question, an ANCOVA analysis was completed. There were three ANCOVA models, using the PAM, PICS and FPI scores as the dependent variable.

The data was screened to ensure the assumptions for ANCOVA are met. The first and second assumptions are related to data level. Covariates are usually continuous interval or ratio level variables. The third assumption requires that there is random selection of subjects. The fourth assumption requires that the dependent variable be normally distributed. The fifth assumption is that there is homogeneity of variance. The sixth assumption is that the relationship between the dependent variable and covariates is linear. The seventh assumption is that relationships between all pairs of covariates are linear. The eighth and final assumption is that

there is homogeneity of regression across groups (Polit, 2010a). These assumptions were verified through examination of the data in SPSS.

## Results

**Demographics.** Tables 1 and 2 present the demographic information related to this study. The mean age was 58.48 (standard deviation [*SD*] =11.44). The majority of the patients were over 50 years of age (75.9%), female (63.4%), and white (87.9%). The majority of patients graduated from high school or have a high school equivalent (66.3%) and are currently unemployed (56.1%). Half of the patients came from the clinic in Ohio and were all of the nurse practitioner patients, with the exception of two. Related to their diagnosis of type 2 diabetes (Table 2), the majority of patients had been diagnosed 5 years or less and also had maintained the relationship with their health care provider for 5 years or less (70.7%). The majority of patients were taking oral medications (60%) related to their type 2 diabetes. Table 1 presents the demographic data for the entire sample and for the participants in each health care provider group.

Table 1 Demographics Table for Sex, Race, and Education (N=82)			
Demographic Characteristic	Total (N=83) n (%)	Nurse Practitioner Patients (n=43) n (%)	Physician Patients (n=39) n (%)
Sex			
Male	30 (36.6%)	13 (30.2%)	17 (43.6%)
Female	52 (63.4%)	30 (69.8%)	22 (56.4%)
Average Age (years)	58.48 (SD=11.44)	54.02 (SD=9.46)	63.39 (SD=11.53)
Race			

White	72 (87.8%)	38 (88.4%)	34 (87.2%)
African American/Black	7 (8.5%)	4 (9.3%)	3 (7.7%)
Other	3 (3.7%)	1 (2.3%)	2 (5.1%)
Education			
Did Not Complete High School	5 (6.0%)	1 (2.3%)	4 (10.3%)
High School Diploma or Equivalent	55 (67%)	33 (76.8%)	22 (56.4%)
Associate/Trade/Tech	16 (19.5%)	8 (18.6%)	8 (20.5%)
Bachelor's Degree or Higher	6 (7.5%)	1 (2.3%)	5 (12.8%)
Employment Status			
Employed	33 (40.2%)	19 (44.2%)	14 (35.9%)
Unemployed/Unable to Work/Retired	46 (56.1%)	22 (51.2%)	24 (61.5%)
Other	3 (3.7%)	2 (4.6%)	1 (2.6%)
Marital Status			
Single/Widowed	23 (28%)	14 (32.6%)	9 (23.1%)
Married	30 (36.5%)	11 (25.5%)	19 (48.7%)
Divorced	29 (35.5%)	18 (41.9%)	11 (28.2%)

Table 2. Data Related to Type 2 Diabetes Diagnosis  
(N=82)

Type of Health Care Provider	n (%)
Physician	39 (48.2%)
Nurse Practitioner	43 (51.8%)
<b>Location</b>	
A	18 (22%)
B	12 (14.6%)
C	6 (7.3%)
D	41 (51.8%)
E	5 (6.1%)
<b>Medication</b>	
None	3 (3.7%)
Oral Medication	49 (60%)
Insulin	4 (4.9%)



Both Oral Medication and Insulin	26 (31.4%)
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Length of Diagnosis

Up to 5 years	37 (45.1%)
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6-10 years	21 (25.6%)
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11-15 years	8 (9.8%)
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16-20 years	7 (8.5%)
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More than 20 years	9 (11%)
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Length of Relationship with Health  
Care Provider

1-5 years	58 (70.7%)
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6-10 years	5 (6.1%)
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More than 10 years	19 (23.2%)
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**Results for research question 1.** *Based on the CCM, what are the effects of Delivery System Design and Clinical Information Systems, together with patient perceptions of Decision Support, Self-Management Support, and Community Resources on HbA1c levels and participation in self-care behaviors for patients with Type 2 diabetes?* The Patient Assessment of Care for Chronic Conditions (PACIC) was used to gather information related to delivery system design, clinical information systems, decision support, self-management support, and community resources. The PACIC was found to be significantly associated with General Diet Score (GDS) ( $p = .020$ ), Specific Diet Score (SDS) ( $p = .027$ ), Exercise ( $p = .032$ ), and Blood Glucose Testing ( $p = .046$ ), when controlling for the covariates of age, sex, race, education, marital status, employment, length of diagnosis, type of health care provider, length of relationship with health care provider, and medication usage. Hemoglobin A1c values ( $p = .849$ ) and foot care ( $p = .390$ ) were not found to have a significant association with the CCM variables as measured by the PACIC. The dichotomous variable of smoking was tested using logistic regression. Smoking status was not found to have a significant association with the CCM variables as measured by the PACIC. Table 3 presents the data for research question 1.

Table 3. Multiple Regression Models for PACIC and Self-Care Behaviors (N=82)					
Outcome Variable	B	SE (B)	Standardized Beta	t-value	p-value
Hemoglobin A1c Levels	-.002	.010	-.022	-.191	.849
General Diet Score	.025	.011	.266	2.371	.020

Specific Diet Score	-.024	.011	-.258	-2.252	.027
Exercise	.027	.012	.253	2.191	.032
Blood Glucose Testing	.033	.016	.231	2.030	.046
Foot Care	.014	.016	.105	.864	.390

Note. PACIC= Patient Assessment of Care for Chronic Conditions tool.

**Results for research question 2.** Among Type 2 diabetic patients, do levels of patient activation (PAM), participation in decision-making for treatment planning (PICS), and facilitation of patient involvement in care (FPI) affect HbA1c levels and patients' performance of self-care behaviors? Patient Activation was found to be significantly associated with General Diet Score (GDS) ( $p = .023$ ) and Foot Care ( $p = .006$ ), but was not a statistically significantly associated with HbA1c levels ( $p = .260$ ), Specific Diet Score ( $p = .182$ ), Exercise ( $p = .440$ ), or Blood Glucose Testing ( $p = .191$ ). In the General Diet Score (GDS) model with the PAM, sex and gender were found to be associated with GDS ( $p = .031$  and  $p = .029$ , respectively). In the Foot Care model with the PAM, level of education was found to be significantly associated with foot care ( $p = .038$ ). Facilitation of patient involvement (FPI) and Perceived Involvement in Care (PICS) were both found to be a significantly associated with Blood Glucose Testing ( $p = .030$  and  $p = .046$ , respectively), but not HbA1c levels, General Diet Score, Specific Diet Score, Exercise, or Foot Care, all  $p > .05$ . In the blood glucose testing model with the PICS, type of

health care provider was found to be significantly associated with blood glucose testing ( $p=.028$ ). Tables 4-7 present the data for research question two, controlling for age, sex, race, education, marital status, employment, length of diagnosis, type of health care provider, and length of relationship with health care provider. The dichotomous variable of smoking was tested using logistic regression. Smoking status was not found to have a significant association with the FPI nor the PICS.

Variable	B	SE (B)	Standardized Beta	t-value	<i>p</i> -value
PAM	.090	.039	.260	2.319	.023
Age	.500	.265	.251	1.884	.064
Sex	-.951	.431	-.256	-2.207	.031
Race	-.107	.617	-.020	-.174	.862
Education	.129	.230	.063	.560	.577
Marital status	.131	.196	.074	.667	.507
Employment status	-.027	.294	-.012	-.092	.927
Length of diagnosis	-.354	.159	-.270	-2.232	.029

Type of health care provider	.622	.520	.174	1.196	.236
Length of relationship with health care provider	.123	.285	.058	.431	.668

Note. PAM= Patient Activation Measure.

Variable	B	SE (B)	Standardized Beta	t-value	p-value
PAM	.157	.055	.330	2.842	.006
Age	.174	.376	.064	.462	.645
Sex	-.468	.612	-.092	-.765	.447
Race	-.167	.875	-.022	-.191	.849
Education	.689	.326	.248	2.116	.038
Marital status	.069	.279	.029	.248	.805
Employment status	-.033	.417	-.010	-.078	.938

Length of diagnosis	.294	.225	.164	1.306	.196
Type of health care provider	-.069	.738	-.014	-.094	.926
Length of relationship with health care provider	-.468	.405	-.161	-1.157	.251

Note. PAM= Patient Activation Measure.

Variable	B	SE (B)	Standardized Beta	t-value	p-value
FPI	.172	.078	.238	2.208	.030
Age	.318	.398	.108	.798	.428
Sex	-.386	.631	-.070	-.612	.543
Race	.636	.922	.079	.690	.493
Education	-.350	.342	-.116	-1.023	.310

Marital status	.347	.295	.133	1.176	.243
Employment status	.421	.440	.122	.955	.343
Length of diagnosis	.308	.233	.158	1.321	.191
Type of health care provider	1.463	.777	.276	1.884	.064
Length of time with health care provider	-.201	.426	-.064	-.473	.638

Note. FPI= Facilitation of Patient Involvement scale.

Variable	B	SE (B)	Standardized Beta	t-value	p-value
PICS	.254	.125	.234	2.033	.046
Age	.204	.399	.069	.512	.610
Sex	-.348	.635	-.063	-.548	.585
Race	.565	.928	.070	.609	.545

Education	-.371	.345	-.123	-1.076	.286
Marital status	.316	.299	.121	1.056	.295
Employment status	.099	.463	.029	.214	.831
Length of diagnosis	.292	.234	.150	1.247	.216
Type of health care provider	1.757	.785	.331	2.238	.028
Length of relationship with health care provider	-.181	.427	-.058	-.423	.674

Note. PICS = Perceived Involvement in Care Scale

**Results for research question 3.** *Do patients who see nurse practitioners for management of Type 2 diabetes experience higher levels of engagement in self-care behaviors and more therapeutic HbA1c levels compared to patients who see a physician?* When running an ANOVA examining outcome behaviors among patients seeing nurse practitioners compared to patients seeing physicians, nurse practitioners were found to be significantly associated with increased days per week of patients checking their blood glucose levels ( $p = .014$ ). Type of health care provider was also found to be significantly associated with smoking ( $p < .01$ ). However, after controlling for the covariates of age, sex, race, education, marital status, employment, length of diagnosis, and length of relationship with health care provider, the statistical significance for both checking blood glucose levels ( $p = .100$ ) and smoking ( $p = .066$ ) were no longer significant. There were no other statistically significant associations found when



analyzing the data with and without the covariates for HbA1c values ( $p = .128$ ), GDS ( $p = .927$ ), SDS ( $p = .687$ ), exercise ( $p = .878$ ), and foot care ( $p = .376$ ).

**Results for research question 4.** *Is there a difference in levels of patient activation (PAM), participation in decision-making (PICS), and facilitation of patient involvement in care (FPI) when a nurse practitioner treats a patient compared to a physician?* There were no statistically significant differences found for any of the dependent variables (patient activation ( $p = .422$ ), participation in decision-making ( $p = .338$ ), and facilitation of patient involvement in care ( $p = .175$ ) between nurse practitioner patients and physician patients when controlling for the covariates of age, sex, race, education, marital status, employment, length of diagnosis, and length of relationship with health care provider.

## Discussion

In this study, the CCM was used as a foundation to examine elements of the CCM and their relationship to the outcome variables of HbA1c levels and self-care behaviors. This study showed that the PACIC was significantly associated with General Diet Score (GDS), Specific Diet Score (SDS), Exercise, and Blood Glucose Testing. Patient Activation was found to be associated with General Diet Score (GDS) and Foot Care. Facilitation of patient involvement (FPI) and Perceived Involvement in Care (PICS) were both found to be associated with Blood Glucose Testing.

In the first research question examining the impact of delivery system design and clinical information systems, decision support, self-management support, and community resources on HbA1c levels and participation in self-care behaviors, the only statistically significant outcomes associated with the PACIC, which represented the components of the CCM, were the self-

reported, self-care behaviors of general diet, specific diet, exercise, and blood glucose testing. In previous studies examining delivery system design within the context of the CCM, patient outcomes improved, specifically HbA1c levels, Foot Care, and Smoking Cessation, diet, and exercise, when the CCM was implemented as a guiding structure in primary care settings among patients with a chronic condition (Ades et al., 2013; Nuno, Coleman, Bengoa, & Sauto, 2012; Peterson et al., 2014; Rathert, Wyrwich, & Boren, 2012; Stellefson et al., 2013; Thota et al., 2012). While general diet, specific diet, exercise, and blood glucose testing are important self-care behaviors, it would be important to further explore why HbA1c values, which were objectively measured data, were not also significantly associated with elements of the CCM.

In the second research question examining the effect of patient activation, participation in decision-making for treatment planning, and facilitation of patient involvement on HbA1c levels and patients' performance of self-care behaviors, patient activation was found to be a predictor of general diet and foot care. Facilitation of patient involvement and participation in decision-making were predictive of blood glucose testing. Again, no predictive relationship was found with HbA1c values. Other studies looking at patient activation showed improvement of HbA1c levels, and significant associations with exercise, foot care, decreases in health care costs, and more positive interactions with health care providers as reported by patients (Hibbard & Greene, 2013; Mosen et al., 2007; Rask et al., 2009; Remmers et al., 2009), showing some similar findings to the results of this study. Recent studies implementing facilitation of patient involvement and shared decision making among patients with type 2 diabetes have been implemented with a focus on improving HbA1c values, however, noting that with the complexity of a chronic disease, such as type 2 diabetes, there are many factors that contribute to the overall

outcomes of the patients (Inzucchi et al., 2015; Inzucchi et al., 2102; Joseph-Williams, Elwyn, & Edwards, 2014).

Looking at the third and fourth research questions comparing nurse practitioners and physicians, none of the findings were statistically significant. The third research question was examining the type of health care provider and the predictive relationship with HbA1c values and participation in self-care behaviors. However, again, there was no relationship with HbA1c levels. In the last research question examining differences in patient activation, participation in decision-making, and facilitation of patient involvement in care when a nurse practitioner treats a patient compared to a physician, there were no significant predictors for any of the outcome variables. Varied data exist related to patient outcomes of nurse practitioners and physicians. While there tends to be a general consensus that patients are more satisfied with care provided by nurse practitioners among general patient populations, data related to patient outcomes are more inconsistent (Chang et al., 2007; C. Everett et al., 2013; C. M. Everett et al., 2013; Kuo et al., 2015; Stanik-Hutt et al., 2013; ter Bogt et al., 2011). Other studies examining patients with type 2 diabetes found patient satisfaction and/or patient outcomes in nurse practitioner groups to be very similar to those seeing physicians (Kuo et al., 2015; ter Bogt et al., 2011). There are data to show that nurses and nurse practitioners can help to improve patient outcomes through various interventions and programs in conjunction with physicians, among patients with diabetes; however, many studies have found that nurse practitioners provide care for less complex patients than physicians, and little data exist to show a significant difference in patient outcomes for patients strictly seeing nurse practitioners instead of physicians (Chang et al., 2007; C. Everett et al., 2013; C. M. Everett et al., 2013; Hoffman et al., 2005; Kuo et al., 2015; Litaker et al., 2003; Renders et al., 2001; Taylor et al., 2003; ter Bogt et al., 2011). When looking at care provided

by a nurse practitioner compared to a physician, there were no significant findings related to improvements in HbA1c levels and self-care behaviors, nor any significant differences in patient activation, participation in decision-making, and facilitation of patient involvement. This study did not compare patient satisfaction ratings between participants seeing nurse practitioners or physicians. In contrast to the results of this study, many other studies that examine generalized patient populations present data that shows patients are more satisfied with care and outcomes are improved when being treated by nurse practitioners (Chang et al., 2007; Condosta, 2012; Eisenstat et al., 2013; C. Everett et al., 2013; C. M. Everett et al., 2013; Fain & Melkus, 1994; Kinnersley et al., 2000; Roblin et al., 2004; Rudy et al., 1998; Salisbury & Tattersell, 1998; Stanik-Hutt et al., 2013; ter Bogt et al., 2011; Venning et al., 2000). Being that this study had a relatively low sample size, and relatively low number of health care providers, this could explain the contrary results to what is published for other studies.

Of notable importance, having no statistical significance is also important for research questions three and four because it demonstrates that, in this particular study, there was no difference in the standards and variables that were measured comparing nurse practitioners and physicians. The patients who were cared for by both types of providers experienced similar outcomes with regard to self-care behaviors, HbA1c, levels of patient activation, participation in decision-making, and facilitation of patient involvement in care. Therefore, this is an important finding supporting the notion that care received by NP patients and MD patients is not different.

### **Limitations**

There were some limitations with this study. First, the sample size was smaller than desired, as a sample size of 112 participants would have been necessary to ensure the study had a power of .80. The goal of 112 patients was not met; the entire sample size was 82 patients after

two years of data collection; however, some statistically significant results were detected through the data analysis. The majority of the sample was White, female, had completed high school or had a high school equivalency, and were unemployed, therefore the sample was not very diverse, and findings are only generalizable to patients with these characteristics. Second, the locations did not to provide a variety of patients demographically. Almost all of the nurse practitioner patients were seen in only one of the five locations, which was a clinic for the underserved population of the area. When looking at the overall number of patients on record with type 2 diabetes (approximately 29 million people) (Gardner, 2016), this sample size may not be representation of all patients who have been diagnosed with type 2 diabetes.

Design limitations also were factors in this study. Data collection was very time consuming, as it required one researcher to individually meet with each participant. Because of the Health Insurance Portability and Accountability Act (HIPAA), recruiting patients was difficult. The staff at the primary care offices was not permitted to let the researcher know in advance if potential participants would be in the office on that day. The researcher would take turns visiting offices, hoping to connect with participants. The researcher would arrive at one of the five offices and potentially not see a patient the entire day, thus another reason data collection took such a long period of time. The study also used a variety of tools which were perceived to be too time consuming by some of the participants. Completing the tools was also an issue for those participants who had issues with vision, reading comprehension, and difficulty writing. For these participants, the researcher would read the questions aloud to the participant and have the participant verbalize their answer. If the participant could not write, due to arthritis or other issues, the researcher would circle the chosen responses in front of the participant as they responded to the questions.

For the FPI tool, the Cronbach's alpha for this study was .303. After reviewing the responses from this particular tool, it appears many of the participants did not carefully read some of the questions or may not have understood some of the questions. Many patients put the same answer for questions that were worded oppositely of a previous question. Participants were reminded to read the questions carefully and the researcher verbalized to the participants that some questions may look similar but were actually worded oppositely of the previous question. Despite this direction, many participants did not distinguish between the two questions. This makes the findings of this particular tool less reliable and less valid because after visually inspecting each participant's forms, this potential error was noted quite frequently.

There were a total of six forms that needed to be completed by each participant. The FPI tool was placed fourth in the stack of forms. At this point, survey fatigue may have become an issue for these participants. The number of surveys and length of time to complete all of the paperwork may have become overwhelming for participants.

### **Future Research**

While some significant predictors were found among the various research questions, none of them were found to have a relationship with HbA1c levels. Being that the HbA1c levels are the standard by which control of diabetes is measured (American Diabetes Association, 2015; Casagrande et al., 2013), it was somewhat surprising to not find any relationships among the variables and HbA1c levels. Based on the data analysis, no matter how high participants rated themselves in the areas of patient activation, facilitation of patient involvement, and participation in decision making, there were not notable improvements in HbA1c values. This can lead future research to examine the qualitative aspects of the patients' personal views of these variables. Qualitative studies may also examine what participation means to patients, self-care barriers and

challenges, and personal definitions of diet recommendations based on current American Diabetes Association recommendations for patients. While a patient may feel that he or she was highly activated and involved in their care, the patient may have been lacking the education or other means to truly carry out the behaviors needed to affect HbA1c. Future research could look at interventions to enhance or increase how the health care provider involves the patient in his or her care and enhancing how well the patient is actually involved in that care in order to positively influence HbA1c levels.

The PACIC and PAM were found to be predictors of the General Diet Score (GDS). Future studies could have diet as an outcome measure focusing on interventions that enhance or improve patient activation, as measured by the PAM and PACIC. For the PACIC, interventions that looking at decision support, follow-up, problem solving, and goal setting would be appropriate when looking at diet as an outcome measure. The self-care behaviors are important components in individual patient management and control of type 2 diabetes (Booth et al., 2013; Haas et al., 2013; Rise et al., 2013). When patients carry out the appropriate self-care behaviors, often HbA1c values improve (Booth et al., 2013; Haas et al., 2013; Rise et al., 2013). If the data show a predictive relationship with these self-care behaviors, which if carried out on a regular basis help improve diabetes control, then examining why HbA1c values were not significantly affected is an important next step.

Based on the data analysis, it would be important to examine if the patients' defining factors of self-care behaviors matched the American Diabetes Association (ADA) guidelines and recommendations. For example, if a patient reports following a diet and eating the appropriate amounts of fruits and vegetables per week, what does that translate into from a food diary perspective, and is their diet developed using appropriate dietary recommendations? Looking at

the ADA dietary recommendations for patients with diabetes, patients should be educated in many areas in addition to fruits, vegetables, proteins, and fats. These recommendations include, but are not limited to, looking at eating patterns, fructose, trans fat, alcohol, omega-3 fatty acids, and noncaloric sweeteners (Evert et al., 2013). In terms of exercise, what is the quantity and quality of the exercise they are reporting? The recent ADA recommendation discuss the incorporation of both aerobic and resistance exercise, as well as including flexibility and balance (Colberg et al., 2016). Research looking at the details of self-reported food intake and exercise participation may be helpful considering the detailed recommendations that are now available (Colberg et al., 2016; Evert et al., 2013). It would be important to look into this further to find out at what point the self-care variables are able to predict HbA1c levels. Research objectively examining self-care behaviors in comparison to HbA1c values will provide valuable data in terms of what patients are actually doing versus what they are reporting.

It would be beneficial to continue this research to gain a larger patient population to evaluate whether the non-significant results changed as the sample size increased. It would also be beneficial to gather a more diverse population, as type II diabetes affects many races and ethnicities. Future research to find connections and relationships among self-care behaviors and HbA1c values would also help to determine at what point self-care behaviors become predictive of HbA1c values.

### **Conclusion**

In conclusion, the results of this study were valuable in helping to address some of the many questions related to HbA1c values and self-care behaviors for patients with type 2 diabetes. Using the CCM as a framework for this study was appropriate as the CCM has been used in various other studies focusing on the management of Type 2 diabetes (Bodenheimer et



al., 2002b; Dancer & Courtney, 2010; Frei et al., 2014; Koh et al., 2013; National Institutes of Health and the Centers for Disease Control and Prevention, 2011; Parchman, Michael L,MD, MPH et al., 2007; Peterson et al., 2014; Robert Wood Johnson Foundation, 2016a; Siminerio et al., 2006; Siminerio et al., 2004; Smith et al., 2008; Stellefson et al., 2013), and it provided a comprehensive view of variables that may impact self-care and control of Type 2 diabetes.

While this study did not have any significant findings related to variables that were associated with HbA1c values, there were some significant factors associated with self-care behaviors, specifically GDS, SDS, exercise, blood glucose testing, and foot care. It is important to acknowledge that while there were not any statistically significant results related to differences among nurse practitioners and physicians, that finding is significant because it demonstrated no differences in care between nurse practitioners and physicians. There is still much to be learned about variations in types of health care providers, and examining ways to provide care to patients to ensure optimal outcomes for those who have been diagnosed with type 2 diabetes. There are many avenues for future research based on the results of this study, including looking at the quality of self-care behaviors compared to self-reported frequency to find ways of improving HbA1c levels in patients with type 2 diabetes.

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## Appendices

**Appendix A**

**Demographics Form**

1. Name: \_\_\_\_\_

2. Age: \_\_\_\_\_

Please circle the selection that is your answer for the following questions.

3. Sex:            Male            Female

4. Race:

White            African American/Black            Asian

Alaska Native/American Indian            Native Hawaiian/ Other Pacific Islander

Other: \_\_\_\_\_

5. Level of education completed:

Did not complete high school            High school graduate/Diploma/ GED

Trade/Technical/Vocational Training            Associate Degree

Bachelor's Degree            Master's Degree

Professional Degree            Doctoral Degree

6. Marital Status:

Single/Never Married

Married/Domestic Partner

Divorced

Widowed

Separated

7. Employment status:

Employed

Unemployed

Homemaker

Student

Military

Retired

Unable to work

8. How long have you been diagnosed with type 2 diabetes? \_\_\_\_\_

9. Do you take medication for type 2 diabetes?

No Medication

Oral medication/Pills

Insulin/Shots

Both oral medication/pills AND insulin/shots

10. What type of practitioner are you seeing for this visit:

Physician

Nurse Practitioner

Questions About the Practitioner You Are Seeing TODAY

Length of time that you have been seeing this practitioner: \_\_\_\_\_

Number of visits to practitioner within the last 12 months: \_\_\_\_\_

Were you asked to make follow-up appointment?

Yes

No

Were you referred to any other services related to diabetes? Yes No

If YES, who were you referred to:

Endocrinologist                      Dietician              Diabetes Educator

Podiatrist                      Optometrist/Ophthalmologist

Other: \_\_\_\_\_

Were you given a printed out report of any results or goals of treatment? Yes No

Did you discuss goals of treatment? Yes No

#### Questions About the OTHER Practitioners You Have Seen

Have you seen any other this practitioners at this office: Yes No

If answering YES to question 12, please list other practitioners you have seen in THIS OFFICE:

\_\_\_\_\_

Have you had visits to other care providers within last 12 months related to diabetes:

Yes No

If you answered YES to question 16, please circle the reasons you visited these other practitioners

Endocrinologist                      Dietician              Diabetes Educator



Podiatrist

Optometrist/Ophthalmologist

Other: \_\_\_\_\_

## Appendix B

### 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 others want 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 am confident I can help prevent or reduce problems associated with my health**

Disagree Strongly                      Disagree                      Agree                      Agree Strongly  
N/A

**4. I know what each of my prescribed medications do**

Disagree Strongly                      Disagree                      Agree                      Agree Strongly  
N/A

**5. I am confident that I can tell whether I need to go to the doctor/nurse practitioner or whether I can take care of a health problem myself**

Disagree Strongly      Disagree      Agree      Agree Strongly  
N/A

**6. I am confident that I can tell a doctor/nurse practitioner concerns I have even when he or she does not ask**

Disagree Strongly      Disagree      Agree      Agree Strongly  
N/A

**7. 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

**8. I understand my health problems and what causes them**

Disagree Strongly      Disagree      Agree      Agree Strongly  
N/A

**9. I know what treatments are available for my health problems**

Disagree Strongly      Disagree      Agree      Agree Strongly  
N/A

**10. I have been able to maintain (keep up with) lifestyle changes, like eating right or exercising**

Disagree Strongly      Disagree      Agree      Agree Strongly  
N/A

**11. I know how to prevent problems with my health**

Disagree Strongly                      Disagree                      Agree                      Agree Strongly  
N/A

**12. I am confident I can figure out solutions when new problems arise with my health**

Disagree Strongly                      Disagree                      Agree                      Agree Strongly  
N/A

**13. 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

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## Appendix C

### Facilitation of Patient Involvement Scale (Martin et al., 2001)

Directions: Please indicate how often your physician or nurse practitioner typically does the following things, using these responses:

*(1) none of the time*

*(2) a little of the time*

*(3) some of the time*

*(4) a good bit of the time*

*(5) most of the time*

*(6) all of the time*

1. My doctor gives me all the information that I need to make the decisions that are right for me.
2. My doctor ignores my opinion about treatment options.
3. When prescribing a new medication, my doctor asks if I have any questions about the medication(s) and possible side effects.
4. My doctor discourages my questions.
5. My doctor explains all the treatment options to me so that I can make an informed choice.
6. My doctor strongly encourages me to express all of my concerns about the prescribed treatment.
7. My doctor discourages me from expressing my personal opinion about my medical condition.
8. My doctor's office staff makes it hard for me to be involved in my own medical care.
9. My doctor makes it difficult for me to communicate my concerns about treatment decisions.

## Appendix D

### Perceived Involvement in Care Scale

Available from:

Lerman, C. E., Brody, D. S., Caputo, G. C., Smith, D. G., Lazaro, C. G., & Wolfson, H. G.

(1990). Patients' perceived involvement in care scale: Relationship to attitudes about illness and medical care. *Journal of General Internal Medicine*, 5, 29-33. doi:[10.1007/BF02602306](https://doi.org/10.1007/BF02602306)

## Appendix E

### Assessment of Care for Chronic Conditions

Staying healthy can be difficult when you have a chronic condition. We would like to learn about the type of help with your condition you get from your health care team. This might include your regular doctor, his or her nurse, or physician's assistant who treats your illness. Your answers will be kept confidential and will not be shared with your physician or clinic.

**Over the past 6 months, when I received care for my chronic conditions, I was:**

	<u>None of the time</u>	<u>A Little of the Time</u>	<u>Some of the Time</u>	<u>Most of the Time</u>	<u>Always</u>
1. Asked for my ideas when we made a treatment plan.	<input type="checkbox"/> <sub>1</sub>	<input type="checkbox"/> <sub>2</sub>	<input type="checkbox"/> <sub>3</sub>	<input type="checkbox"/> <sub>4</sub>	<input type="checkbox"/> <sub>5</sub>
2. Given choices about treatment to think about.	<input type="checkbox"/> <sub>1</sub>	<input type="checkbox"/> <sub>2</sub>	<input type="checkbox"/> <sub>3</sub>	<input type="checkbox"/> <sub>4</sub>	<input type="checkbox"/> <sub>5</sub>
3. Asked to talk about any problems with my medicines or their effects.	<input type="checkbox"/> <sub>1</sub>	<input type="checkbox"/> <sub>2</sub>	<input type="checkbox"/> <sub>3</sub>	<input type="checkbox"/> <sub>4</sub>	<input type="checkbox"/> <sub>5</sub>
4. Given a written list of things I should do to improve my health.	<input type="checkbox"/> <sub>1</sub>	<input type="checkbox"/> <sub>2</sub>	<input type="checkbox"/> <sub>3</sub>	<input type="checkbox"/> <sub>4</sub>	<input type="checkbox"/> <sub>5</sub>
5. Satisfied that my care was well organized.	<input type="checkbox"/> <sub>1</sub>	<input type="checkbox"/> <sub>2</sub>	<input type="checkbox"/> <sub>3</sub>	<input type="checkbox"/> <sub>4</sub>	<input type="checkbox"/> <sub>5</sub>
6. Shown how what I did to take care of myself influenced my condition.	<input type="checkbox"/> <sub>1</sub>	<input type="checkbox"/> <sub>2</sub>	<input type="checkbox"/> <sub>3</sub>	<input type="checkbox"/> <sub>4</sub>	<input type="checkbox"/> <sub>5</sub>
7. Asked to talk about my goals in caring for my condition.	<input type="checkbox"/> <sub>1</sub>	<input type="checkbox"/> <sub>2</sub>	<input type="checkbox"/> <sub>3</sub>	<input type="checkbox"/> <sub>4</sub>	<input type="checkbox"/> <sub>5</sub>
8. Helped to set specific goals to improve my eating or exercise.	<input type="checkbox"/> <sub>1</sub>	<input type="checkbox"/> <sub>2</sub>	<input type="checkbox"/> <sub>3</sub>	<input type="checkbox"/> <sub>4</sub>	<input type="checkbox"/> <sub>5</sub>
9. Given a copy of my treatment plan.	<input type="checkbox"/> <sub>1</sub>	<input type="checkbox"/> <sub>2</sub>	<input type="checkbox"/> <sub>3</sub>	<input type="checkbox"/> <sub>4</sub>	<input type="checkbox"/> <sub>5</sub>
10. Encouraged to go to a specific group or class to help me cope with my chronic condition.	<input type="checkbox"/> <sub>1</sub>	<input type="checkbox"/> <sub>2</sub>	<input type="checkbox"/> <sub>3</sub>	<input type="checkbox"/> <sub>4</sub>	<input type="checkbox"/> <sub>5</sub>
11. Asked questions, either directly or on a survey, about my health habits.	<input type="checkbox"/> <sub>1</sub>	<input type="checkbox"/> <sub>2</sub>	<input type="checkbox"/> <sub>3</sub>	<input type="checkbox"/> <sub>4</sub>	<input type="checkbox"/> <sub>5</sub>



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**Over the past 6 months, when I received care for my chronic conditions, I was:**

	<u>None of the time</u>	<u>A Little of the Time</u>	<u>Some of the Time</u>	<u>Most of the Time</u>	<u>Always</u>
12. Sure that my doctor or nurse thought about my values, beliefs, and traditions when they recommended treatments to me.	<input type="checkbox"/> <sub>1</sub>	<input type="checkbox"/> <sub>2</sub>	<input type="checkbox"/> <sub>3</sub>	<input type="checkbox"/> <sub>4</sub>	<input type="checkbox"/> <sub>5</sub>
13. Helped to make a treatment plan that I could carry out in my daily life.	<input type="checkbox"/> <sub>1</sub>	<input type="checkbox"/> <sub>2</sub>	<input type="checkbox"/> <sub>3</sub>	<input type="checkbox"/> <sub>4</sub>	<input type="checkbox"/> <sub>5</sub>
14. Helped to plan ahead so I could take care of my condition even in hard times.	<input type="checkbox"/> <sub>1</sub>	<input type="checkbox"/> <sub>2</sub>	<input type="checkbox"/> <sub>3</sub>	<input type="checkbox"/> <sub>4</sub>	<input type="checkbox"/> <sub>5</sub>
15. Asked how my chronic condition affects my life.	<input type="checkbox"/> <sub>1</sub>	<input type="checkbox"/> <sub>2</sub>	<input type="checkbox"/> <sub>3</sub>	<input type="checkbox"/> <sub>4</sub>	<input type="checkbox"/> <sub>5</sub>
16. Contacted after a visit to see how things were going.	<input type="checkbox"/> <sub>1</sub>	<input type="checkbox"/> <sub>2</sub>	<input type="checkbox"/> <sub>3</sub>	<input type="checkbox"/> <sub>4</sub>	<input type="checkbox"/> <sub>5</sub>
17. Encouraged to attend programs in the community that could help me.	<input type="checkbox"/> <sub>1</sub>	<input type="checkbox"/> <sub>2</sub>	<input type="checkbox"/> <sub>3</sub>	<input type="checkbox"/> <sub>4</sub>	<input type="checkbox"/> <sub>5</sub>
18. Referred to a dietitian, health educator, or counselor.	<input type="checkbox"/> <sub>1</sub>	<input type="checkbox"/> <sub>2</sub>	<input type="checkbox"/> <sub>3</sub>	<input type="checkbox"/> <sub>4</sub>	<input type="checkbox"/> <sub>5</sub>
19. Told how my visits with other types of doctors, like an eye doctor or other specialist, helped my treatment.	<input type="checkbox"/> <sub>1</sub>	<input type="checkbox"/> <sub>2</sub>	<input type="checkbox"/> <sub>3</sub>	<input type="checkbox"/> <sub>4</sub>	<input type="checkbox"/> <sub>5</sub>
20. Asked how my visits with other doctors were going.	<input type="checkbox"/> <sub>1</sub>	<input type="checkbox"/> <sub>2</sub>	<input type="checkbox"/> <sub>3</sub>	<input type="checkbox"/> <sub>4</sub>	<input type="checkbox"/> <sub>5</sub>



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## **Appendix F**

### **Summary of Diabetes Self Care Activities**

## **Appendix G**

### **Permission to Use Instruments**

#### **Patient Activation Measure, Appendix B**

The PAM was purchased for doctoral dissertation use through the Insignia Health Website (Insignia Health LLC, 2012)

#### **Facilitation of Patient Involvement, Appendix C**

Permission to use the FPI scale was granted by Dr. Leslie Martin via email.

Dec 8, 2013

Hi,

Sorry for the delay; I rarely use this email address anymore (and you should have received an automatic email telling you that and giving you my new email address, which is lrmartin@llu.edu -- sorry that apparently didn't happen). In any case, you're welcome to use the FPI; simply cite the original article, that's all we ask.

Best,

Leslie

#### **Perceived Involvement in Care Scale, Appendix D**

Permission to use a copy of the PICS was granted by Dr. Lerman through email.

Dec 1, 2013

Hello

The items are published in the paper. I know longer have a copy but you are welcome to use it

Caryn Lerman Ph.D

Department of Psychiatry and Annenberg Public Policy Center

University of Pennsylvania

#### **Patient Assessment of Care for Chronic Conditions (PACIC), Appendix E**

The PACIC is available in the public domain and can be found on the Improving Chronic Illness Care website. <http://www.improvingchroniccare.org/>

## **Summary of Diabetes Self-Care Activities (SDSCA), Appendix F**

A copy of the SDSCA was available in the public domain and permission for use was also provided by Dr. Toobert.

Dec 2, 2013

Dear Courtney,

You have our permission to use the Summary of Diabetes Self-Care Activities Questionnaire in your research project. The instrument is in the public domain, and permission is not required. (But you have it anyway). Attached is the 2000 Diabetes Care article with the SDSCA psychometric information. At the end of the article, there is an appendix with the questionnaire, and the scoring information. I have also attached a user-friendly copy of the SDSCA instrument.

Best of luck with your research

Deborah

## Appendix H

### Approval from Duquesne University

To: Courtney Proie  
From: Linda Goodfellow, IRB Chair  
Subject: Protocol #2014/01/26 - Approval Notification  
Date: 02/24/2014

The protocol **An Examination of Factors Affecting Hemoglobin A1c Levels and Self-Care Behaviors among Type 2 Diabetic Patients in Primary Care Settings** has been approved by the IRB Chair under the rules for expedited review on **02/24/2014**.

University HIPAA Officer, Dr. Joan Kiel, has reviewed and approved the health information procedures as HIPAA-compliant.

The consent forms are stamped with IRB approval and one year expiration date. You should use the stamped forms as originals for copies that you distribute or display. I have also stamped the recruitment flier and it can be accessed via Mentor.

The approval of your study is valid through 02/24/2015, by which time you must submit an annual report either closing the protocol or requesting permission to continue the protocol for another year. Please submit your report by **01/26/2015** so that the IRB has time to review and approve your report if you wish to continue it for another year.

If, prior to the annual review, you propose any changes in your procedure or consent process, you must complete an amendment form of those changes and submit it to the IRB Chair for approval. Please wait for the approval before implementing any changes to the original protocol. In addition, if any unanticipated problems or adverse effects on subjects are discovered before the annual review, you must immediately report them to the IRB Chair before proceeding with the study.

When the study is complete, please provide the IRB with a completed termination report. Keep a copy of your research records, other than those you have agreed to destroy for confidentiality, over a period of five years after the study's completion.

If you have any questions, feel free to contact me.

Linda Goodfellow, PhD, RN  
IRB Chair  
goodfellow@duq.edu

# Appendix I

## Approval from Allegheny Health Network



ALLEGHENY-SINGER  
RESEARCH INSTITUTE

West Penn Allegheny Health System

320 East North Avenue, Pittsburgh, PA 15212-4772  
412.359.3156

Institutional Review Board 01  
FWA00015120

March 28, 2014

Michele Prior, MSN, RN  
Department of Nursing

RE: RC-5886 "An Examination of Factors Affecting Hemoglobin A1C Levels and Self-Care Behaviors among Type 2 Diabetic Patients in Primary Care Settings"

Dear Ms. Prior:

The IRB acknowledges receipt of the above-referenced non-funded protocol including:

- Protocol Version (Proie Protocol Summary);
- Recruitment flyer; and
- Informed Consent Form (AGH ICF 1).
- Total number of subjects approved at the Primary Care Offices is: 112.

This protocol has been reviewed via the "expedited review" process (Category # 5, 7) and is approved by the IRB in accordance with Institutional, Federal and State regulations. It is the responsibility of the investigator to obtain any other necessary approvals prior to implementation of the research. Your approved protocol will be subject to review within one year.

Approved: March 28, 2014  
Approval Period Expires: March 27, 2015

Attached is a copy of the approved, stamped Informed Consent Form for your use.

Please be aware of the record keeping responsibilities involved in your protocol. A copy of the *Principal Investigator Responsibilities* is also attached for your use. Your approved protocol will be subject to review within one year from the date of initial review by the IRB.

Sincerely,

Handwritten signature of Athanasios Colonias.

Athanasios Colonias, MD  
Vice-Chairman  
Institutional Review Board

AC/clp

**Appendix J**

**Approved Consent Form Duquesne University**

DUQUESNE UNIVERSITY  
600 FORBES AVENUE ♦ PITTSBURGH, PA 15282

**CONSENT TO PARTICIPATE IN A RESEARCH STUDY**

**TITLE:** An Examination of Factors Affecting Hemoglobin A1c Levels and Self-Care Behaviors among Type 2 Diabetic Patients in Primary Care Settings

**INVESTIGATOR:** Courtney D. Proie, PhD-C, MSN, RN



**ADVISOR:** Melanie Turk, PhD, MSN, RN  
School of Nursing  
518 Fisher Hall, 600 Forbes Ave.  
Pittsburgh, PA 15282  
412-396-1817

**SOURCE OF SUPPORT:** This study is being performed as partial fulfillment of the requirements for the doctoral degree in nursing at Duquesne University.

**PURPOSE:** This is being done so we can learn how patients do with seeing a medical provider, how involved patients are in their own illness and care, if patients help make decisions related to their treatment, and if patients feel that their doctor or nurse practitioner is trying to involve them in the care process for patients with type 2 diabetes. This study also wants to learn about how patients are followed by their practitioners and referred to other services, programs, or practitioners related to the care of type 2 diabetes. Lastly, this study wants to look at the differences in care for patients seen by nurse practitioners and physicians in the primary care setting.

This research project seeks to examine how a patient's involvement in the treatment of their type 2 diabetes can affect the overall blood sugar control and the ability to care for one's self by participating in self-care behaviors specific to type 2 diabetes. You will be asked to complete questionnaire forms about involvement in your care and your perception of your practitioner's willingness to include you in the decision-making process related to treatment of your type 2 diabetes. You will be given instructions on how to complete each questionnaire and a private area will be provided for your comfort. The questionnaires should take approximately 30 minutes to complete. By assessing your participation in daily self-care behaviors and your overall blood sugar control, in addition to reviewing the responses you provide on the questionnaires, the research study investigator will seek to find a relationship between all of these variables mentioned above.

In addition to completing a series of questionnaires related to these topics, you will be asked to have one blood draw to obtain a hemoglobin A1c value if you have not had one done in the past 6 months. The hemoglobin A1c test is a blood test that gives a measure of your overall blood sugar levels for the previous 2-3 months. You are also being asked to give your consent to allow the investigator to obtain your most recent Hemoglobin A1c value from a research nurse who is an employee of the West Penn Allegheny Health System, part of the Allegheny Health Network.

These are the only requests that will be made of you.

**RISKS AND BENEFITS:**

You may not gain any immediate benefit by taking part in this study. A potential benefit that could be derived from this study relates to knowledge about the types of healthcare practitioners that patients may benefit from seeing. In addition, possible benefits may include learning how practitioners facilitate the involvement of patients in their care and decision making, related to the management of type 2 diabetes.

There are no risks greater than those encountered in everyday life.

**COMPENSATION:**

To compensate you for your time, you will receive a \$15 Giant Eagle or Wal-Mart gift card when all the questionnaires are completed. Participation in the project will require no monetary cost to you. If you choose to take the questionnaires home rather than complete them at the office, a stamped envelope is provided for the return of the completed questionnaires within 7 days to the investigator.

**CONFIDENTIALITY:**

Your name will never appear on any survey or research instruments. No identity will be made in the data analysis. All written materials and consent forms will be stored in a locked file in the researcher's home. You will be identified on these research records by only a study ID number rather than your name, and the information linking these ID numbers with your identity will be kept separate from the research records. Only the researchers listed on the first page of this form and the research nurse will be able to gain access to your records. All information about your involvement in this study—including answers provided on the demographic form and questionnaires—will be handled in a confidential way. Your responses will only appear in statistical data summaries. All materials will be destroyed at the completion of the research.

**RIGHT TO WITHDRAW:**

You are under no obligation to participate in this study. You are free to withdraw your consent to participate at any time. There will be no impact on your care in the provider's office should you choose not to participate or withdraw your consent to participate.

**SUMMARY OF RESULTS:**

A summary of the results of this research will be supplied to you, at no cost, upon request.

**VOLUNTARY CONSENT:**

I have read the above statements and understand what is being requested of me. I also understand that my participation is voluntary and that I am free to withdraw my consent at any time, for any reason, without any consequence or impact in my care. On these terms, I certify that I am willing to participate in this research project.

I understand that should I have any further questions about my participation in this study, I may call Courtney Proie, Investigator, at [REDACTED], Dr. Melanie Turk, Advisor,



at 412-396-1817, and Dr. Linda Goodfellow, Chair of the Duquesne University Institutional Review Board 412-396-6548.

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Participant's Signature

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Date

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Participant's Name (please print)

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Researcher's Signature

---

Date

## Appendix K

### Approved Consent Form at Allegheny Health Network Sites

#### INFORMED CONSENT FORM AND AUTHORIZATION TO DISCLOSE PROTECTED HEALTH INFORMATION FOR A RESEARCH STUDY

**Title of research study (RC# 5886):** *An Examination of Factors Affecting Hemoglobin A1c Levels and Self-Care Behaviors among Type 2 Diabetic Patients in Primary Care Settings*

**Principal Investigator:** Michele Prior, MSN, RN

**Co-investigator:** Courtney D. Proie, PhD-C, MSN, RN

**SPONSOR:** This study is being performed as partial fulfillment of the requirements for the doctoral degree in nursing at Duquesne University.

**PURPOSE:** This is being done so we can learn how patients do with seeing a medical provider, how involved patients are in their own illness and care, if patients help make decisions related to their treatment, and if patients feel that their doctor or nurse practitioner is trying to involve them in the care process for patients with type 2 diabetes. This study also wants to learn about how patients are followed by their practitioners and referred to other services, programs, or practitioners related to the care of type 2 diabetes. Lastly, this study wants to look at the differences in care for patients seen by nurse practitioners and physicians in the primary care setting.

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There are no risks greater than those encountered in everyday life.

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Participation in the project will require no monetary cost to you. If you choose to take the questionnaires home rather than complete them at the office, a stamped envelope is provided for the return of the completed questionnaires within 7 days to the investigator.

**CONFIDENTIALITY:**

Your name will never appear on any survey or research instruments. No identity will be made in the data analysis. All written materials and consent forms will be stored in a locked file in the researcher's home. You will be identified on these research records by only a study ID number rather than your name, and the information linking these ID numbers with your identity will be kept separate from the research records. Only the researchers listed on the first page of this form and the research nurse will be able to gain access to your records. All information about your

involvement in this study—including answers provided on the demographic form and questionnaires—will be handled in a confidential way. Your responses will only appear in statistical data summaries. All materials will be destroyed at the completion of the research.

**RIGHT TO WITHDRAW:**

You are under no obligation to participate in this study. You are free to withdraw your consent to participate at any time. There will be no impact on your care in the provider's office should you choose not to participate or withdraw your consent to participate.

**SUMMARY OF RESULTS:**

A summary of the results of this research will be supplied to you, at no cost, upon request.

**VOLUNTARY CONSENT:**

I have read the above statements and understand what is being requested of me. I also understand that my participation is voluntary and that I am free to withdraw my consent at any time, for any reason, without any consequence or impact in my care. On these terms, I certify that I am willing to participate in this research project.

I understand that should I have any further questions about my participation in this study, I may contact Michele Prior, Primary Investigator at [REDACTED] or Courtney Proie, Co-Investigator, at [REDACTED], Allegheny Singer Research Institute [REDACTED] or asri@wpahs.org, Dr. Melanie Turk, Advisor, at 412-396-1817, or Dr. Linda Goodfellow, Chair of the Duquesne University Institutional Review Board 412-396-6548.

**What if I am injured while taking part in this study?**

If you are injured or made sick while taking part in this research study, emergency medical treatment will be provided at the usual charge. No funds have been set aside by Allegheny Health Network or Allegheny-Singer Research Institute to pay you in case you are injured. You do not waive any of your legal rights to compensation, if any, by signing this form.

**Authorization to Use and Disclose Individually Identifiable Health Information for a Research Study**

Before you can take part in this research study, the Allegheny Health Network is required to obtain your authorization to use and/or disclose (release) your health information. This section describes to you how, and to whom, your health information will be used and/or disclosed (shared) while you are participating in this research study. It is important that you read this

carefully. Allegheny Health Network and its' researchers are required by law to protect your health information.

**The following is a list of health information that will be used and/or disclosed:**

- *Medical records*
- *AIC lab results*
- *Questionnaire results*

**The following is a list of entities that may use and/or disclose your health information as part of this study:**

- Those who oversee the study will have access to your health information, including the following:
  - Allegheny Health Network (AHN)
  - Allegheny Singer Research Institute (ASRI)
  - AHN Compliance Office
  - The ASRI-WPAHS IRB
- Your health information may also be shared with government agencies that have oversight of the study or to whom access is required under the law:
  - Department of Health and Human Services
- The following persons and/or organizations outside of this institution may also use, disclose and receive you health information in connection with this study:
  - **Co-Investigator:** Courtney D. Proie, PhD-C, MSN, RN

In order to participate in this study, you must agree to share your health information with the persons and organizations listed above. If these persons or organizations that you authorize to receive and/or use protected health information, are not health plans, covered health care providers or health care clearinghouses subject to federal health information privacy laws, they may further disclose the protected health information and it may no longer be protected by the federal health information privacy laws.

**Expiration of Authorization**

This authorization will not expire unless you revoke it in writing. You may revoke or end this authorization by writing to the Principal Investigator:

Michele Prior, MSN, RN

C/O Allegheny General Hospital  
15<sup>th</sup> Floor South Tower  
320 East North Ave,  
Pittsburgh, Pa 15212

If you revoke your authorization, you will also be removed from the study. Revoking your authorization only affects the use and sharing of your health information after the written request is received. Any health information obtained prior to receiving the written request may be used to maintain the integrity of the study.

**Authorization**

By signing this document (authorization), you authorize that your health information can be used and/or disclosed as described.

If you choose to not sign this document, you will not be permitted to participate in this research study.

***Signature Block***

Your signature below indicates your permission to take part in this research and to the use and disclosure of your protected health information:

_____	_____
Signature of subject	Date/Time
_____	
Printed name of subject	
_____	_____
Investigator Signature	Date/Time
_____	
Printed name of Investigator	
_____	_____
Signature of witness to signature	Date/Time
_____	
Printed name of person witnessing signature	