The Effectiveness of an Ambulatory Care Health System Redesign on Patient Engagement, Healthcare Utilization, and Clinical Indicators

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LOYOLA UNIVERSITY CHICAGO

THE EFFECTIVENESS OF AN AMBULATORY CARE HEALTH SYSTEM REDESIGN ON PATIENT ENGAGEMENT, HEALTHCARE UTILIZATION AND CLINICAL INDICATORS

A DISSERTATION SUBMITTED TO THE FACULTY OF THE GRADUATE SCHOOL IN CANDIDACY FOR THE DEGREE OF DOCTOR OF PHILOSOPHY

PROGRAM IN NURSING

BY

NANCY J. MADSEN

CHICAGO, IL

MAY 2019
ACKNOWLEDGEMENTS

First, I will forever be indebted to the Marcella Niehoff School of Nursing (MNSON) Faculty and Loyola University Chicago for the many opportunities they provided me with as a graduate student, the most incredible being the opportunity to represent MNSON as the second Jonas Scholar. I am very grateful to the Jonas family and the Jonas Foundation for welcoming me into the Jonas family and generously supporting my work. I am especially thankful to Dr. Lisa Burkhart, my dissertation chair for her countless hours of support, her ability to cocoon me from policy changes and to ferret out opportunities for me, and her unwavering belief in me. Her guidance throughout my journey was unfathomable.

I would also like to thank my committee members, Dr. Frances Vlasses, Dr. Joanne Kouba and Dr. Cara Joyce for both their expert advice and encouragement. I will be forever grateful to Dr. Vlasses for graciously allowing me to extend her HRSA funded study to include my research. Dr. Kouba's knowledge of dietetics was invaluable and she could always be counted on for inspiration and kind words. Finally, I could not have begun to really understand the high level statistics needed without Dr. Cara Joyce who was always willing to make time for me, and answer a multitude of questions.

A special thanks to the I-Care-PATH team and family practice clinics who embraced my work. Thanks to Julia Havey, Susan Zelisko, Stephen Birch, Erich von Abele, Elizabeth Huggins and the Health Science Library staff for all their help throughout my study. I could not have
completed this research without all of their support. To my manager, coworkers and HIM director: I thank you for allowing me to complete this journey and supporting me throughout these 6 ½ years. To my friends and LUMC colleagues, especially Patricia Hise and Nanci Stark: thanks for your encouragement and friendship throughout this long, arduous process.

To my cohort, Dr. Mary-Beth Desmond, Dr. Jennifer Woo and soon to be Dr. Deborah Sindewald, and to my extended cohort especially Dr. Jacqueline Tulley, I cannot begin to thank you. As a group, we understood the importance of supporting each other so that we all could complete this journey together. The celebration of the milestones continues to be a source of incredible enjoyment and accomplishment.

To my entire extended family, who I know thought I was crazy to even begin this journey but who nonetheless were always supportive. First to my late grandparents, Christian and Johanna Johansen who believed in a college education for their daughters as well as their son, in a time and place when that was not only unheard of but also not appreciated, thanks for paving the way. To my late parents, Arild and Lu Johansen who taught me to be tough and never give up, thanks for giving me the strength and fortitude to complete this journey. Dr. Laurie Johansen, my sister-in-law, friend and MNRS roomie was a source of wisdom, commiseration and guidance. LuAnn Svendsen, my sister was able to remind me to "stop wallowing and get going" when I needed strength to keep going on the dissertation battle. Our children, Kristian and Kamilla provided computer expertise, support, brainstorming and laughter!

Finally, my husband, my partner, my soulmate, Jorn-Erik – where to even begin? We did it! No words can express my sincere appreciation for the countless sacrifices you made for me to actualize this journey. You have believed in me since the day we met. You have always been my foundation and source of security. I will always remember your loving support of this journey.
This is dedicated to my late parents, Arild and Lu Johansen, and our children, Kristian and Kamilla, all of whom unwittingly inspired me to embark on this journey. To my parents who not only always believed in me but also gave me both the skills to "pull myself up by my bootstraps" and the bootstraps to do it (as well as siblings to remind me). They also always encouraged me to stand up for what is right, and to make a difference in this world. Finally, to our children, Jorn-Erik's and my pride and joy, I hope and pray that we have in some way inspired you as our parents inspired us.
I cannot believe that the purpose of life is to be "happy."
I think the purpose of life is
- To be useful
- To be responsible
- To be compassionate.
It is, above all
- To matter
- To count
- To stand for something
- To have made some difference
- That you lived at all.

Leo Rosten
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ABSTRACT

Diabetes is a lifelong debilitating and deadly chronic disease affecting nearly one out of every eleven Americans. This public health problem costs $245 billion annually in the United States. Long term research trials have shown that diabetes complications can be prevented with good glycemic control, but it is difficult for patients to maintain control without much support from their healthcare team. U.S. healthcare remains fragmented. With the passage of the Affordable Care Act, there are opportunities to redesign health care delivery to minimize fragmentation and improve patient outcomes.

The aim of this study is to determine if a redesigned care delivery model of nurse-led interprofessional collaborative care-coordinated teams improved patient engagement, healthcare utilization and clinical indicators for adults with Type II diabetes. This was a retrospective, longitudinal, matched design using secondary data from one year prior to the intervention to one year post intervention. The study sample included two groups: 204 patients with Type 2 diabetes who were care coordinated in the redesigned primary care clinic and a matched sample of patients at the same health system receiving standard care. Dependent variables included patient engagement (missed visits, influenza immunizations, and annual eye examinations); healthcare utilization (number of hospitalizations, hospital days and emergency room visits); and clinical indicators (Hgb A1C, weight, systolic and diastolic blood pressure). Findings indicated a statistically significant improvement in Hgb A1C for both the pre/post data and the Intervention/Matched data, and a statistically significant improvement in weight
change and diastolic blood pressure at goal (<90) for the pre/post intervention group. However, eye examinations were significantly better in the matched comparison group. There was no difference in healthcare utilization for either the pre/post intervention group or the intervention group in comparison to the propensity matched group.
CHAPTER ONE

INTRODUCTION

Diabetes is a lifelong debilitating and deadly disease affecting nearly one out of every eleven Americans (Centers for Disease Control and Prevention [CDC], 2014a). It is a national public health problem costing the United Stated billions of dollars annually making it an expensive disease that essentially affects every American’s pocketbook, whether or not personally afflicted (Centers for Disease Control and Prevention [CDC], 2014c). Long-term diabetes research trials have demonstrated not only that maintaining good glycemic control can prevent diabetes complications but also that patients need a lot of support from their healthcare team to accomplish the necessary daily health behavior changes (Gerstein et al., 2008; The Diabetes Control and Complications Trial Research Group [DCCT], 1986). Changing health behavior is a very difficult endeavor.

The current healthcare system in the United States remains fragmented and, with the passage of new healthcare legislation, is in a state of flux. The goal is to change from a healthcare system focused on acute, episodic care to one focused on health prevention and promotion. Research is needed to guide this American healthcare system redesign. This study will determine whether one potential health system redesign—that of a nurse-led, interprofessional, collaborative, care-coordinated team approach in primary care—improves patient engagement, healthcare utilization, and clinical indicators for the Type II diabetic population.
Magnitude and Importance of the Problem

Uncontrolled diabetes leads to death. In 2010, diabetes was listed as the seventh leading cause of death in the United States (Centers for Disease Control and Prevention [CDC], 2014c). The Centers for Disease Control (2014) further suggest that diabetes as a cause of death is likely underreported since the data indicates that only about 35-40% of death certificates of the diabetic population list diabetes as a diagnosis of the deceased. In the Swedish population, research demonstrated that the risk of mortality in Type 2 diabetes substantially increases with poor glycemic control, renal complications or impaired renal function, and younger age of diabetes onset (Tancredi et al., 2015). According to Healthy People 2020, diabetes lowers life expectancy by as much as fifteen years (Office of Disease Prevention and Health Promotion, 2016).

Consequently, diabetes is a very serious, deadly disease.

Diabetes is prevalent in the United States. The CDC estimates that approximately 29.1 million Americans or 9.3% of the U.S. population have diabetes (Centers for Disease Control and Prevention [CDC], 2014c). Of these numbers, only 21 million Americans have been diagnosed with diabetes, with about 8.1 million Americans unaware that they have diabetes. Approximately 1.7 million people are diagnosed with diabetes in the United States each year (Centers for Disease Control and Prevention [CDC], 2014c) and one of every three adults is projected to develop diabetes by 2050 (Boyle, Thompson, Gregg, Barker, & Williamson, 2010). In Illinois, the prevalence of diagnosed diabetes has been increasing from 5.4% in 1995 to 9.4% in 2014 (Centers for Disease Control and Prevention [CDC], 2015b). Diabetes continues to be a major public health problem in the United States.

Type 2 diabetes is the most prevalent type of diabetes in the adult population accounting
for 90-95% of all diagnosed cases (Centers for Disease Control and Prevention [CDC], 2014c). Although Type 2 diabetes affects all ages from the very young to the very old, it is most prevalent in the adult population with one in four older adults (65 or older) currently diagnosed with diabetes (Kirkman et al., 2012). Today, in the 65 years or older adult population, 25.9% or 11.2 million older adults are living with diabetes (Centers for Disease Control and Prevention [CDC], 2014c). These people are often living with not just one chronic illness but several (Parekh, Goodman, Gordon, Koh, & HHS Interagency Workgroup on Multiple Chronic Conditions, 2011; Partnership for Solutions, 2004), creating an even larger health burden for our nation.

Diabetes is a serious chronic disease that affects people for a long time. According to the CDC, approximately 60% of diabetics have been diagnosed for ten years or less, with about 40% diagnosed for more than 10 years, and of those, 4.7% have been diagnosed for more than 35 years (Centers for Disease Control and Prevention [CDC], 2014b). Although Type 2 diabetes is a more predominate affliction as people age, just over 5,000 children less than 20 years of age were diagnosed with Type 2 diabetes in 2008 and 2009, demonstrating that Type 2 diabetes is occurring at earlier ages than ever before and will continue to be a healthcare problem for many years to come (Centers for Disease Control and Prevention [CDC], 2014c). Furthermore, Type 2 diabetes tends to be insidious and is often first detected when a complication of the disease reveals a diagnosis of diabetes (Khardori & Griffing, 2016; Spears, Schub, & Pravikoff, 2015). In fact, at the time of diagnosis of Type 2 diabetes, the patient has likely had undiagnosed diabetes for 4-7 years (Khardori & Griffing, 2016). As more American children are diagnosed with Type 2 diabetes, both the prevalence and the number of years patients live with this serious, debilitating disease is likely to increase.
Many complications are associated with diabetes. Despite large national studies demonstrating the decrease of diabetes sequelae with good blood sugar control, there remains a high prevalence of diabetes complications (Centers for Disease Control and Prevention [CDC], 2014c; Centers for Disease Control and Prevention [CDC], 2015b; Skyler et al., 2009; The Diabetes Control and Complications Trial Research Group [DCCT], 1993; UK Prospective Diabetes Study Group, 1998). Diabetes is linked to both micro- and macro-vascular complications including heart disease, stroke, neuropathy, nephropathy and retinopathy (Centers for Disease Control and Prevention [CDC], 2014c). Diabetes is the leading cause of renal failure, adult-onset blindness and lower limb amputations (Institutes of Health [NIH], 2017). In 2011, diabetes accounted for 44% of all diagnosed renal failure cases as well as 60% of non-traumatic lower-limb amputations in adults (Centers for Disease Control and Prevention [CDC], 2014c). Between 2009 and 2012, 71% of adults (18 or older) with diabetes had a blood pressure greater than or equal to 140/90 mm Hg or were on antihypertensive medications and 65% had an LDL cholesterol level greater than or equal to 100 mg/dl (Centers for Disease Control and Prevention [CDC], 2014c), increasing the risk of heart disease and stroke (American Diabetes Association [ADA], 2017). In 2010, the incidence of hospitalization for strokes was 1.5 times higher and for heart attacks was 1.8 times higher for the adult diabetic population than those who were not afflicted with diabetes (Centers for Disease Control and Prevention [CDC], 2014c). With patients living with diabetes longer, the complications of diabetes are also likely to increase.

Diabetes is a disease that places a major financial burden on our healthcare system. The CDC estimated that in 2012, diabetes costs the United States 245 billion dollars (Centers for Disease Control and Prevention [CDC], 2014c). The cost of healthcare for a person with diabetes in 2012 was 2.3 times that of a person without diabetes (Centers for Disease Control and
Diabetes and hypertension were responsible for much of the growth in Medicare spending from 1987–2006 (Thorpe, Ogden, & Galactionova, 2010). Diabetes in and of itself is very expensive, but when the cost of the many complications attributed to diabetes are included, it becomes even more taxing to the American healthcare system. In fact, estimates of the costs of complications are as much as 250% higher than the cost of diabetes without complications (Liebl, Khunti, Orozco-Beltran, & Yale, 2015).

Approximately 6% of the Medicare budget ($29 billion), was spent on chronic kidney disease alone in 2012 (Centers for Disease Control and Prevention [CDC], 2015a), and it has been estimated that in the last decade, diabetes accounts for about 8% of the increase in Medicare costs (Thorpe, 2012). An estimated 72% of kidney failure patients (approximately three out of four cases) developed kidney failure due to diabetes and hypertension (Centers for Disease Control and Prevention [CDC], 2015a). It is estimated that 40-60% of the cost of diabetes care has been for inpatient care for the complications of diabetes (Liebl et al., 2015). Consequently, preventing diabetic complications has the potential to significantly reduce the cost of healthcare in the United States.

**Preventing Complications**

The complications from diabetes are preventable. It is well recognized that the sequelae of diabetes occur and progress most often in patients who are not able to maintain good glycemic control (Skyler et al., 2009; The Diabetes Control and Complications Trial Research Group [DCCT], 1993; UK Prospective Diabetes Study Group, 1998). The current evidence-based recommendation for optimal diabetes type II management is to maintain A1C levels of < 7.0% (American Diabetes Association [ADA], 2016; American Diabetes Association [ADA], 2017). This level has been demonstrated to reduce microvascular complications (kidney disease,
retinopathy and peripheral vascular disease) while decreasing macrovascular disease in newly diagnosed patients with no previous heart disease (American Diabetes Association [ADA], 2016; American Diabetes Association [ADA], 2017). Improvements in glycemic control have demonstrated effectiveness in delaying the complications of diabetes.

Current national recommendations to delay the complications of Type 2 diabetes involve improved glycemic control. The National Institute of Health (NIH) recommends improving blood sugar, blood pressure and cholesterol as the most important methods of decreasing the complications of diabetes (National Institute of Diabetes and Digestive and Kidney Diseases [NIDDK], 2016). Healthy People 2020 sets target goals for population health for diabetes in the United States (Office of Disease Prevention and Health Promotion, 2016). For example, the goal of improving glycemic control is to decrease the number of diabetics with A1C of > 9% from 17.9% to 16.1% and to increase the proportion of diabetics with A1Cs < 7% from 53.5% to 58.9%. Generally, goals for the next decade are set at 10% improvement of actual health indicators for diabetes. While these goals are not necessarily lofty, they do provide information on overall goals for improving diabetes management in the United States. These goals are set not only to improve the quality of life for people afflicted with diabetes but also to reduce both the economic burden and the incidence of diabetes sequelae. Healthy People 2020 lends further credence to the need for improving glycemic control, lipid levels and blood pressure; increasing the numbers who receive both annual foot and eye exams; and providing diabetes education (Office of Disease Prevention and Promotion [ODPHP], 2019).

Diabetic patients must change their health behaviors to prevent complications. They must assume responsibility for managing health behaviors including diet, exercise, smoking; monitoring their diabetes status through blood testing, foot care and medication use; as well as
optimally navigating the healthcare system by setting and keeping appointments as needed (Lorincz et al., 2011). Health behaviors are not easy to change. However, for diabetic patients, it has been recognized that even small changes in health behavior effectively improve health outcomes (Golay et al., 2013). Golay et al. further indicated that patient engagement in their own health can be challenging but is necessary to effectively achieve even the smallest changes in health behaviors. In the ambulatory setting, patients spend the majority of their time outside of the clinic setting and, therefore, must be prepared to manage their own health.

Health behavior change begins with diabetes education. Diabetes self-management education incorporates health behavior changes including exercise, healthy eating, managing emotions, managing medications, communicating with the healthcare team, using community resources, problem solving, and decision making. Diabetes self-management education, by empowering diabetic patients to make health behavior decisions, not only lowers A1C levels in patients with A1Cs greater than 7% but also improves health outcomes for diabetic patients regardless of A1C levels (Lorig, Ritter, Ory, & Whitelaw, 2013). A meta-analysis of diabetes self-management education and support programs in older adults found a small but significant reduction in both A1C and total cholesterol levels with an insignificant reduction in both systolic and diastolic blood pressure (Sherifali, Bai, Kenny, Warren, & Ali, 2015). In their joint position statement, the American Diabetes Association, the American Association of Diabetes Educators, and the Academy of Nutrition and Dietetics state that there are numerous tasks and decisions about health that diabetic patients must manage to achieve optimal health outcomes (Powers et al., 2015). They further state that diabetes self-management education and support are essential ingredients for people with diabetes to effectively manage their own health and modify their own health behaviors (Powers et al., 2015).
Healthcare System Infrastructure Limitations

The US healthcare system was not designed to prevent health problems. Healthcare in the US has focused on acute care (Haas, Swan, & Haynes, 2013; Institute for Healthcare Improvement [IHI], 2016; Loehrer, McCarthy, Coleman, & Cross-Continuum Study Panel, 2015; McCarthy & Klein, 2010). However, the number of days a patient is hospitalized for acute conditions has been decreasing (Thomas et al., 2015). This trend has led to patients, especially those with chronic conditions like diabetes, frequently discharged with continued healthcare needs, which are left for the patient and primary care physician to manage (Thomas et al., 2015). Patients with chronic diseases require more health care to successfully manage these diseases, and, if not well-managed, these patients will require more acute care. This creates a cyclical hospital-home utilization pattern.

The current healthcare system is not providing safe healthcare. In 1999, the Institute of Medicine (IOM) published their first report on the quality of healthcare in the United States in which they estimated that between 44,000 to 98,000 people die every year due to medical errors in U.S. hospitals. They further surmised that these findings were not due to individual healthcare providers but rather should be extrapolated to the U.S. healthcare system (Institute of Medicine, 1999). They pointed out that these problems with our healthcare system are due to many factors including the increased complexity of the system, increased specialization in healthcare fields leading to increased fragmentation of care, the silence surrounding errors, as well as the acute-care-focused, fee-for-service payment structure of healthcare (Institute of Medicine, 1999). The report suggested that multiple patients with multiple problems see multiple providers in multiple locations, which increases the potential for mixed messages, duplication of care, increased costs, and increased confusion for the patient, which then leads to errors (Institute of Medicine, 1999).
This report put an end to the silence surrounding healthcare errors (Institute of Medicine, 1999). It maintained that patient errors were not the product of the individual healthcare provider but of the healthcare delivery system and, therefore, every healthcare organization should have a patient safety committee focused on identifying problems and improving their systems of care (Institute of Medicine, 1999). To ensure patient safety, the IOM made the following two recommendations: 1) to provide monitoring of reportable error events and 2) to analyze and identify solutions to these errors by developing the Center for Patient Safety within the Agency for Healthcare Research and Quality (AHRQ) (Institute of Medicine, 1999). This began the American search for a safer healthcare system.

The current healthcare system is not providing quality healthcare. In their second report, Crossing the Quality Chasm, the IOM (2001) focused on the quality of the system of healthcare rather than individual patient safety. Thoroughly analyzing all the literature of the time, they concluded that the U.S. healthcare system continued to be flawed and needed redesign to improve the quality of healthcare in the US (Institute of Medicine, 2001). They found the need to focus on redesigning care for the chronically ill patient to ensure seamless care across both settings and clinicians, as well as focusing on team effectiveness and collaboration rather than encouraging healthcare members to work in silos (Institute of Medicine, 2001). Interprofessional collaborative care is defined as two or more healthcare workers from different professions working together with patients and families to ensure the delivery of the highest quality care (World Health Organization, 2010). To achieve this, they further recommended a focus on information technology to communicate within and between healthcare systems effectively as well as to focus on outcomes and improving performance through evidence and best practice (Institute of Medicine, 2001).
Despite significant efforts to improve safety after the IOM report, the National Patient Safety Foundation (NPSF) reported in 2015 that patient safety continues to be a significant problem in the US. The NPSF suggested that improving healthcare would require a shift from reactive healthcare to a systems approach, which includes partnering with patients and all members of the healthcare team to increase safety across the continuum of care (National Patient Safety Foundation, 2015). Furthermore, they recommended that interventions focus not only on the safety culture of the health system but also on teamwork and patient engagement (National Patient Safety Foundation, 2015).

Healthcare in the US still continues to be fragmented (Haas et al., 2013; Institute of Medicine, 2001). In fact, the focus of the triple aim has been on coordinating care through primary care redesign and population health management in the lived environment rather than acute care (Institute for Healthcare Improvement [IHI], 2016). Most recently, the National Safety Patient Foundation Lucian Leape Institute recommended five areas of focus necessary to improve patient safety. Improved care integration and patient/consumer engagement continue to be prominent focal points for improved patient safety (National Patient Safety Foundation Lucian Leape Institute, 2016). This report delineated the many barriers to integrating care (National Patient Safety Foundation Lucian Leape Institute, 2016). First, increased specialization of health care professionals with a subsequent decrease in the number of family practitioners and generalists has led to increased fragmentation and decreased integration (National Patient Safety Foundation Lucian Leape Institute, 2016). A second barrier is the public’s belief that our current health care model is the best in the world, which leads to a reluctance to embrace changing the healthcare system (National Patient Safety Foundation Lucian Leape Institute, 2016). Finally, even the U.S. method of healthcare reimbursement, which focuses on fee-for-service (FFS)
rather than value, is a barrier to integrating care (Lucian Leape Institute Round Table, 2012; National Patient Safety Foundation Lucian Leape Institute, 2016). It has been recognized that FFS programs reward more care from more providers rather than coordinated care. This, along with the growing belief in specialization, has contributed to the fragmentation of care and has left patients unsure how to manage their conditions (Calsyn & Lee, 2012; Chernys, 2013).

The increased number of specialty areas in medicine has created more fragmented health care in which no single provider has assumed the responsibility of coordinating the care of the whole patient (Schoen et al., 2011). To be effective, healthcare must involve relationships between the consumer, the provider and the community (Stange, 2009). Without someone managing the whole patient, care can cause harm and cost significantly more (Calsyn & Lee, 2012; Chernys, 2013; Stange, 2009).

It has become clear that currently patient care is disorganized and that patients do need assistance to “navigate” the “complex maze of providers and health systems” (Eidus, Pace, & Staton, 2012). For example, diabetic patients often see multiple providers for just diabetes-related conditions, which can include their primary care provider, other ancillary health care professionals (e.g., social worker, nurse, dietitian, and physical therapist), and specialty care providers (e.g., nephrologist, cardiologist, psychologist, and podiatrist). Considering the likelihood of multiple chronic conditions, the list of potential providers grows. Without proper communication between providers, the plan of care from one provider can negate the plan of care from another provider, which becomes very confusing for the patient. The IOM report, Crossing the Quality Chasm (2001), demonstrated a model of care in which health professionals were providing excellent care focused on their specialty area in isolation from the rest of the care team with no one taking responsibility for managing the health needs of the whole patient. This lack of
coordination created frustration for the provider and mixed messages for the patient, who was often given conflicting advice from his many care providers. Furthermore, with the countless number of providers diabetic patients see, there is often difficulty keeping multiple appointments in multiple locations.

Assisting patients to effectively navigate the current healthcare system is difficult, even for healthcare providers. The Commonwealth Fund publishes a report called *Mirror, Mirror* that compares the quality of healthcare in industrialized nations (Davis, Stremikis, Squires, & Schoen, 2014). In their 2014 update, all primary care doctors in the 10 nations surveyed, including the US, indicated that they struggled to coordinate care for their patients and to effectively communicate with all other care providers (Davis et al., 2014). In addition, the *Mirror, Mirror* report indicates that unsafe and poorly coordinated care is responsible for decreasing the quality of care in the US (Davis et al., 2014). Progress in care coordination and care processes continues to be slow. In *Mirror, Mirror*’s 2017 update, despite continuing to spend more than any of the other 10 high-income countries, the US made no progress in their ranking on coordinated care or overall care which includes 4 subdomains: coordination, safety, prevention and engagement. In fact, the US continues to rank 5th out of 11 in overall care processes and 6th in the subdomain of coordinated care (Schneider, Sarnak, Squires, Shah, & Doty, 2017). Finding a new model of care that can assist diabetic patients to meet their health goals and effectively navigate the healthcare system remains an essential ingredient to improve health outcomes for the Type 2 diabetic population in the U.S. (Schneider et al., 2017).

**Health Care Redesign Solutions**

Care coordination was seen as an essential ingredient to improve population health. The Agency for Healthcare Research and Quality (Agency for Healthcare Research and Quality,
2014) through a systematic review of over 40 definitions of “care coordination” integrated these definitions to the following:

Care coordination is the deliberate organization of patient care activities between two or more participants (including the patient) involved in a patient’s care to facilitate the appropriate delivery of health care services. Organizing care involves the marshalling of personnel and other resources needed to carry out all required patient care activities and is often managed by the exchange of information among participants responsible for different aspects of care.

Transitional Care Coordination Models emerged as a solution to the short-term hospital readmission dilemma. In the 1990s, due to the high rate and cost of 30-day hospital readmissions, the United States began to focus on care transitions with care coordination emerging as a solution to prevent hospital readmissions. Since the 1990s, the evidence supporting transitional care coordination models has grown significantly. The evidence indicated that care transitions could be better managed with care that is well-coordinated, particularly for the increasing number of U.S. citizens with chronic illnesses (Institute of Medicine, 2001).

Likely from the success of these transitional care coordination programs and the IOM reports, U.S. health policy began to focus on care coordination as a method to improve population health. The policy goal was to prevent hospital admissions to decrease the skyrocketing cost of healthcare for Medicare patients. With the recognition of health care fragmentation, policy makers began to understand the need for care coordination for all patients whether transitioning from one level of care to another. Consequently, the IOM emphasis on the need for increased quality through care that is coordinated became a focus for the redesign of US healthcare systems (Institute of Medicine, 2001).
Patient Protection and Affordable Care Act

Despite legislative weakening of the Patient Protection and Affordable Care Act (ACA), it remains the US health care financing legislation (Congress.gov, 2010). The ACA focused on the need for increased health promotion efforts to provide higher quality of health care at lower costs (Henry J. Kaiser Family Foundation, 2013; Kaiser Family Foundation, 2011; Congress.gov, 2010). To meet this goal, the ACA provided funds for transitional care coordination for high-risk Medicare participants and emphasized the need for interprofessional collaborative and coordinated care to increase health outcomes and decrease hospitalizations (Henry J. Kaiser Family Foundation, 2013; Kaiser Family Foundation, 2011; Congress.gov, 2010).

In addition, the ACA encouraged interprofessional care coordination through such programs as CMS demonstration projects, which received $10 billion dollars in funding for improving quality and reducing costs for chronically ill patients enrolled in both Medicare and Medicaid (Henry J. Kaiser Family Foundation, 2013; Congress.gov, 2010). The ACA supported payment reform measures including Accountable Care Organizations, bundled payments and penalties for hospital readmissions (Henry J. Kaiser Family Foundation, 2013; Congress.gov, 2010). These reforms were meant to increase quality and promote coordinating care efforts and collaboration among all health professionals. The US government and the Commonwealth Foundation weighed the evidence for care coordination. Both demonstrate their beliefs through healthcare policy and reports that interprofessional care coordination will improve quality of care and should be promoted as an important element in health care redesign processes.

With new financing incentives, there is an opportunity to develop multidisciplinary models of care that are care-coordinated and fully collaborative. However, research is needed to guide the development and evaluation of these new models of care.
New healthcare models are emerging. Research has demonstrated that transitional care coordination models in the acute care setting do improve the quality of care through a decreased need for emergency room visits and hospital readmissions in the 30 days post-hospitalization (Naylor et al., 1994; Naylor et al., 1999; Naylor et al., 2004; Naylor, Aiken, Kurtzman, Olds, & Hirschman, 2011a; Naylor et al., 2011b; Robinson, 2010). Transitional care coordination involves engaging the patient and/or caregiver in planning and assisting in achieving health care goals through a 30-day post-acute care continued relationship with the healthcare team. By decreasing emergency room visits and hospital readmissions, these transitional care models have also been cost-effective (Naylor et al., 1994; Naylor et al., 1999; Naylor et al., 2004; Naylor et al., 2011a; Naylor et al., 2011b; Robinson, 2010). The motivation for transitional care models was the need to decrease healthcare utilization and spending rather than targeting long-term healthcare goals or health behavior change. The focus of these care-coordinated models has been to provide short-term support for patients during the first month post-discharge because it has been demonstrated that many patients seem to struggle with both understanding and following their discharge plan of care, leading to readmissions (Coleman, 2003). Research has supported the effectiveness of transitional care to prevent 30-day readmissions, but less is known about long-term benefits of the transitional care models or the effects of fully integrated multidisciplinary care coordination on health behavior, and health outcomes (Coleman, 2003). However, the financial success of transitional care coordination models demonstrated that patients need assistance in understanding and following their discharge plan of care to meet even short-term (30-day) post-acute care health goals (Coleman, 2003).
New Legislative Opportunities

Acknowledging the acute care focus and high degree of fragmentation of our current healthcare system, the ACA highlights a redesigned healthcare system that focuses on population health emphasizing prevention rather than illness. The ACA was designed to radically alter the way healthcare is delivered in the US by placing the focus for care improvement on the primary care team through the use of Patient-Centered Medical Homes (PCMH) and Accountable Care Organizations (ACO) (Haas et al., 2013). One critical element of the PCMH and ACO is the emphasis on care coordination to improve population health (Burton, 2012). The goal is to work with the individual to help him/her achieve his/her healthcare goals while learning what will work for the population (Institute for Healthcare Improvement [IHI], 2016).

According to the Agency for Healthcare Research and Quality [AHRQ], the PCMH with care coordination and collaboration at the helm is designed to improve “patient outcomes; patient safety; patient experience; and possibly lower costs through reduced duplication of services, increased delivery of preventive services and more evidence-based patient care…” (E. Taylor, Lake, Nysenbaum, Peterson, & Meyers, 2011). Along with the IHI, the Commonwealth Fund, the National Committee for Quality Assurance (NCQA), the National Patient Safety Foundation (NPSF)—and government departments like the U.S. Department of Health and Human Services (HHS), and AHRQ—recognize the need for radical change with an emphasis on learning what successfully improves the health of the population while rejecting those efforts that do not demonstrate improvements in population health. Research is needed to guide this health system redesign.

However, despite the passage of the ACA, the US continues to experience low scores in all five areas of the 2014 and 2017 Mirror, Mirror reports (i.e., quality/care process, access,
efficiency, equity, and healthy lives/health care outcomes) compared to the other ten countries (Davis et al., 2014; Schneider et al., 2017). This demonstrates that radical change in any system does not come quickly or easily and the U.S. healthcare system remains in last place when it comes to healthcare performance and first place in cost. The NPSF in their report, Free from Harm (2015) recommended coordinating care, increased collaboration, and partnering with patients and families as key ingredients to improve patient safety. Their report further states that to ensure safety, our healthcare system must include all areas of care including ambulatory care where the majority of patient care occurs, and it must focus on communication, teamwork, and patient engagement. Based on the success of transitional care models in the acute care setting, healthcare models are being developed for the ambulatory setting. However, to effectively improve the healthcare system in the United States and the health of the U.S. population, much more research needs to be done to identify the best ambulatory programs to provide the best care to patients with chronic health needs.

One suggested healthcare redesign model focuses on nurse-led interprofessional collaborative care-coordination teams in primary care. Interprofessional collaborative teams involve members from different healthcare professions partnering with each other and the patient to share responsibility for the patient’s health outcomes while providing support to patients in their efforts to meet their health goals. The Interprofessional Collaborative Care Coordination Model of care [ICCCM] is a nurse-led team-partnered approach in the ambulatory care setting including the patient as the primary team member. These healthcare teams share responsibility with the patient and help the patient identify healthcare needs and goals through education and active patient engagement. Team members include the patient’s caregiver/support system, the nurse, physician, social worker, and dietitian as indicated by the patient’s identified goals and
healthcare needs. To increase patient engagement, patient convenience and collaboration with and among team members, all team members are available to the patient in the same location.

Care-coordination assists patients both in navigating the many facets of the healthcare system and improving their health self-management skills. This system combines ten essential elements including engaged leadership, data-driven improvement, empanelment, team-based care, patient-team partnership, population management, continuity of care, prompt access to care, comprehensiveness and care-coordination to build a model for increased patient engagement, revamped patterns of healthcare utilization and improved patient outcomes (Bodenheimer, Ghorob, Willard-Grace, & Grumbach, 2014).

Research Hypotheses

Diabetes is a deadly and costly chronic disease. The US continues to be poorly designed to address chronic conditions. Despite emerging models of care, none has emerged as the gold standard. Care-coordination and interprofessional teams have been identified as potentially improving patient engagement, healthcare utilization and clinical indicators, but it is unclear whether these care delivery elements truly improve healthcare. Therefore, this research study determined the effectiveness of this nurse-led Interprofessional Collaborative Care Coordination Model of care [ICCCM] in the Type 2 diabetes population in terms of patient engagement, healthcare utilization and health outcomes over time and in comparison to a matched sample. This study addressed the following questions:

- H1a: Adult patients with Type 2 diabetes had better patient engagement (number of missed visits (no show encounters/same day cancellations), annual influenza immunizations, and annual eye examinations) after one year's participation in the ICCCM model in comparison to one year prior to participation in the ICCCM model.
• **H1b:** Adult patients with Type 2 diabetes, who received care at the ICCCM (intervention) site, had better patient engagement (number of missed visits (no show encounters/same day cancellations), annual influenza immunizations, and annual eye examinations) after one year than a sample of matched patients with Type 2 diabetes who received standard primary care within the same health system over that same year.

• **H2a:** Adult patients with Type 2 diabetes had better health care utilization (fewer hospitalizations, fewer hospital days, and fewer emergency room visits) after one year's participation in the ICCCM model in comparison to one year prior to participation in the ICCCM model.

• **H2b:** Adult patients with Type 2 diabetes who received care at the ICCCM (intervention) site had better health care utilization (fewer hospitalizations, fewer hospital days, and fewer emergency room visits) after one year than a sample of matched patients with Type 2 diabetes who received standard primary care within the same health system over that same year.

• **H3a:** Adult patients with Type 2 diabetes had better clinical indicators (percent of patients with Hgb A1C levels > 9.0; change and difference in Hgb A1C, weight, and systolic and diastolic blood pressure, systolic blood pressure < 140, diastolic blood pressure < 90) after one year's participation in the ICCCM model in comparison to one year prior to participation in the ICCCM model.

• **H3b:** Adult patients with Type 2 diabetes who received care at the ICCCM (intervention) site will have better clinical indicators (percent of patients with Hgb A1C levels > 9.0; change in Hgb A1C, weight, and systolic and diastolic blood pressure, systolic blood pressure < 140, diastolic blood pressure < 90) for one year than a sample of matched
patients with Type 2 diabetes who received standard primary care within the same health system over that same year.
CHAPTER TWO

LITERATURE REVIEW

The focus of this research will be to determine whether care-coordination in interprofessional teams improves patient engagement, health care utilization, and clinical health indicators for patients with Type 2 diabetes. Care-coordination as a delivery system redesign first emerged in 1985 and since then, care-coordination has been incorporated into a variety of care models with varying degrees of team collaboration. To understand care-coordination in the U.S. health care system, this literature review takes a historical approach describing both the models and research conducted on those models.

Care-coordination includes collaborating interprofessionally to meet the total health care needs of patients across the lifespan. However, details of interprofessional collaboration have not been included in most care-coordination model descriptions, making it difficult to determine whether interprofessional collaboration was included in the models. Therefore, the final section of this literature review will focus on what is known about interprofessional collaborative care in the primary care setting.

**Literature Review Search Strategy**

First, a literature review was conducted to identify what is known about care-coordinated teams as a method of healthcare system redesign and the effect of this redesign on patient engagement, health care utilization, and clinical outcomes. This search was followed by a search of interprofessional collaborative care models for patients with chronic conditions in the primary
care setting. A total of 238 articles were included in the literature search, as described in Table 1. The literature search included three core strategies:

1. a focused literature review of Pubmed, Cumulative Index of Nursing and Allied Health Literature (CINAHL), PsychInfo, the Cochrane library, and Joanna Briggs Institute;
2. mining selected articles for applicable references as well as mining Scopus for articles that cited identified seminal articles; and
3. a Google search of websites (government, public and private) on the Patient Centered Medical Home, care-coordination and collaboration.

Websites reviewed for additional information and articles include the Agency for Healthcare Research and Quality (AHRQ), the Patient-Centered Primary Care Collaborative, National Committee for Quality Assurance (NCQA), American College of Physicians, Care Coordination (Group Health Research Institute), FamiliesUSA, Institute for Healthcare Improvement (IHI), Congressional Budget Office (CBO), National Center for Interprofessional Practice and Education (NEXUS), and the National Quality Forum (NQF).

All articles in each search were reviewed for relevance by first evaluating the title. If the title was relevant, the abstract was reviewed and if relevant, the article was reviewed. Care-coordination articles were rejected if they (a) pertained to populations outside the US; (b) pertained to children with diabetes transitioning to adult care; (c) did not mention any nursing involvement as part of the care-coordination intervention; (d) focused on electronic monitoring devices or internet-based interventions; (e) focused on a highly specific patient population in which disease management was unrelated to diabetes management (e.g., HIV disease; obstetrics,
pediatrics, cancer, or mental health); (f) focused on acute care, rehabilitation, skilled nursing care or rural health only; and (g) focused only on patient perception/satisfaction or provider perception/satisfaction. However, due to the limited number of articles obtained when searching for articles specific to collaborative care combined with both primary care and chronic illness, articles that included populations with both diabetes and depression as well as articles outside the U.S. were reviewed. The citations of all relevant articles were then searched to elicit any missed applicable articles. Finally, to ensure that nothing was missed, sentinel articles were mined in Scopus to identify additional articles.

<table>
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<tr>
<th>Table 1. Literature Search</th>
<th>Database</th>
<th>Key Words</th>
<th>Search limitations</th>
<th>Number Articles found</th>
<th>Articles chosen to read</th>
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<td></td>
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<td></td>
<td>Collaborative Care</td>
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</table>
A search of the Nexus website database revealed 788 articles of which the vast majority were editorials, individual site models, theories, and standards of collaborative care with most research limited to instruments to measure collaboration or qualitative studies of provider and/or patient satisfaction. Only three quantitative studies of collaborative care interventions were found, and all three evaluated the effectiveness of interventions to improve collaboration from the healthcare team perspective. No studies that evaluated the effect of collaborative care on patient outcomes were found in the Nexus. However, a few quantitative studies were found through detailed Pubmed, CINAHL, and PsychInfo searches with the TEAMcare model, providing the most quantitative research results on patient outcomes from a collaborative care model in the US (Katon et al., 2010). However, articles were identified that described

<table>
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<th>Database</th>
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<th>Articles chosen to read</th>
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<td>Collaborative Practice OR Teamwork</td>
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<td>788</td>
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</table>


collaborative team models in primary care without providing any research evidence as to the
efficacy of these models (Kruger et al., 2012; Pilon, Ketel, & Davidson, 2015; Tapp et al., 2012;
Tracy, Bell, Nickell, Charles, & Upshur, 2013).

Theory and Substructure

The study of the effectiveness of a delivery system redesign is complex. Therefore,
Wagner’s The Care Model provided the theoretical framework to design, describe, and measure
the effectiveness of care coordination in this study. The following section will present both the
concepts of the model and apply each of these concepts to the study environment and health care
redesign.

Wagner’s The Care Model

The theoretical model used to guide this study is based on The Care Model (see Figure 1)
(MacColl Center, 2002). The Care Model is a model of care that includes four major hierarchical
constructs: Community/Health Systems, Services, Productive Interactions and Improved
Outcomes. The Community/Health Systems together form the overarching environment from
which needed Services are identified and provided to the patient and his/her support system. The
Services provided lead to Productive Interactions that the informed, empowered patient and
family have with the prepared and proactive health care team. These Productive Interactions lead
to Improved Outcomes for the patient.
The Care Model

Improved Outcomes

**Community/Health systems.** The green oval of the Care Model establishes that there are two areas in which health care is met, the Health Systems, where patients and families interact with the healthcare team, and the Community where the patient and family reside and often obtain further health resources, services and support (See Figure 1 Wagner Care Model) (MacColl Center, 2016b; MacColl Center, 2016e).

These two co-dependent systems, the Health System and the Community together form the environment that supports the chronically ill patient and his/her support system. Through
partnerships, the Health System and the Community interact to provide the services required for the patient and his/her support system to maintain and promote health. By mobilizing and maximizing the services of both the Community and the Health System, the gaps that exist between health care encounters can be minimized (MacColl Center, 2016c).

**Health system.** The Health System is the provider of health care services to the patient and family. Through an active partnership with the Community, the Health System can ensure that all appropriate, available resources to enhance the health and support the chronically ill patient and his/her support system are provided. The Organization of Health Care within the Health System is designed to provide a culture of excellence within the organizational system to ensure effective, safe and high quality care (MacColl Center, 2016e). Finally, the Community and the Health System together advocate for improved local, state, and federal health policies to positively impact patient outcomes. Thus, the Community and Health System are synergistic open systems within the environment.

**The ICCCM**

The Care Model provides a conceptual framework for a delivery system redesign and the outcomes in this study. Table 2 demonstrates how The Care Model guides the system redesign (see Table 2). It compares the theoretical definition from the model to the application of that concept in this study. The Community/Health System and Services constructs were used in the interprofessional team care-coordination redesign. The redesign affected the Productive Interactions and the effect of the redesign was measured by the Outcomes. Each concept will be defined theoretically and then applied to the study site.
Table 2. Wagner’s The Care Model: Concepts and Adaptation

<table>
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<tr>
<th>The Care Model Concepts</th>
<th>ICCCM Adaptation of The Care Model Concepts</th>
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<tbody>
<tr>
<td>Health System</td>
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</tr>
<tr>
<td>Community</td>
<td>Surrounding collar community of a large Midwestern city</td>
</tr>
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<td>Self-Management Support</td>
<td>Achieved through interprofessional collaboration with patients to identify needs, goals and action plan; problem-solve; and provide resources to help patients achieve their self-management goals</td>
</tr>
<tr>
<td>Delivery System Design</td>
<td>Interprofessional collaborative care-coordination</td>
</tr>
<tr>
<td>Decision Support</td>
<td>Phytel reports used to conduct population level analysis to identify target population and care needs</td>
</tr>
<tr>
<td>Clinical Information Systems</td>
<td>Epic &amp; Phytel</td>
</tr>
</tbody>
</table>

### Services

<table>
<thead>
<tr>
<th>Patient-Centered</th>
<th>Patient/family set goals and assist in developing individualized care plan, care is holistic, individualized, respectful and empowering</th>
</tr>
</thead>
<tbody>
<tr>
<td>Timely and Efficient</td>
<td>Access to care coordinator with touchback phone conversations and portal availability for questions</td>
</tr>
<tr>
<td>Evidence-Based and Safe</td>
<td>The clinic uses best evidence to ensure optimal, safe care</td>
</tr>
<tr>
<td>Coordinated</td>
<td>Nurse Care Coordinators coordinates care with the entire team and network with specialists and hospital/ED staff as appropriate</td>
</tr>
<tr>
<td>Informed, Empowered Patient and Family</td>
<td>Communication with appropriate team members through telephone encounters, face-to-face meetings, group visits, group workshops, support groups to obtain the knowledge and confidence to be informed and empowered.</td>
</tr>
</tbody>
</table>

### Outcomes

<table>
<thead>
<tr>
<th>Patient engagement</th>
<th>Number of clinic no shows/same day cancellations, number of annual eye examinations, number of influenza immunizations</th>
</tr>
</thead>
<tbody>
<tr>
<td>Health care utilization</td>
<td>Number of inpatient hospitalizations/emergency room visits, Number of hospital days</td>
</tr>
<tr>
<td>Clinical indicators</td>
<td>A1C, Systolic and diastolic blood pressure, weight</td>
</tr>
</tbody>
</table>
Health system in this study. The Health System is a tertiary care system that includes two hospitals, 29 clinic locations and three immediate care centers (Loyola University Health System, 2016). This health system is part of a larger Jesuit, Catholic Health System (Loyola University Health System, 2016). The family practice clinic, satellite clinic, and the outpatient clinic comparison sites are among the 29 clinic locations comprising this health system.

The community. The community, as the place where the patient spends the most time, provides resources and policies to assist the patient in managing his/her own health care needs on a daily basis (MacColl Center, 2016b). The Health System can facilitate the use of community resources that influence the ability of the chronically ill patient to achieve optimal self-management. Marshalling available community resources is critical to the achievement of self-management.

In addition, the community government adopts policies, laws, and procedures that have a large impact on the health of the community. For example, the decisions the community government makes on provided services, the allocation of funds, provision of police and fire departments, street maintenance (including signage and lighting, water and sewer systems, parks, pest control and garbage collection) all have an impact on the health of the community. Other services, like special transportation services for the handicapped and elderly, affect the ability of patients to access health care services. Consequently, how each community allocates their resources has a great effect on the health of the community.

The community in this study. Both the comparison and the ICCCM patient populations reside in the same general community. The community included Chicago or one of the six collar counties surrounding Chicago (Loyola University Health System, 2013a). This low income, racially diverse population identified diabetes, hypertension, obesity and hypercholesterolemia as
among the top health problems in their health needs assessment (Loyola University Health System, 2013a).

The Community and the Health System cannot function in a silo, but, rather they are indelibly and synergistically linked through underlying concepts. These four sub-concepts are Self-Management Support, Delivery System Design, Decision Support, and Clinical Information Systems.

**Self-management support.** Self-Management Support means providing the support that patients need to manage their own chronic illness(es). It acknowledges the patient’s role in chronic care management - and the healthcare team provides the support to patients to empower them to manage their own health (MacColl Center, 2016f). To maximize health, chronically ill patients must learn how to live with their chronic illness(es) and cannot rely exclusively on the health system to meet their own health needs. These patients must also learn to successfully navigate both the community and the health system to effectively manage their own health. Therefore, the role of the health care team is not only to provide the support and education needed but also to marshal the services needed by patients to manage their own health. Self-Management Support strategies “include assessment, goal-setting, action planning, problem-solving and follow-up” (MacColl Center, 2016f). Self-Management Support places the patient at the center of the model by emphasizing the patient’s role in his or her own health (MacColl Center, 2016f).

The self-management support concept is actualized in health care in that patients choose when to access health care services. The health care provider (physician or nurse practitioner) leads the team and refers the patient for services as needed. Patients are responsible for navigating the health care system.
**Self-management support in this study.** The nurse care coordinator identifies patients who need help with self-management. The care coordinator initiates a meeting and discusses care-coordination with the patient/care giver. Together with the patient and health care team, the care coordinator develops a mutually agreeable care plan. It is the care coordinator’s responsibility to follow-up with the patient to ensure the success of the care plan.

Communication care strategies include individual face-to-face meetings, phone and portal communication, diabetes education classes, support groups, and group clinic appointments. This model empowers patients to enhance self-management skills and meet health goals (Burkhart, et al., 2019).

**Delivery system design.** The Delivery System Design is the system structure designed to manage patient care. The Care Model Delivery System changes the Delivery System Design from one of reactive care to one that focuses on being proactive by maintaining optimal health (MacColl Center, 2016d). It incorporates all the components of the care system. This includes the defined roles of each team member, planned interactions with patients/families, the provision of culturally competent and literacy-competent care and the provision of coordinated care for complex, chronically ill patients that includes planned, regular follow-up care (MacColl Center, 2016d). Since the IOM published the report *Crossing the Quality Chasm: A New Health System for the 21st Century* (Institute of Medicine, 2001), it has been recognized that quality must be built into the core of the delivery system. A major goal of the delivery system is to make continual improvements in the delivery system based on the latest evidence, changes in health care, and analysis of their own data.

**Delivery system design in this study.** The traditional ambulatory clinic Delivery System Design requires the patient to identify when he or she needs to seek health care services. The
patient makes the appointment and bears the responsibility of maintaining a relationship with the provider. The clinic staff often function alongside each other, each performing the tasks necessary for their job but rarely communicating as a team to identify and meet patient needs (Burkhart, et al., 2019).

The ICCC M focuses on interprofessional collaborative care-coordination in an ambulatory primary care clinic. In this redesign, both the registered nurse and the nurse practitioner functioned as care coordinators and team leaders (personal communication Amber Garrett, Care Coordinator, 1/30/2017). Their care-coordinating responsibilities include developing and coordinating the plan of care, empowering both patients and families to participate in their own care, marshaling all available services, serving as the team leader to ensure everyone is working toward the same goals, and using the information system to monitor progress and proactively engaging with patients who are struggling to meet their care plan goals (I-Care-PATH meeting, 2014). In addition, an on-site dietitian and social worker complete the team and provide additional education and services for this highly complex group of patients (personal communication with Kimberly Koziol, Clinical Coordinator, 3/20/2017).

**Decision support.** Decision Support is the health information health professionals use to assist in making clinical judgments regarding care. It provides both person- and population-specific information that is linked with health knowledge to make health decisions to improve the quality of care provided. Clearly, the Decision Support system is very tightly linked with the Clinical Information System. In the Care Model, Decision Support focuses on engaging the patient/family through the most innovative evidence-based educational methods to help the patient identify his/her preference for care (MacColl Center, 2016c). From these preferences, the patient and the health care team collaborate to design individualized care plans for treatment.
Through effective decision support, care provided by specialists is integrated with that of primary care.

Decision support in this study. Decision Support is operationalized with a software called Phytel (IBM Phytel), which is an administrative program that extracts EHR data to help guide population and individual care (IBM Phytel, 2016). Phytel reports identify patients with scheduled appointments who require appointment reminders and needed lab work prior to their appointments (IBM Phytel, 2016). These reports are also used for population health statistics and to identify patients who have not completed recommended follow-up tests (Burkhart, et al., 2019).

Clinical Information Systems. Clinical Information Systems (CIS) are the systems within the environment that collect and organize individual patient clinical health data as well as aggregated population data. Due to the vast amount of data that are required to manage individual and population needs in a timely, efficient and effective manner, these systems are for the most part electronic. The CIS provides the organizational method to document and manage patient clinical information, particularly for disease management. Disease management information includes identifying patients in need of more intensive health support, providing reminders for both staff and patients, monitoring outcomes of the care model, sharing information electronically, and assessing the overall performance and quality of the model (MacColl Center, 2016a).

Clinical information systems in this study. All 29 clinics use EpicCare (Epic Systems, Verona, WI) and Phytel as the clinical information system. EpicCare is an electronic health record that houses the patient’s medical data for all 29 clinic sites and both hospitals within this
academic medical center. Phytel is a data management program for ambulatory care that pulls the data from Epic and organizes the data in a useful way for patient care (Burkhart, et al., 2019).

As Wagner’s The Care Model graphic demonstrates (see Figure 1), the Community and the Health System cannot be completely separated from each other. Therefore, both the Community and the Health System together make up the core elements of The Care Model. Although the Community does impact the concept of Self-Management Support, as the green inner circle darkens, the Community impact on Delivery System Design, Decision Support, and Clinical Information Systems diminishes. The Community and the Health System cannot function in a silo, but, rather they are indelibly and synergistically linked through the underlying tiered concepts.

Services. Services are helpful interventions provided to the patient and support system by the Community and Health System. The services provided to the chronically ill patient must be Patient-Centered, Timely and Efficient, Evidence Based and Safe, and Coordinated to be effective in producing both an informed, empowered patient and family and a prepared, proactive practice team (MacColl Center, 2002). These service attributes align with the IOM Report (2001).

Patient-centered. Patient-centered care makes the patient the center of the team, putting the informed patient in control of his own goals of care. Through a patient-centered care plan, the health care team can provide the patient with needed support and encouragement by collaborating with the patient and his support system to establish health care goals, action plans, solutions to problems and appropriate follow-up as well as to facilitate the use of community resources to provide increased support for self-management.
According to Morgan and Yoder (2012), there are four key attributes which demonstrate patient-centered care. Patient-centered care must be holistic, individualized, respectful, and empowering (Morgan & Yoder, 2012).

**Patient-centered in this study.** The Patient-Centered concept is applied to both usual care and the ambulatory care ICCCM redesign. In the standard care clinic, the patient makes an appointment to see the provider with a list of health concerns, which the provider respectfully addresses. The provider attempts to individualize the care to the needs and resources available to the patient. Patients are at the center making requests based on their recognition of their health care needs. Although the provider does bring up concerns and health maintenance suggestions, it is up to the patient to schedule follow-up appointments and manage his own health care for any problems that cannot be addressed at the time of the appointment. Although care is centered around the patient’s identified needs, the patient may be ill-equipped to accurately identify these needs. The care is respectful and individualized but it may or may not be holistic or empowering. Much will depend on the ability of the provider to address the whole patient and communicate in a manner that empowers the patient in a single 10-15 minute clinic visit (Burkhart, et al., 2019).

The Patient-Centered concept is applied to the ICCCM in that when the patient is identified as needing care coordination, the appropriate care coordinator contacts the patient and sets up an initial meeting (I-Care-PATH meeting, 2014). In the initial meeting, the care coordinator provides information about the opportunities available through care-coordination (I-Care-PATH meeting, 2014). Then, patients with complex health care needs in collaboration with the entire healthcare team set care goals demonstrating the PCC aspect of this innovation. In this case, the PCC intervention is a holistic approach to the patient and family/caregiver. The health care team works to understand patients from all aspects of their lives including physical,
psychosocial, cognitive, and spiritual. After understanding a patient’s health care needs and the many facets of these needs, the care coordinator and patient mutually develop goals and weave together the potential action plans to meet those goals. This process respects the needs, goals and desires of the patient. The resulting care plan includes a wide range of services; for example, multidisciplinary team visits, phone and portal support, support groups, and individualized team member visits. The support and education provided by the care coordinator and health care team empowers the patient and his/her family/caregiver to take control of the patient’s own health.

**Timely and efficient.** Timely care is care that is provided promptly (Institute of Medicine, 2001). Eliminating long wait times for patients to get appointments and long wait times at the point of care is especially important for patients with chronic illnesses who need more frequent healthcare visits. Without timely care, patients will be forced to wait until their healthcare is unmanageable. If the patient is unable to engage with their primary healthcare team, they will wait until care needs are emergent, at which time they will access the emergency department and hospital to get their health care needs met. This will lead to increased care fragmentation as well as increased cost. Thus, health care, to be effective, must be timely.

Efficient care eliminates healthcare waste by eliminating unnecessary repetition of services (Institute of Medicine, 2001). Providing efficient care is another method of ensuring that the patient’s care is not fragmented, but rather that care is holistic, with one health care team member coordinating the services of all healthcare providers. To provide efficient care, one provider must assume the responsibility for ensuring the care of the whole patient and coordinating specialty services.

**Timely and efficient in this study.** Timely and Efficient care applies to both usual care and the ICCCM ambulatory care redesign. The standard care clinic providers have 10-15 minute
appointments allotted for each scheduled patient appointment. Although they attempt to provide timely, efficient, and holistic care for each patient, it is difficult to address all of the needs of complex patients with limited time and without the assistance of the full team. Furthermore, standard care relies on the patient to schedule needed appointments at appropriate intervals.

In the ICCCM, the patient and caregiver have access to the care coordinator prior to or after the primary care provider (PCP) appointment as required and identified by either the PCP or care coordinator (I-Care-PATH meeting, 2014). This ensures that the patient’s healthcare needs are being met in a timely fashion. In addition, with the use of technology, the care coordinator reaches out to patients when decision support reports indicate a need for follow-up (I-Care-PATH meeting, 2014).

In the ICCCM model of care, during their appointments, patients may see other team members during, before, or after the PCP appointment (I-Care-PATH meeting, 2014). Extending the visit helps to ensure that all individual patient needs can be met. In addition, rather than waiting for the patient to contact the clinic, the care coordinator reaches out to the patient to make sure their needs are being met (I-Care-PATH meeting, 2014). Patients are encouraged to contact their care coordinator with any problems they encounter (I-Care-PATH meeting, 2014). This relationship ensures that care needs can be met in a much more timely and efficient manner with the goal of minimizing urgent care, emergency care and hospitalizations.

**Evidence-based and safe.** Evidence-based care is care that is based on the current best evidence from rigorous research findings combined with clinical expertise and patient values. Although the concept of evidence-based practice originated in medicine, it is currently considered an interdisciplinary approach to practice and is firmly based on the patient’s values, goals and preferences (Lilienfeld, Ritshcel, Lynn, Cautin, & Latzman, 2013).
Safe care means that the patient is free from unintended injury related to the care provided (Institute of Medicine, 2001). Standardizing care is an important component of providing safe care (Haas, Swan, & Haynes, 2014). Many of the errors that occur in healthcare are related to poor communication between healthcare providers.

**Evidence-based and safe in this study.** The Evidence-Based and Safe concept was not evaluated or measured for this study. Since all 29 clinics follow the same policies, procedures and mission, an assumption of this study is that they provide the same degree of safe and evidence-based care.

**Coordinated.** Coordinated care means organizing the care provided between health professionals and the patient so that patients receive appropriate and optimal health care services (Agency for Healthcare Research and Quality, 2014). Effective and efficient communication between the patient and all healthcare providers is an attribute of care-coordination. With optimal communication, waste and redundancy of care is minimized. Thus, coordinating healthcare is a multidimensional task that incorporates many of the concepts of The Care Model.

**Coordinated in this study.** Coordination is operationalized differently in the standard care and in the ICCCM redesign. In standard care, the PCP bears the responsibility of effectively coordinating all the health care needs of their patients. In the ICCCM redesign, the care coordinator communicates with all team members and the patient. The nurse care coordinator develops an individualized plan of care based on physician recommendations, decision support recommendations, team feedback, and patient/family decisions (I-Care-PATH meeting, 2014). The care coordinator follows the plan and is responsible for providing transitional care and communicating with care providers outside the clinic (I-Care-PATH meeting, 2014). By utilizing
the full capacity of the registered nurse to coordinate the care of the complex patient, care is effectively coordinated.

**Productive interactions.** Productive interactions are the methods that empower patients to produce their own health outcomes. In chronic care management, it is the patient and family who live with the chronic condition and only through their actions can the disease trajectory be altered. Interactions occur between the health care practice team and the patient and family in every health care model. To be productive interactions, the patient and family are placed squarely in the driver’s seat rather than being a bystander in their own health care.

**Productive interactions in this study.** Productive interactions are operationalized in both usual care and in the ICCCM redesign. In standard care, productive interactions are operationalized in that the physician or APN answers the patient/care giver questions, coordinates the care, and educates the patient in the allotted 10-15-minute appointment. Additional needs are met through referrals to other clinics. In the ICCCM redesign, the nurse care coordinator uses motivational interviewing techniques to assist the patient/care giver in identifying their health goals and meeting them. These interactions are not limited to the clinic visit but rather extended by encouraging follow-up visits, phone visits and portal visits. While in the clinic, if social work, dietary or psychological needs are identified, the respective team member attempts to meet with the patient/caregiver at the time of the visit. However, if this is not possible, appointments with the appropriate team member can be made within the same clinic location (Burkhart, et al., 2019).

**Prepared, proactive practice team.** The Prepared, Proactive Practice Team means that every member of the team is actively engaged in assisting the patient and his/her support system to meet their health care goals. The team is prepared in that they understand the health care needs
of the patient and can apprise the patient of their health care management options. Proactive means that the healthcare team is focused on the prevention of future problems rather than being strictly reactionary. For example, a proactive team member uses the clinical information system to identify patients with increased care needs to reach out to and interact with these individuals.

Team is critical to the success of the Care Model. Team means that each member is vested in working together toward the common goal of informing, educating and supporting the patient and family. Practice team includes all the members of the healthcare team working together to inform and empower patients and their families. The practice team includes lay caregivers, nursing staff, care managers, physicians, administrative staff as well as ancillary professionals like social workers, dietitians, psychologists, pharmacists, and physical and occupational therapists as needed to meet the individual patient’s needs.

**Prepared, proactive practice team in this study.** Prepared, Proactive Practice Teams are operationalized differently in the standard clinic and in the ICCCM redesign. In the standard clinic, care is provided by the PCP or APN. The patient care tech “rooms” the patient and obtains basic health data measurements and information. The nurse and patient care tech provide any care needs ordered by the PCP or APN. The nurse also triages phone calls from patients daily. The Team huddles at the beginning of the clinic to discuss particular patient needs for the day but after the basic health data is obtained, the nurse and patient care technician provide only specifically ordered care.

The Prepared, Proactive Practice Team is applied to the ICCCM in that standard practice is for the care coordinator to meet with the patient as well as the physician/APN. The care coordinator uses motivational interviewing to determine the patient’s progress and continued goals of care. The Team huddles at the beginning of the clinic to discuss patient needs for the
day. The care coordinator also organizes bimonthly team meetings with the nurses, social worker and dietitian to ensure a continuously improving model of care, as well as monthly team meetings with the physicians to discuss specific patient needs. The care coordinator also establishes the care plan with the patient/care giver and contacts the patient/care giver between clinic visits as needed to assure goal attainment (Burkhart, et al., 2019).

**Informed, empowered patient and family.** Informed and empowered patients and families mean that they understand the health intervention options available to them, and they have the confidence and health literacy to make individual health care decisions and meet the challenges of their own health care plan.

In the Care Model, the prepared, proactive practice team informs and empowers the patient and family to make lifestyle changes, utilize available resources within the environment and learn how to optimize their own health. A prepared, proactive practice team means that the interprofessional health care team optimizes the delivery system to make evidence-based decisions using the retrieved clinical information to help patients, together with their family, self-manage their own health. The informed, empowered patient and family is informed and empowered by the prepared, proactive practice team to ensure that they have all the necessary tools and resources to self-manage their chronic illness and improve their disease trajectory and ultimately their health outcomes. In the Care Model, every construct is inextricably linked to ensure that all aspects of health care are united in the effort to ensure one goal—to empower the patient and family to achieve better outcomes.

**Informed, empowered patient and family in this study.** The Informed and Empowered Patient and Family is operationalized differently in standard care and in the ICCCM redesign. In the standard care workflow, patients with diabetes are asked to schedule quarterly appointments
with their PCP to assist them in their diabetes management and address any questions or health
problems patients identify as well as addressing their diabetes control. Educational and education
materials are provided within the scheduled appointment.

The Informed and Empowered Patient and Family is applied to the ICCCM workflow in
that the care coordinators contact patients not only prior to their appointments but also regularly
based on a schedule developed between the patient and the care coordinator to ensure that all the
patient's needs are being met. The care coordinator helps the patient and their support system
identify and meet their healthcare goals. Through both telephone and face-to-face meetings,
potential needs are identified. Then the PCP, care coordinator or other appropriate team member
can further address these needs with the patient through education and support provided either
through face-to-face or telephone communication. These interactions help inform and empower
the patient and family. The health care goals and decisions made by the patient and his or her
family in conjunction with the health care team provide the patient with Self-Management
Support through care-coordination, assessment of health literacy and subsequent provision of
educational needs and services. This workflow relies on nurse-led interprofessional collaborative
practice. The nurse coordinates care and delegates leadership of patient care to the team member
who can best address the care needs. On-going communication between both team members and
the patient ensures coordinated care (Burkhart, et al., 2019).

Thus, the ICCCM workflow creates the informed, empowered patient and family through
productive interactions with the prepared, proactive practice team. As demonstrated, this
interprofessional collaborative care-coordinated practice is a redesign of the standard ambulatory
healthcare system.
**Improved outcomes.** Outcomes are the consequences of the Healthcare system/community care of health care services through productive interactions between the proactive healthcare team and the informed and empowered patient and family. Outcomes are measures of health that are used to determine if the disease trajectory has improved and if the model is delivering quality care. There are both short-term and long-term outcome measures. Short-term outcome measures are measures that change within a short time period, considered one to three years (W.K. Kellogg Foundation, 2004). Long-term outcome measures take a long time to identify in a population, from four to six years (W.K. Kellogg Foundation, 2004). For example, A1C levels can change every two to three months and are a good short-term measure of diabetes management. A long-term outcome measure for diabetic patients would be the number of patients experiencing a cardiac event, retinopathy or nephropathy.

**Improved outcomes in this study.** This study measures short term outcomes. These include patient engagement (number of missed visits, annual influenza immunizations and annual dilated eye examinations), appropriate healthcare utilization (number of hospitalizations, emergency room visits and hospital days), and clinical indicators (percent of patients with Hgb A1C levels > 9.0; change and difference in Hgb A1C, weight, and systolic and diastolic blood pressure, systolic blood pressure < 140, diastolic blood pressure < 90).

Figures 2, 3 and 4 provide the substructure of The Care Model describing how the Outcomes were measured.
Figure 2. The Care Model substructure A

The Care Model Theory Substructure

Concepts:

Outcomes

Concept Components:

Patient Engagement

Healthcare Utilization

Clinical Outcomes

Variables:

Clinic Missed Visits

Annual Eye Examination

Annual Influenza Vaccination

See Figure #2

See Figure #3

Adapted from Wagner’s 7-Jug Care Model

Figure 3. The Care Model substructure B

The Care Model Theory Substructure

Concepts:

Outcomes

Concept Components:

Patient Engagement

Healthcare Utilization

Clinical Outcomes

Variables:

See Figure #1

Hospitlizations

ED Visits

Hospital Days

See Figure #3

Adapted from Wagner’s 7-Jug Care Model
Summary of Literature Review

The literature will be described in the following areas: Home Health Care Team Model, Carondolet Model, Community Care Management Model, Transitional Care Models, Medicare-Coordinated Care Demonstration Projects, Physician Group Demonstration Projects, Case Management, Primary Care Models, Patient Centered Medical Home Model, and Multidisciplinary Collaborative Models.

Models of Care-Coordination Late 20th Century

Care-coordination models emerged in the later 20th Century. The following sections will describe these early models: Home Health Care Team Model, the Carondelet Model, and the Community Care Management Model.

Home Health Care Team Model. The Home Health Care Team Model was a physician-led team approach including a physician, nurse practitioner (NP), and social worker (Zimmer,
Groth-Juncker, & McCusker, 1985). Interventions included home visits by each team member to develop an interdisciplinary care plan followed primarily by NP home visits but including other team member visits as needed, weekly team conferences, and 24-hour emergency phone service (Zimmer et al., 1985). A random control trial (RCT) of a population of 167 high-risk, chronically ill and often terminally ill patients found a significant improvement in caregiver satisfaction in the treatment group at both 3 months ($p < 0.0001$) and six months ($p < 0.002$) (Zimmer et al., 1985). However, there was no statistically significant difference in healthcare utilization, which was attributed to the high rate of mortality in this population (Zimmer et al., 1985).

**Carondelet Model.** The Carondelet Model followed a high-risk Medicare population with nurse-managed care-coordination throughout the patient’s lifespan (Ethridge & Lamb, 1989; Ethridge, 1997). Continuous care through nurse-managed care-coordination was an effective means of increasing quality and decreasing costs (Ethridge & Lamb, 1989; Ethridge, 1997). The focus of this model was to improve patient care for seniors and the medically disabled population by providing the full continuum of care (Ethridge & Lamb, 1989; Ethridge, 1997).

**Carondelet Model description.** This Carondelet Model used a risk assessment tool to identify, enroll and periodically match patients based on need and risk with both nursing and community services. The nurse care manager assisted in the development and selection of individualized educational and clinical interventions and coordinated these services at all levels of care (primary, secondary and tertiary) (Lamb & Zazworsky, 1997). In this model, the nurse case manager assumed the central role of coordinating all patient care to provide all needed services and ensure that no patient fell through the cracks of the healthcare system (Ethridge & Lamb, 1989; Ethridge, 1991).
**Carondelet research findings.** No specific statistical findings from Ethridge’s work have been published, and the specific number of patients who were case managed was not provided. The data provided is based on the discharge data set extracting the diagnosis related group for COPD and total hip replacements at the Carondelet hospital for fiscal years 1986-1988. Administrative data provided the total number and length of hospitalizations in the years following the case management intervention for COPD and total hip replacements.

The literature does provide a description of Ethridge’s methodology and information regarding the cost savings of this nurse managed care-coordinated approach. In their analysis, Ethridge and Lamb claimed that case-managed patients with chronic obstructive pulmonary disease (COPD) or total joint replacements had fewer readmissions, decreased length of hospital stay, and decreased use of emergency room services than non-case-managed patients (Ethridge & Lamb, 1989). It is unclear how they identified participants from the nurse managed care-coordinated group verses standard care. However, they reported that the case-managed COPD group was hospitalized earlier with less acuity (4.4 vs. 5.5 in non-case-managed group) (Ethridge & Lamb, 1989). Subsequently these patients were able to be discharged on average 3.5 days sooner than the non-case-managed group (6-day length of stay (LOS) for case-managed vs. 9.5-day LOS for non-case-managed group) (Ethridge & Lamb, 1989). In the total hip replacement group, despite higher acuity (4.9 vs. 4.4), these patients also had shorter LOS (8.1-day LOS in case-managed group vs. 10.2-day LOS in non-case-managed group) (Ethridge & Lamb, 1989). It appeared that the case managers were able to decrease LOS in this surgical group by impacting the end of the hospitalization rather than the beginning (Ethridge & Lamb, 1989). Based on this discrepancy, Ethridge and Lamb (1989) surmised that the effect of care-coordination is complex and needs to be individualized based on the type of conditions treated. Although this research
was not published, Ethridge and Lamb (1989) reported that their care-coordinated nursing model improved the cost and quality of individual health care.

**Community Care Management model.** The Community Care Management model was an advanced practice nurse (APN)-led care-coordinated model of care utilizing intensive face-to-face clinical management combined with close collaboration between the physician and the APN who was assigned to a specific physician practice (Quinn, Prybylo, & Pannone, 1999). High-risk patients were identified through a health risk assessment utilizing an acuity tool, which was also the basis for future care planning, patient education, health care team coordination and communication (Quinn et al., 1999).

Research demonstrated that this model decreased hospital admissions and healthcare costs (Quinn et al., 1999). Quinn et al. (1999) found that patients (n= 174) had experienced a 54% reduction in acute care admissions with a subsequent cost savings of $3,602 per patient \((p < 0.001)\) in the six months after initiating this care-coordinated intervention compared to six months prior. Although statistically significant, a highly problematic limitation of this study was the fact that over half \((n = 114)\) of the patients had been identified during an acute care admission prior to beginning the intervention (Quinn et al., 1999). Therefore, medical costs prior to initiation of the intervention were likely overestimated skewing the results toward significant decreased spending in the post-intervention period (Quinn et al., 1999). Thus, regression to the mean was identified as a potential problem, questioning the validity of the findings (Quinn et al., 1999).

**Transitional Care Models: 1990s to the Present**

Beginning in 1990, a new model of care emerged, called Transitional Care. Transitional care differs from care-coordination in that it focuses the care during high-risk times, rather than
only with high-risk patients. This high-risk time is the 30-days immediately post-hospitalization. Transitional care models have become more popular due to the Medicare regulation both prohibiting reimbursement for 30-days post-discharge for certain diagnoses and adjusting payment for all-cause readmissions based on each hospitals’ risk adjusted readmission rate (CMS.gov, 4/18/2016).

Transitional care is the care offered to patients when transitioning from one level of service/care provider to another and CMS has defined readmissions as occurring within 30-days of the initial hospital stay (James, November 12, 2013). Landmark research by Naylor (1994; 2004), Coleman (2006), and Jack (2009) demonstrated the potential of care-coordination and discharge planning to effectively transition patients out of the hospital to minimize the costly problem of hospital readmissions. Although there are many transitional care models, two major models focus primarily on the time after discharge when the patient is transitioning back to ambulatory care. These two successful transitional care models, Naylor’s Transitional Care Model (TCM) and Coleman’s Care Transition Intervention model (CTI), were developed based on nurse-led care-coordination (Coleman, Parry, Chalmers, & Min, 2006; Naylor et al., 1994; Naylor et al., 1999; Naylor et al., 2004; Naylor et al., 2011b; Naylor et al., 2014). These models have demonstrated that nurse-led care-coordinated research or clinic-based transitional care models reduce hospital readmissions and are cost-effective. The final transitional care model discussed, Hewner’s Population-Based Care Transition model (PBCT) is based on the TCM intervention but uses population health technology to identify and enroll the patients at highest risk of readmission. The following sections describe each model in more detail.

Naylor’s Transitional Care Model. The Naylor TCM uses APNs to provide care coordination from the day of hospital admission until one to three months post-discharge. During
the post-discharge phase, the APNs visit patients in their homes within 48 hours of discharge and then weekly to bimonthly, and maintain access to care through daily phone “office” hours.

Although Naylor’s model population is hospitalized patients transitioning to home, the transition time period grew from two weeks (Naylor et al., 1994) to four weeks (Naylor et al., 1999) to two to three months (Naylor et al., 2004) post discharge.

**Naylor’s Transitional Care Model research results.** Research of the Transitional Care Model consistently demonstrated that the model was effective in reducing both 30-day hospital readmissions and admissions over a longer length of time for a variety of populations. In their 1999 random control study of 363 geriatric patients, they found a statistically significant decrease in readmissions at 24 weeks ($p < .001$) (Naylor et al., 1999). Naylor et al. (1999) also found the total number of days spent in the hospital post-index admission was significantly shorter at 24 weeks, with 270 hospital days for the intervention group (177 patients) and 760 hospital days for the control group (186 patients) ($p < 0.001$).

Naylor et al.’s 2004 RCT evaluated the effect of TCM on 239 older adults with heart failure and comorbidities. In this study, 38% of the control group and 37% of the intervention group had DM. This three-month TCM intervention demonstrated a statistically significant decrease in hospital admissions up to one year with 88.1% (104/118) admissions in the year after the index admission for the intervention group, compared to 133.9% (162/121) admissions for the control group patients ($p = 0.047$) (Naylor et al., 2004). This translated into a statistically significant decrease in healthcare costs of $6,152 on average per patient for the intervention group and $9,618 for the control group ($p = 0.002$) after removing the costs of the program (Naylor et al., 2004). Quality of life was significantly improved from baseline at only one timepoint: 12 weeks ($p < 0.05$) and patient satisfaction improved from baseline to both 2 and 6
weeks post-intervention ($p < 0.001$) which were the only two timepoints in which patient satisfaction was measured in the study (Naylor et al., 2004).

Naylor et al.’s 2014 prospective comparative study of 202 cognitively impaired, community-dwelling older adults compared the TCM intervention to augmented standard care (ASC) and resource nurse care (RNC) (Naylor et al., 2014). ASC included cognitive screening while inpatient, and RNC consisted of trained RNs acting as resource nurses during hospitalization to provide care directly to the patient or to coach care of other nurses to the patient (Naylor et al., 2014). In their time-to-event data model, findings demonstrated that there was an accelerated time to readmission or death for both the ASC (1.75 ($p = .05$)) and the RNC (1.93 ($p = .02$)) in comparison to the TCM (Naylor et al., 2014). The TCM was an effective transitional care model with decreased hospitalizations for up to one year after the index admission and subsequent decreased cost.

**Naylor’s third-party TCM.** Naylor (2011b) expanded the use of the TCM intervention to a commercial insurance group with the APNs hired by the insurance company; this revised model excluded patient visits in the hospital (Naylor et al., 2011b). A study with 105 participants (45 TCM, 60 standard care without TCM) demonstrated statistically significant decrease in hospital readmission at 3 months ($p < 0.041$) but no statistically significant difference in readmissions at 6 or 12 months (Naylor et al., 2011b). This demonstrates that either the first visit in the hospital is an important dimension to the intervention or the insurance company affected the quality of the intervention. More research is needed to clarify why this model was less successful than the initial model.

**Coleman’s Care Transitions Intervention (CTI) model.** The CTI model focuses their intervention exclusively on the acute hospitalization phase followed by the first 28 days of post-
hospital discharge. The CTI was developed based on discharge needs expressed during patient focus groups making it a more evidence-based, patient-centered approach (Parry, Coleman, Smith, Frank, & Kramer, 2003). In this model, nurses provide care coaching/coordination through one hospital visit followed by one home visit within 24-72 hours of discharge and three phone calls during the subsequent 28 days post-discharge (Coleman et al., 2006). The focus of these meetings is to empower the patient to take an active role in his/her own care by concentrating on patient medication self-management, maintaining the patient’s personal health record, and encouraging appropriate follow-up with active patient participation. Patients are encouraged to ask questions and learn to identify red flags early (Coleman et al., 2006). The goal of the CTI is to improve the patient’s self-care ability, so that the patient can coordinate his/her own care (Coleman et al., 2006).

The CTI significantly decreases readmissions. In a quasi-experimental study of the CTI model, a population of 158 elderly adults with at least one of nine chronic conditions receiving CTI care was compared to 1,235 control subjects who received standard care (Coleman et al., 2004). Findings indicated that the percent of rehospitalizations significantly decreased in the intervention group for all time periods:—30-day (0.52 Odds Ratio (OR) with confidence interval (CI) 0.28–0.96; \( p = 0.04 \)), 90-day (0.43 OR, CI 0.25–0.72; \( p = 0.002 \)), and 180-day (0.57 OR, CI 0.36–0.92; \( p = 0.02 \)) (Coleman et al., 2004). However, the percent of emergency department visits or observation visits was only significantly reduced at 90 days (0.61 OR, CI 0.39–0.95; \( p = 0.03 \)) (Coleman et al., 2004).

In a random control trial of 750 elderly patients with at least one of eleven chronic conditions, Coleman et al. (2006) found the CTI intervention group had significantly fewer all-cause readmissions at 30 days (0.59 OR, CI 0.31–1.00; \( p = .048 \)) and 90 days (0.64 OR, CI 0.42–
0.99; \( p = .04 \) with no significant difference at 180 days (0.80 OR, CI 0.54–1.19; \( p = 0.28 \)). However, when they looked at readmissions for the same diagnosis as the initial admission, the adjusted intervention group had statistically significant fewer admissions at both 90 days (0.50 OR, CI 0.26–0.96; \( p = .04 \)) and 180 days (0.55 OR, CI 0.30–0.99; \( p = .046 \)) with no significant difference at 30 days (\( p = 0.18 \)) (Coleman et al., 2006). Research indicated that the Coleman model decreased all-cause readmissions for the first 90 days but only had an impact on readmissions for the same initial diagnosis post-hospitalization after 30 days.

**Hewner’s Population-Based Care Transition (PBCT) model.** Hewner’s model relied on a nurse-developed informatics algorithm to identify the population at highest risk of hospital readmission in a regional managed care organization. The complexity algorithm provided the means to stratify patients based on their chronic disease complexity hierarchy into four groups: complex chronic, major chronic, minor chronic and no chronic conditions (Hewner, 2014).

PBCT services were provided based on the hierarchy of needs with the complex chronic population receiving full integrative services, the major chronic receiving care-coordination services, minor chronic receiving linkage services only and the population without chronic conditions receiving health promotion services only (Hewner, Seo, Gothard, & Johnson, 2014; Hewner, 2014). Hewner (2014) indicated that as patients were placed in higher complexity groups, the previous interventions from the lower complexity groups were added to the intervention in higher complexity groups. Therefore, although all four groups received health promotion services, only the major chronic condition group and the complex chronic condition group received care-coordination services (Hewner, 2014).

In this model, the PBCT makes the initial call to the patient, identifies their risk and refers the patient based on the intensity of services needed (Hewner, 2014). For example, if the
patient needs ongoing home health care that has not been previously arranged, the nurse arranged for follow-up by the visiting nurse or APN (Hewner, 2014). If the primary problem is complex medication regimens, the nurse care coordinator refers the patient to the pharmacist for reconciliation and education (Hewner, 2014). Upon discharge from pharmacy services, the pharmacist evaluates and refers the patient to the nurse care coordinator or other services based on need (Hewner, 2014). In this model, transitional care management nurses made one to four calls and one to four home visits to the patient after discharge with those complex patients who required more follow-up being referred to other enhanced programs (Hewner, 2014).

Hewner et al. (2014) found in their pre-/post-study of 27,890 Medicare patients that the inpatient hospitalization rate decreased from 497/1000 high-risk patients (complex chronic condition and major chronic conditions groups) in 2008 to 449/1000 in 2009. This was equivalent to 2,055 prevented hospitalizations in the two high-risk groups. Hewner (2014) equated decreased admissions in the chronic disease groups to a 2009 decrease of $54 per member per month cost (from the 2008 cost) with a total reduction of $16,923,708 in one year. Unfortunately, Hewner et al. (2014) were unable to interpret the results for 30-, 60-, and 90-day readmissions as the hospital did not code this information (Hewner et al., 2014).

**Systematic reviews of transitional care models.** Several systematic reviews were conducted to evaluate transitional care models and the interventions associated with each model (Hansen, Young, Hinami, Leung, & Williams, 2011; Kansagara et al., 2016; Verhaegh et al., 2014).

In a systematic review of interventions to reduce hospital readmissions, Hansen et al. (2011) found that most of the 43 hospital-based interventional studies reviewed (60.3%) were unable to account for admissions to other institutions and estimated that this failure could miss
about 20% of hospitalizations indicating a potentially significant error in the evidence provided. They found that bundled interventions like the TCM and CTI tended to be the most successful interventions (Hansen et al., 2011). There were only seven single intervention RCT studies, with only one reaching statistical significance (Intervention = early discharge planning) (Absolute Risk Reduction 11.0%, \( p < .05 \)) (Hansen et al., 2011). They surmised that studies that used bundled interventions might have a cumulative effect since single interventions like discharge planning, discharge education, and discharge phone calls alone were generally unsuccessful (Hansen et al., 2011). Furthermore, Hansen et al. (2011) did find that when interventions were bundled together with other interventions as in CTI and TCM, the combination of multi-faceted interventions like care-coordination did prove successful.

Another systematic review of transitional care studies demonstrated mixed results (Verhaegh et al., 2014). Verhaegh et al (2014), evaluated 26 random control trials of transitional care interventions and found that less than half (10) evaluated short-term 30-day readmissions with more focusing on longer admission periods: 18 studies included intermediate (31-180 days) and 7 long-term (181-365 days) admission rates. Furthermore, most of the interventions that had a positive effect on readmission and admission rates in all three time periods provided care-coordination (Verhaegh et al., 2014). These studies focused on heart failure, COPD, asthma or general internal medicine or surgical patient populations (Verhaegh et al., 2014). They also found that the most successful studies included high intensity transitional care in elderly populations (age > 60) (Verhaegh et al., 2014).

Kansagara et al.’s (2016) systematic review of previous systematic reviews of transitional care interventions found that interventions that included discharge planning from the hospital to post-hospital timeframe, that were flexible and individualized were most successful. However,
they also found the strength of the evidence low due to the heterogeneity of the interventions, populations, clinical settings, and implementation strategies (Kansagara et al., 2016). They did find that the most robust interventions, including nurse-provided discharge planning and care coordination, provided the greatest benefit in reduced readmissions (Kansagara et al., 2016). This demonstrates that transitional care with nurse-led care coordination is effective in decreasing hospital readmissions and admissions for up to one year post-discharge.

**Care Coordination Models in the 21st Century**

This section will review the research on care coordination models from the 21st century including the Medicare-Coordinated Care Demonstration Projects, the Physician Group Demonstration Project, and case management and nursing care-coordination.

**Medicare-coordinated care demonstration projects.** The Balanced Budget Act of 1997 mandated the Secretary of Health and Human Services to conduct large random control trials on care-coordination in the chronically ill Medicare fee-for-service population (CMS.gov, 2017). The purpose was to determine if care-coordination could improve quality of care without increasing cost (CMS.gov, 2017). Therefore, in 2001, the government funded 15 Medicare-Coordinated Care Demonstration (MCCD) sites providing care-coordination services with the goal of finding an economically feasible solution to America’s highly fragmented decentralized system that rewards providers for delivering care but not for coordinating care (Nelson, 2012b).

However, findings from these demonstration projects did not show savings to offset costs (Nelson, 2012a; Nelson, 2012b). In fact, among the 15 MCCD random control trials funded, CMS found only two demonstrated a significant change on the number of hospitalizations \( p < .05 \) and no significant reduction on overall general Medicare expenses, excluding the cost of the care-coordination project itself (Peikes, Chen, Schore, & Brown, 2009). Of the two with
significant effects on hospitalizations, Mercy had 0.168 fewer hospitalizations per person per
year (17% less than the control group mean, $p = .02$) and Charlestown had 0.118 more per person
hospitalizations per year (19% more than the control group, $p = .04$) (Peikes et al., 2009). In
addition, two programs, Health Quality Partners and Mercy Medical Center, demonstrated a
substantial, albeit not significant, decrease in treatment group expenditures compared to the
control group (Peikes et al., 2009).

In addition to the MCCD, CMS conducted five other large-scale demonstration projects
on coordinated care (Nelson, 2012a). All of these demonstration projects primarily involved
care- coordination telephonic interventions with fewer face-to-face interventions. In their
analysis of all six CMS demonstration projects, the CBO found that most of the 34 programs that
participated in disease management or care-coordination projects were unable to decrease costs
and increase quality (Nelson, 2012a).

Findings revealed that although these programs were not budget-neutral, hospital
admissions were decreased when there was an established face-to-face relationship between the
patient and the care manager or the care manager collaborated face-to-face with physicians
(Nelson, 2012a). Increased in-person interaction between the care manager and patients lowered
hospital admissions by 7% (average) ($p = 0.01$) and reduced regular Medicare spending by 3%
(average) ($p = 0.10$) (Nelson, 2012a). For those programs that included care managers who had
increased direct interactions with physicians, hospital admissions fell by an average of 7% ($p =
0.09$) with regular Medicare spending decreased on average by 6% ($p = 0.01$) (Nelson, 2012a).
However, programs that emphasized telephone interaction rather than in-person interaction with
the patient did not have a significant effect on Medicare spending or hospital admissions
In response to the original findings, several MCCD sites either modified their model to include localized care-coordination or continued a focus on localized care-coordination interventions to improve outcomes.

**Washington University’s MCCD model.** Washington University did demonstrate both decreased hospitalizations and cost savings after redesigning the intervention (Peikes, Peterson, Brown, Graff, & Lynch, 2012). After the first four years, Washington University replaced long-distance care managers with local care managers (Peikes et al., 2012). This change meant more in-person contact, stronger patient/care manager relationships, and more aggressive transitional care with inpatient care manager visits as well as closer follow-up with primary care providers (Peikes et al., 2012). In a study comparing patients pre-redesign (N=2,144) to post-redesign (N=2,166), hospitalizations were reduced by 11.7% and spending by 9.6%, albeit not statistically significant (90% CI = -$250 to $119) (Peikes et al., 2012). However, this savings offset the care management fees (Peikes et al., 2012). Finally, when they evaluated only the patients at the highest risk for hospitalizations, they found that the results were more dramatic with 17.0% fewer hospitalizations and decreased monthly Medicare spending by 14.8% with a total savings of 9.7% or $286 per patient per month after deducting the cost of the care management intervention (Peikes et al., 2012).

The change in method of care-coordination from off-site to in-person, face-to-face visits in combination with telephone visits increased the opportunity to build trusting relationships (Peikes et al., 2012). By maintaining close communication with the primary clinic and in-person visits with the patient, this study demonstrated the potential of care-coordination services to decrease hospitalizations and Medicare expenses in both the general population and a high-risk population (Peikes et al., 2012).
Mercy Medical Center MCCD model. This model used care coordination as a method of changing patient behavior and providing coordination across all providers rather than focusing only on physician practice (Burwell, 2014). Nurse care coordinators (NCC) met with patients and their caregivers face-to-face initially and monthly for at least the first year with intermittent phone communication as needed. This built a trusting relationship and promoted adherence to treatment plans (Burwell, 2014). NCCs provided education about chronic conditions and preventive care and served as the communication hub for the patient and providers (Burwell, 2014).

In a RCT of 1,392 patients (696 randomized to control and 696 randomized to treatment by the outside evaluator Mathematica), Mercy reduced hospitalizations by 9.8% ($p = 0.07$) while increasing costs by 10.3% (program fees included) ($p = 0.08$) (Burwell, 2014). The high-risk participants ($n = 1050$) (those with congestive heart failure, coronary artery disease or COPD, and a hospitalization in the year prior to participation) demonstrated a 14.4% reduction in hospitalizations ($p = 0.02$) (Burwell, 2014). However, this high-risk group had a 3.5% increase in cost (program fees included) ($p = 0.62$) (Burwell, 2014). Neither the full cohort nor the high-risk group had an impact on quality of care measures (immunization rates or recommended monitoring for disease-specific care like glucose testing) other than podiatry visits. There was a statistically significant increase in podiatry visits for patients with diabetes (Schore, Peikes, Peterson, Gerolamo, & Brown, 2011). However, disease-specific quality measures were underpowered and may not have been able to detect a difference in quality (Schore et al., 2011). There was no difference in two-year survival after enrollment (Burwell, 2014). Consequently, although this model significantly reduced hospital admissions in the highest risk group, it did not demonstrate significant cost reduction in any group (Burwell, 2014).
Health Quality Partners (HQP) MCCD model. The Health Quality Partners, under the Healthcare Cost and Utilization Project (HCUP), had a nurse-led care-coordination model similar to the Mercy Medical Center Model, in which the aim was to change patient behavior rather than physician practice (Burwell, 2014). Nurses initially worked on building a relationship with the patient and caregiver followed by improving self-management (Burwell, 2014). In the first year of the demonstration project, the nurse case manager met both monthly with patients and caregivers and contacted patients by phone (Burwell, 2014). Finally, NCM served as the “communication hub” for all members of the team (Burwell, 2014).

Due to early success, HQP was afforded several extensions to their RCT (Burwell, 2014). HQP had demonstrated a 17% reduction in hospitalizations with no additional Medicare costs between 2002-2012 (Burwell, 2014). However, after the extension for high-risk patients from 2011–2014, the intervention no longer had an effect on hospitalizations, ED visits or cost reduction (Peterson, Zurovac, Mutti, Stepanczuk, & Brown, 2015). In fact, total Medicare expenditures increased by 16% (Peterson et al., 2015). Post hoc analysis revealed that the most likely explanation for this phenomenon was improvements in usual care since both transitional care was being offered by affiliated hospitals and patient centered medical homes were being established (Peterson et al., 2015). In the post hoc analysis, Peterson et al. (2015) found that there was no change in hospitalization rates pre-extension to post-extension but that the usual care hospitalization rate was 34% lower ($p = 0.009$) in the post-extension compared to the pre-extension. There was no difference in ED visits between the pre- and post- extension period for the control group, and the treatment group’s ED visit rate increased significantly from pre- to post- extension ($p < 0.001$), which does not support the theory that usual care improved during this time period (Peterson et al., 2015). It is possible that changes afforded by the latest evidence
in medical research and new medications had also improved standard care since the initiation of HQP’s RCT in 2001 (Peterson et al., 2015). For these reasons, Peterson et al. (2015) indicated that the current HQP program was unlikely to sustain success in the current changing healthcare environment.

**MCCD quality measures.** The Medicare-Coordinated Care Demonstration sites (Mercy Medical Center and Health Quality Partners Models) did also measure some diabetes-related quality-of-care variables including influenza immunizations, eye exams and frequency of A1C blood tests (Schore et al., 2011). They found that for Health Quality Partners care-coordination model had a statistically significant (p < 0.1) improvement in influenza and pneumococcal vaccinations but no effect on eye examinations or frequency of A1C blood tests (Schore et al., 2011). Mercy Medical Center’s care-coordination project had no effect on any of these three quality-of-care measures but did have a statistically significant improvement in podiatry examinations (p < 0.1) (Schore et al., 2011).

**Physician Group Demonstration Project: Value-based payment.** The Physician Group Demonstration Project was a legislative mandate designed to determine if value-based payments could save Medicare funds while increasing process and outcome quality measures (Kautter et al., 2012; Nelson, 2012b). The Physician Group Demonstration Project included 10 Physician Group Practices of varying sizes from 292 physicians to 1,291 physicians (Kautter et al., 2012; Nelson, 2012b). Physicians received bonus payments if they could demonstrate that Medicare expenses were at least 2% below the expected target (based on risk) with any additional expenses for other providers, hospitalizations, etc., included in Medicare expenses (Kautter et al., 2012; Nelson, 2012b). Although each group was given much autonomy to determine how to add value and save cost, and many different interventions were provided, all
ten physician groups provided nurse-led care-coordination in some capacity generally in the form of disease management services or care-coordination for certain high-risk patient groups (e.g. CHF, diabetes) (Kautter et al., 2012; Nelson, 2012c).

The Physician Group Project also measured quality measures including hgb A1C > 9.0%, Blood pressure < 140/90, eye exams and influenza vaccinations (Kautter et al., 2012; Nelson, 2012b). The Physician Group Project sites were rewarded financially for meeting these along with a number of other quality goals (Kautter et al., 2012; Nelson, 2012b). Data was provided for annual eye examinations which indicated a statistically significant improvement over the 5 years (Difference in difference 1.52%, \( p < 0.01 \)) but did not reach significance in the first two years even at the 1% level (difference in difference 0.4%) (Kautter et al., 2012; Department of Health & Human Services, 2009). However, more data is reported at the end of the study (year 5) and there was significant variability in the sites when they evaluated each site individually. Seven of the sites showed eye examination rates with a statistically significant difference between the control clinic and the intervention clinic but two significantly improved in the control group (\( p < 0.001 \)) and 5 improved in the intervention clinic (\( p < 0.01 \) in 4 sites and \( p < 0.001 \) in 1 site) (Kautter et al., 2012).

Unfortunately, for A1C ≤ 9, blood pressure < 140/90, and influenza examinations, the data for the control sites was not reported since it was not included in Medicare claims data, and, therefore, only the annual percent changes at each intervention site for these variables were included. However, since each of the ten sites had complete autonomy in identifying strategies for quality and savings, it was not possible to evaluate the individual contribution of nursing care-coordination (Kautter et al., 2012).
The Physician Group Demonstration Project had reimbursement tied to 10 quality measures including annual eye examinations, annual influenza immunizations for those with diabetes over age 50, b/p < 140/90, and A1C ≤ 9 (Department of Health and Human Services, 2009). Although they found an increase in the overall percent of patients achieving these quality measures over the 5 years with results per site generally positive, the results were not always positive despite linking reimbursement to the quality measures. Since the control groups were reporting only on measures that could be electronically retrieved from the billing data, it was not always possible to determine whether these results were statistically significant in comparison to standard care. Finally, findings must be viewed cautiously as the control sites were not aware their data was being analyzed and the intervention sites were not only aware but were receiving financial incentives for improvement (Department of Health and Human Services, 2009).

**Case management.** The Case Management Society of America defines case management as “a collaborative process of assessment, planning, facilitation and advocacy for options and services to meet an individual’s health needs through communication and available resources to promote quality cost-effective outcomes” (Case Management Society of America (CMSA), 2015). According to the Medical Surgical Nursing Certification Board (MSNCB) (2018), care-coordination and transition management are umbrella terms for care practice roles that provide "individualized patient-centered assessment and care planning across settings, providers and levels of care." This role includes many different titles including "care coordinator, care manager, nurse navigator and case manager" as well as others (Medical Surgical Nursing Certification Board, 2018). According to a review by Joo and Huber (2018), the key ingredient to case management is care-coordination (Joo & Huber, 2018). Case managers are members of the care-coordination team who often provide the one-on-one services of care-coordination, liaison
with other team members, and self-care promotion activities with the individual patient and family. According to a study by Park and Huber (2009), 93.3% of case managers in the US are registered nurses (Park & Huber, 2009).

Current models of case management (CM) have begun to focus on preventing hospitalizations, rather than focusing on preventing 30-day readmissions. These models identified high-risk patient populations to improve health and healthcare quality. Case management models focus on monitoring and addressing patients' needs across the life span.

*Case management models improve blood sugar control.* Research indicates that these nurse case management models improved glucose management in the Type 2 diabetes population (Mullen & Kelley, 2006). In their retrospective study, Mullen and Kelley extracted medical record data from a previously unpublished CM intervention study of 52 adult patients (29-80) with diabetes who had completed the case management intervention with an A1C ≤ 7.0. The unpublished results of this CM intervention by Serwer, Escobedo, Kelley and Shimeall as cited by Mullen and Kelley (2006) found a mean decrease in A1C of 2.6% (from 10.4% to 7.8% during the program). The length of this case management program was unclear but case management involved an initial assessment in a multidisciplinary clinic followed by nurse case manager weekly calls for 12 weeks, monthly calls for 3 months and then quarterly calls. Based on health status, the nurse case manager could decide to return the patient to weekly supervision at any time. These patients also attended a diabetes education class and attended the diabetes care clinic which included a foot exam, dietitian-provided education, pharmacist review of medication for those with more than 5 medications, and a primary care provider visit with continued follow-up.
From this CM program, Mullen and Kelley (2006) evaluated 19 patients’ medical records who started the CM intervention with a baseline A1C ≥ 8.0% and had successfully finished the diabetes CM program with an A1C value of ≤ 7.0%. They found not only the expected significant changes in the A1C value between the beginning of the study and completion of the study (specific length of time unspecified) \( p < .001 \) but also a sustained change between the beginning of the study and six months following completion \( p < .001 \) (Mullen & Kelley, 2006). However, only 19 patients of the potential 53 eligible patients had complete data for all data points and therefore a major limitation is the rejection of data from over half the patients who did not have complete data in this retrospective study. No description of the differences between these two groups is provided. The implication of this study was that case management not only improved A1C outcomes but this improvement was maintained after a six-month period without continued case management services.

Watts and Sood (2016) evaluated a registered nurse case manager program in the Veterans Health Administration type 2 diabetes population. They did a quality improvement retrospective study of 15,636 patients' computerized record system and evaluated pre- and post-data (Watts & Sood, 2016). In this study, the nurse case managers were also certified diabetes educators and they evaluated all patients with type 2 diabetes who had an initial nurse case manager and at least one follow-up visit over a 10-year period (Watts & Sood, 2016). These case managers appeared to work independently within VA patient aligned care team clinics with patients with A1C levels > 9% (Watts & Sood, 2016). Patients participated in the quality improvement intervention until their blood glucose was stable when they returned to their PCP for further management (Watts & Sood, 2016). Patients were followed for 14-26 months and using t-tests to compare pre- and post-data demonstrated a significant A1C reduction of 2.1%
This study demonstrated the effectiveness of nurse case management on diabetes control for patients with uncontrolled type 2 diabetes.

C. B. Taylor et al. (2003) compared usual care to nurse CM in which the nurses used evidence-based algorithms to titrate medications and provide recommendations for care. Case management included an initial 90-minute consultation, weekly group class for 4 weeks and phone calls at 4, 5, 8, 12, 16, 20, 28, 36 and 44 weeks with additional calls scheduled as needed (C. B. Taylor et al., 2003). Usual care was care provided by their primary care physician along with a folder of information on diabetes (C. B. Taylor et al., 2003). Taylor et al. (2003) studied a population of 127 patients with Type 2 diabetes and a baseline A1C > 10% who had either hyperlipidemia, hypertension or cardiovascular disease (C. B. Taylor et al., 2003). In their RCT, they found that more patients in the intervention group (43%) achieved an A1C ≤ 7.5%, (p < 0.03) with a mean improvement in A1C of 1.14% drop in the intervention group compared to 0.35% increase in the control group (p = 0.01) (C. B. Taylor et al., 2003). This indicated that case management was significantly more effective in improving diabetes control for patients than usual care.

In 2006, Shojania et al. published a meta-regression analysis of 50 RCTs, 3 quasi-randomized trials and 13 controlled before and after trials to evaluate the effectiveness of 11 quality improvement strategies in Type 2 diabetes management on A1C. When they compared the mean post-intervention difference in A1C for all 26 studies, they found a -0.42% difference (95% CI, -0.29% to -0.54%) (Shojania et al., 2006). Additionally, when they separated the studies based on intervention strategies, they found two quality improvement strategies had greater statistically significant A1C reductions: a change in the care team and the provision of RN case management services (Shojania et al., 2006).
The change in the care team was employed by 26 studies with a total average A1C reduction of 0.67%; 95% CI, 0.43% to 0.91% (Shojania et al., 2006).

The change in care team intervention included the following four categories:

1. addition of a new team member of a discipline other than medicine
2. addition of more than one new team member or description of multidisciplinary
3. role of nurse or pharmacist adjusted
4. description of "shared care" between specialist and PCP (Shojania et al., 2006).

Teams that included members of other disciplines demonstrated statistically significant decreases in A1C post intervention (Shojania et al., 2006). Comparing the 16 studies using multidisciplinary team interventions to the 10 studies of team care without multidisciplinary team interventions, A1Cs were reduced on average by 0.37% more ($p < .001$) (Shojania et al., 2006). This indicates that RN case management and a multi-disciplinary team approach were the most effective quality improvement strategies in improving diabetes control for patients with diabetes.

Use of RN case management services was employed by 26 studies with a total average A1C reduction of 0.52%; 95% CI 0.31% to 0.73% (Shojania et al., 2006). When comparing the 26 studies with case management with the 24 studies that did not incorporate case management into the intervention, there was an average A1C reduction of 0.22% more (95% CI 0.00% to 0.44; $p = 0.04$) (Shojania et al., 2006). Further analysis described case management interventions based on four elements: (a) the professional background of the case manager, (b) the relationship between the clinic and the case manager, (c) the type of patient contact the case manager engaged in, and (d) whether the case manager could make medication adjustments or not (Shojania et al., 2006). They found that in the 11 studies where case managers could adjust
medications, A1Cs were reduced by 0.96% (mean) (95% CI, 0.52% to 1.41%) compared to 0.41% (95% CI, 0.20% to 0.62%) in the 15 trials that did not permit case managers to adjust medications (Shojania et al., 2006). From their meta-regression, they concluded that although most of the 11 quality improvement interventions produced some improvement in A1C, the most effective strategies on A1Cs were multidisciplinary team-based care and case management in which the case manager used algorithms to adjust medication (Shojania et al., 2006).

Egginton et al. (2012) performed a systematic review and meta-analysis of care management in a diabetes population in the United States, which included 52 studies. In their meta-analyses of the 17 studies of diabetes care management interventions that provided complete A1C measures, there was a significant difference in A1C means pre- and post-intervention (-0.22%; p = 0.02) (Egginton et al., 2012). However due to the significant heterogeneity in the studies (including sample characteristics, treatment variations, and the quality of the study design), Egginton et al. (2012) were unable to identify a specific intervention or team characteristic that was more significant in improving A1C measures.

**Case management effect on other diabetes health outcomes.** Results of the effect of CM on other health outcomes in the diabetes population is mixed. Gabbay et al. (2006) used a nurse CM intervention with the nurse fully integrated in the primary care clinic. In their random control trial of 332 patients with type 2 DM (150 intervention and 182 control randomized by odd/even numbers), they found that nurse CM improved both health process and health outcome measures (Gabbay et al., 2006). Although only the per cent change was reported, they claimed statistically significant improved process measures of completed annual ophthalmological exams (68% in IG vs. 26% CG), foot exams (64% IG vs. 47% CG), microalbuminuria screening (72% IG vs. 34% CG), dietitian visits (53% IG vs. 3% CG), certified diabetes educator visits (70% IG
vs. 3% CG), pneumonia vaccinations (50% IG vs. 6% CG), and smoking cessation counseling (96% IG vs. 76% CG) (Gabbay et al., 2006). They found significantly improved systolic blood pressure (mean systolic blood pressure decreased 9 mm HG (from 137 to 128) at 6 months and 8 mm (from 137 to 129) HG at 12 months, p < 0.001), and diastolic blood pressure (mean decrease of 5 mm HG at 6 and 12 months (from 77 to 72), p < 0.001) (Gabbay et al., 2006).

Gary et al. (2009) used a combined NCM/community health worker (CHW) intervention compared to usual care with an added lay educator reminder call for preventive health care screening visits. In an RCT study with a sample of 542 low-income urban African American adult Type 2 diabetes patients (488 completed the 24-month study, 235 intervention, 253 control), findings indicated that the NCM/CHW intervention was associated with a statistically significant reduction in ER visits (Gary et al., 2009). Specifically, at 24 months there was a 23% reduction in ER visits, (adjusted rate ratio (RR), 0.77; 95% CI, 0.59–1.00, p ≤ 0.05%) which increased to 34% when comparing those with the most NCM/CHW visits to those with usual care (95% CI, 0.43–1.00, p ≤ 0.05%). However, although hospitalizations also decreased, the decrease was not significant (Gary et al., 2009). Furthermore, this rate reduction in ER visits was greatest when there were more NCM/CHW visits (RD, 31.0% decrease; adjusted RR, 0.66; 95% CI, 0.43 to 1.00; adjusted rate reduction 34%; p ≤ 0.05%) (Gary et al., 2009). They also found a significant decline in A1C in those with a higher number of CHW/NCM visits vs. the usual care group (A1C -0.68%, p = .03), but this did not remain significant after adjustment for baseline A1C values, age and amount of time between baseline and final data point (Gary et al., 2009). This study demonstrated that the number of touches provided by care management might significantly decrease both A1C and ER visits.
Ishani et al. (2011) compared CM provided by a nurse who used an algorithm protocol to adjust medication with usual care. In their RCT (randomized based on computerized randomization in blocks of six) of 556 patients (278 intervention, 278 control) with Type 2 diabetes with at least one baseline value above goal (blood pressure > 140/90; LDL cholesterol > 100 or A1C > 9), findings indicated that the CM group was significantly more likely to achieve all three target measures after one year (61 (29%) vs 28 (10.1%) p < 0.01) (Ishani et al., 2011). This was also true for individual measures of blood pressure (40.6% intervention group vs. 15.9% control, p < 0.01) and A1C (40.5% vs 24.6%, p = 0.047) (Ishani et al., 2011). Findings supported the use of nurse case management in improving cardiac risk factors in patients with diabetes, particularly when the case manager could adjust medications per algorithms (Ishani et al., 2011).

In a population of patients with both Type 2 diabetes and hypertension, Edelman et al. (2015) evaluated telephonic nurse CM with focused bimonthly calls (IG) vs. bimonthly calls unrelated to diabetes or hypertension (CG) with inconclusive results. In their RCT of 377 patients with hypertension and diabetes with A1Cs > 7.5% at baseline, eligible patients were stratified by clinic and baseline blood pressure control and randomized on a 1:1 ratio to the intervention group (n= 193) or the control group (n=184) (Edelman et al., 2015). No difference in A1C or blood pressure was found between the two groups despite the fact that this intervention had been used to improve blood pressure effectively in an academic center (Edelman et al., 2015). However in this study, both groups improved A1C with no improvement in systolic blood pressure (Edelman et al., 2015). From these insignificant results, Edelman et al. (2015) surmised one of four possible explanations: (a) that the intervention might not translate well into a fee-for-service community setting; (b) that the intervention despite literature to the
contrary might not be efficacious; (c) that there was regression to the mean in the usual care group; or (d) that the study was underpowered for the effect size.

Micklethwaite, Brownson, O’Toole, and Kilpatrick (2012) evaluated a care team program (RN/RD team), which was a hospital-based program reaching out to the communities and clinics. The care team provided diabetes initial assessments to an underserved population followed by case management with face-to-face visits every six to eight weeks as well as patient education, and support in the participants’ individual clinic (Micklethwaite, Brownson, O’Toole, & Kilpatrick, 2012). This was a pre-/post-study of a subset of 81 participants who had used hospital services prior to enrollment (Micklethwaite et al., 2012). The primary outcome was cost effectiveness, and Micklethwaite et al. (2012) found that the total cost savings for the program was $551/patient per year due to decreased hospital facility use primarily for inpatient but also for emergency department and outpatient hospital use. Although they measured pre-/post-BMI, blood pressure, cholesterol and A1C for all 81 patients, only A1C significantly decreased from 8.31 to 7.54 (-0.77, \( p = 0.0036 \)) (Micklethwaite et al., 2012).

**AHRQ’s comparative effectiveness review of case management.** In 2013 AHRQ published a comparative effectiveness review of case management as a strategy for chronic illness management. They found that the interventions provided by case managers were based on the target population and varied greatly making these studies more difficult to compare (Hickam et al., 2013). Consequently, they separated the case management research based on population (Hickam et al., 2013). For Type 2 diabetes populations, they found that although case management did improve glucose management, it did not improve either lipid or BMI/weight management or reduce mortality or hospital utilization (Hickam et al., 2013).
**Nurse case management and cost of care.** Xing, Goehring and Mancuso (2015) evaluated a NCM intervention that included an initial comprehensive assessment, development of an individualized action plan, initial face-to-face meeting with both the patient, and PCP to refine the action plan—followed by phone or face-to-face meetings with the patient at least monthly and updated health action plans every six weeks. In their retrospective comparative effectiveness study of high-risk functionally limited Medicaid patients from 2007-2012, they used a nearest neighbor propensity score matching for factors including age, race, ethnicity, sex, medical risk score etc. to match the 907 CM patients with 907 usual care patients (propensity scores < 0.10 after matching) (Xing, Goehring, & Mancuso, 2015). They found that inpatient hospital costs were significantly decreased ($318, p = .01) in the intervention group (Xing et al., 2015). However, although the case managed group had decreased medical costs of $248 per member per month adjusted for program costs, the difference was not significant (p = .09) (Xing et al., 2015).

**Nurse care coordination.** Snaterse et al., in their 2016 meta-analysis of nursing care-coordination (NCC) random control studies in a population with cardiovascular disease, found 18 random control trials from 1994-2013 that met inclusion criteria with sample sizes that ranged from 138 to 2142 participants. In their meta-analysis, they found that NCC significantly lowered systolic B/P 2.96 mm Hg, (95% CI 1.53–4.40 mm Hg), LDL cholesterol 0.23 mmol/L, (95% CI 0.10–0.36 mmol/L), and improved smoking cessation rates by 25% (risk ratio 1.25; 95% CI 1.08–1.43) (Snaterse et al., 2016). In the nine studies that evaluated weight loss, only one demonstrated a statistically significant weight loss of 1 kg (p = 0.007) (Snaterse et al., 2016).

Snaterse et al. (2016) found it difficult to compare studies as there was no shared definition of nurse care-coordination. They also noted that the interventions were often broadly
structured over varied time frames making it difficult to pinpoint either the specific elements of
the intervention or the necessary time frame of these interventions to accurately and fairly
compare the effect of nurse care-coordination (Snaterse et al., 2016).

One conclusion is that the effectiveness of care-coordination may differ based on the
health system. Therefore, it is important to conduct research at each institution to determine if
that model, or a modification of a care-coordination model, is needed to improve quality, cost
and satisfaction of health care. This is consistent with the IOM study Best Care at Lower Cost:
The Path to Continuously Learning Health Care in America in that each health system must be a
learning community (Committee on Learning Health Care Systems in America & Institute of
Medicine, 2013; Interprofessional Education Collaborative, 2016).

**Nurse care management.** Holtrop et al., (2017) used a matched-pair cluster RCT in 10
primary care practices in midwestern US to evaluate both patients with DM2 and obesity. Five of
the clinics were randomly selected to participate in this care management intervention in which a
nurse joined the clinic and provided care management to all patients with either obesity or
diabetes type II with A1C > 9% (Holtrop et al., 2017). All patients who participated in the clinics
and met eligibility criteria were included in the study. Data was extracted from the EHR for the
year of participation (Holtrop et al., 2017). Patients in the five intervention clinics were matched
to a similar patient in one of the other 5 control clinics (Holtrop et al., 2017). These patients were
matched on baseline A1C, LDL levels, systolic blood pressure levels, disease status and initial
enrollment date (within 3 months) (Holtrop et al., 2017). Since there was some imbalance in the
two groups despite matching, differences were statistically controlled (Holtrop et al., 2017).
Findings indicated that in the diabetes group (n=443 pairs), A1C significantly improved to <7%
(95% CI, 3%-20%) (Holtrop et al., 2017). However, the care management intervention had no
effect on weight, systolic blood pressure or LDL cholesterol in type 2 diabetes (Holtrop et al., 2017). Interestingly, in the obese nondiabetic group (n=253 pairs), the adjusted difference in difference in weight was statistically significant with a 3.6% weight decrease (from baseline) (95% CI, -5.5, -1.7) (Holtrop et al., 2017).

Kearns (2017) found no statistically significant difference in any healthcare utilization (emergency room visits, hospitalizations (number or length of inpatient stay), urgent care visits or readmission rate) in his 3-year randomized cluster trial of a primary care redesign study intervention. His study, based on Wagner's Care Model, added certified diabetes educators (either nurse or pharmacist) to 5 of 10 randomly selected PCP clinics to manage care for patients with diabetes within the clinic (Kearns, 2017). The patients in both the control (9,988) and intervention group (9,708) were located initially through an electronic search of the EHR for all patients with any diabetes ICD-coded diagnosis or anyone referred for diabetes education (Kearns, 2017). The clinics were randomly selected for either care management or usual care and the patients were randomized by the clinic to which they belonged (Kearns, 2017). Each care manager (n=3) had an assigned medical assistant, both of whom were embedded in the five clinics as team members providing team continuity (Kearns, 2017). Usual care clinics personnel were scheduled for the other clinics as needed and did not work exclusively with any particular PCP or clinic (Kearns, 2017). Kearns (2017) found no significant change in any healthcare utilization after 1 or 2 years of the intervention. However, he stated that the benefits of care management may not be in resource utilization but in improving the quality of patient care (Kearns, 2017).
Collaborative Practice Models

The IOM, now the National Academy of Medicine, identified collaboration as a key element to improving quality (Institute of Medicine, 2001). This section will focus on the research surrounding collaborative practice as a method of achieving improved patient engagement, improved healthcare utilization, and clinical outcomes. There is very limited research on collaborative care models within the US. However, since it is unlikely that findings from other countries with significantly different healthcare systems can be extrapolated to the US health system, the data from Belgium's Interdisciplinary Diabetes Care Teams (Borgermans et al., 2009), Canada's interdisciplinary nurse navigator intervention (Dajczman et al., 2013), Canada's IMPACT clinic (Tracy, Bell, Nickell, Charles, & Upshur, 2013) or Canada's adaptation of the TEAMcare model (Johnson et al., 2014) were not included in this literature review.

TEAMcare model. This western Washington healthcare redesign program was a 12-month collaborative care model with physician-supervised nurse care management incorporating elements of both the Chronic Care Model and previous studies implementing collaborative care for patients with depression (McGregor, Lin, & Katon, 2011). The team included the TEAMcare nurse care manager (TCM), primary care provider (PCP), PCP’s care team, and TEAMcare consultants (physicians, psychiatrists, and psychologist) (McGregor et al., 2011). TCMs were integrated in the clinic they served and received two days of training on motivational interviewing, behavioral activation, depression management strategies, and diabetes and heart disease management (McGregor et al., 2011). TEAMcare psychiatrists assisted the PCP in determining the best antidepressant regimen for each patient in the intervention group (McGregor et al., 2011). Initially the TCM saw patients weekly to develop the relationship and ensure patient goal progression by providing patient self-management education and support,
care-coordination and continuity (W. Katon et al., 2012; W. J. Katon et al., 2010; McGregor et al., 2011). Weekly visits were gradually decreased so that by the end of the year, the mean number of face-to-face TCM visits was 10 and phone visits was also 10 with the majority of face-to-face clinic visits occurring in the first six months (McGregor et al., 2011). TCMs had set protocol parameters to transition to maintenance care or relapse prevention based on the patient’s progress to goals (McGregor et al., 2011). In addition, the TCM participated in weekly caseload reviews with the consultants who supervised care (McGregor et al., 2011).

In an RCT (intervention group = 106 and control group = 108), TEAMcare was tested in 14 Group Health primary care clinics in Washington recruiting a population of 214 patients with either poorly-controlled DM2 (A1C ≥ 8.5%) or coronary heart disease (CHD) (systolic B/P > 140 mm/HG or LDL cholesterol > 130 mg/dl) and a depression score ≥ 10 on the patient health questionnaire-9 (PHQ-9) (W. J. Katon et al., 2010; McGregor et al., 2011). Findings indicate that at 12 months, the intervention group demonstrated statistically significant improvement in the outcome composite measure that included the difference in A1C, LDL cholesterol, systolic blood pressure and SCL-20 depression score (p < 0.001) (W. J. Katon et al., 2010). However, this difference in A1C, LDL cholesterol and systolic blood pressure was not sustained at 24 months despite the TCM focus on diabetes and CHD (W. Katon et al., 2012).

Lin et al.'s (2014) post hoc analysis of the TEAMcare data found that clinical benefits of TEAMcare occurred early in the intervention and were most favorable for those with poor control of the outcome at baseline. Since Katon et al.’s (2012) inclusion criteria mandated only one of three baseline criteria: A1C ≥ 8.5% or systolic B/P > 140 mm/HG or LDL cholesterol > 130 mg/dl, Lin et al. (2014) divided the groups into “more vs. less favorable control” for each of these 3 baseline values (Lin et al., 2014). Despite being underpowered, they found that in the
less favorable A1C control group, the A1C remained significantly decreased at 18 months (-0.86, \( p = 0.028 \)) with an insignificant decrease from baseline at 24 months (Lin et al., 2014). This indicated that the benefits of a 12-month TEAMcare program for diabetes could last for at least an additional 6 months (Lin et al., 2014). They also found that the improvement in systolic B/P was for the most part sustained for the 24 months (although not statistically significant) (Lin et al., 2014). However, in the groups with more favorable control, there was no difference in medical control for A1C or systolic blood pressure (Lin et al., 2014). This indicated that the benefit of collaborative care coordination would likely be greatest with patients in less favorable control and could last beyond the length of the intervention.

**Buena Salud program.** This was an insurance-sponsored 'enhanced primary care model'. The multi-disciplinary team added two nurses, two outreach workers and a case manager (all bilingual) to the primary care team (Goff et al., 2017). It is unclear whether these team members were integrated into the clinic or whether they worked outside the clinic (Goff et al., 2017). Most patients who participated in the self-management program were referred by their PCP (Goff et al., 2017). No information on the workflow was provided other than that the team members used patient monitoring tools, concentrated on patients with chronic conditions and worked to develop trusting relationships with this Hispanic population (Goff et al., 2017). This study of the intervention was a retrospective medical record review of 72 patients in the intervention and 247 in the matched group (Goff et al., 2017). All patients had type 2 diabetes and the match was based on the date the intervention patient started the study with up to 3 patients matched to each intervention patient (Goff et al., 2017). There were differences in the groups in that the control group was older (54 vs 50) with a lower baseline A1C and were less likely to have anxiety or depression and more likely to be HIV infected (Goff et al., 2017).
Findings indicated an increase in diastolic blood pressure for the intervention group of 2.6 (95% CI = 0.8 – 4.3; p = 0.004) and no significant difference in A1C, systolic blood pressure, emergency room visits or hospitalizations (Goff et al., 2017).

**ImpACT model.** This VA team model augmented the PACT teams at the VA (Wu, Slightam, Wong, Asch, & Zulman, 2018). PACT teams included the PCP, nurse, clinical associate and administrative assistant (Wu et al., 2018). The ImpACT model included a nurse practitioner, social worker, recreation therapist, administrative coordinator and a supervising physician who were co-located in the same clinic to enhance communication and teamwork (Wu et al., 2018). These members had weekly meetings to discuss high acuity patients and worked with patients for a complete assessment of physical, mental, emotional, and social health (Wu et al., 2018). They assisted with goal setting, coordinating care, managing chronic conditions and provided transitional care (Wu et al., 2018). They provided 24 hour phone service (Wu et al., 2018).

They randomly selected 150 participants for the ImpACT model with standard care being the PACT model which the remaining 433 patients received (Wu et al., 2018). Two years after starting the ImpACT Model, Wu et al. (2018) evaluated the ImpACT model patients both two years pre- and two years post- ImpACT model and compared the ImpACT model patients with the RCT patients receiving usual VA care (PACT model). They evaluated continuity of care by the number of PCP visits and found a significant increase in both the post data and in the ImpACT group over the usual care group (p <0.001) (Wu et al., 2018). They also evaluated telephone encounters and missed visits as variables of care access (Wu et al., 2018). Similarly, they found significant increases in telephone encounters for the ImpACT group post-intervention over the usual care group (p <0.001) but no significant difference in missed visits (Wu et al.,
They used personal health record (PHR) registration and advanced directive (AD) discussion/completion to measure patient engagement and found significant improvement in AD discussion or completion ($p < 0.001$) (Wu et al., 2018). Wu et al. (2018) did not report on healthcare utilization. Findings indicated that the ImPACT model enhancement to the PACT medical home interdisciplinary model improved care continuity, portal registration and AD discussion or completion with no improvement in missed visits (Wu et al., 2018).

**Gaps in the Research**

Care-coordination does improve A1C, but it does not improve weight, LDL cholesterol, or healthcare utilization in the diabetes population. Care-coordination is most successful in higher risk populations. Less is known about how care-coordination works or the essential elements of the care-coordination intervention other than, as Hansen et al. (2011) pointed out, it appears this intervention is more successful when individual interventions are bundled together.

Much less research has been done on collaborative care and what the essential elements of a successful collaboration look like. In analyzing the literature on care-coordination and collaboration, several gaps were identified. The following section will summarize these gaps.

**Gap 1: Little is known about how collaborative care should be integrated into healthcare redesign in primary care.** Although it is clear that care-coordination and team care are effective in improving A1C outcomes in the Type 2 diabetes population, little research has been done on what is the best model of care to collaborate and deliver care-coordination. More research is needed to evaluate the effectiveness of care-coordination and case management within the primary care setting. Primary care provides the on-going relationship and has the potential to optimize health and prevent complications. Primary care research is needed to identify optimal team membership, the best model of care delivery within the team, and how to
measure team effectiveness in terms of patients and patient care outcomes (Haas, Vlasses, & Havey, 2016).

Most of the research on system redesign incorporating interprofessional collaboration and care-coordination in primary care has been done in other countries with very different health systems or in a large U.S.-managed care system rather than in the general population within the primary care clinic.

**Gap 2: Few studies provided a well-defined description of the care-coordination intervention.** As Popejoy et al. (2015) point out, it is difficult to identify or measure care-coordination as there is not a well-defined ontology of this concept. Consequently, further research to identify and define the specifics of care-coordination interventions especially in primary care settings is essential if the goal is to quantify the impact of these interventions (Popejoy et al., 2015). Most studies, including the PCMH research, bundled care-coordination with other strategies, making an evaluation of the benefits of care-coordination in isolation difficult. Consequently, care-coordination interventions need to be very specifically defined so that interventions are equivalent and future meta-analyses can be successfully performed. Studies that evaluate detailed care-coordination strategies for patient engagement, health-care utilization, and health outcomes including patient reported outcomes are needed. Identifying a system of specifically quantifying interventions to ensure compatibility is essential to making the data more homogeneous and thus easier to interpret.

**Gap 3: Optimal dose of care-coordination.** The appropriate dose of care-coordination for each patient population needs to be evaluated. Many studies of care-coordination extend the intervention over different lengths of time and there have been no identified studies of what is the best dose of nurse visits either in the home or in the clinic as well as phone visits to achieve
optimal outcomes at the lowest cost. In fact, it is also not clear what the timing of visit and phone interventions should be (Meisinger et al., 2013).

**Gap 4: Length of care-coordination intervention.** No studies have identified the optimal length of time to continue intensive care-coordination services to achieve optimal long-term results. Mullen and Kelley (2006) found that care-coordination had an effect for a full six months after the intervention. It is possible that after an initial exposure to intense care-coordination, many patients may reap the benefits for some time. It is unclear how much time care-coordination is needed.

**Gap 5: Research focused on the effect of care-coordination on patient-reported outcomes.** Little to no research indicated the effect of care-coordination on patient-reported outcomes. This limits the ability to evaluate patient-centered care. As Egginton et al. (2012) point out, research that focuses on issues that are important to patients like quality of life, symptom improvement, decreased complications, or increased life expectancy—rather than surrogate measures like lab values—is needed if patient-centered care is a goal in health system redesign.

**Gap 6: Team-based care models.** There is little research describing what constitutes an effective team or what the make-up of that team should be to achieve the best care.

**Gap 7: Theory-based research.** Most studies lacked a theoretical framework. A theory would help guide research.

**Gap 8: Electronic health records.** If the U.S. healthcare system is truly to become a system of learning as the IOM suggests, then a focus for each health system must be to use the multitude of data already generated by their unique patient population and patient encounters to improve the effectiveness of the care each health system provides (Committee on the Learning
Health Care System in America & Institute of Medicine, 2013). As both Burkhart et al. (2016) and McMillan et al. (2013) pointed out, there are vast differences in how patients respond based on the patients’ culture, history, and the clinic environment itself. However, few studies were found that demonstrate how a health system has learned from its own health care data.

**Research gaps addressed.** This study will focus on the following gaps (1, 2, 6, 7 and 8) indicated above. First it will evaluate a nurse-led, team-based care-coordination model within a primary care clinic rather than a hospital or specialty care model (Gaps 1 and 6). Second, by specifically defining the model and following a well-researched theory, later comparisons of team-based, nurse-led care-coordination for high-risk diabetic patients will be possible (Gaps 2, and 7). Finally, it will provide a strategy for using secondary patient data from the EHR to improve primary care offered to patients within a health system (Gap 8).
CHAPTER THREE

METHOD

The purpose of this research study was to compare the effectiveness of a new model of care in ambulatory primary care practice, a nurse-led interprofessional care-coordinated collaborative team approach (ICCCM) with standard ambulatory primary care practice. This study was part of the Interprofessional-Collaborative Redesign and Evaluation for Population Access to Health (I-Care-PATH), funded by the Health Resources and Services Administration (HRSA #UD7HP26040, PI-Vlasses). Nurse-led interprofessional collaborative practice teams were developed within a family practice clinic to provide optimal healthcare to residents of a low-income, diverse community as well as to provide interprofessional learning opportunities to students in healthcare professions.

This chapter presents the study design, sampling criteria, variables studied and data collection methods used for this comparative effectiveness research study. The overall aim of this research study was to measure the effectiveness of a nurse-led interprofessional team in primary care on (a) patient engagement, (b) health care utilization, and (c) clinical indicators of high-risk patients with Type 2 diabetes in a low-income, diverse urban setting. Effectiveness was measured pre/post within the ICCCM site and in comparison to similar patients who received standard primary care in the same health system. To address this overall aim, the following hypotheses were addressed:
• H1a: Adult patients with Type 2 diabetes had better patient engagement (number of missed visits (no show encounters/same day cancellations), annual influenza immunizations, and annual eye examinations) after one year's participation in the ICCCM model in comparison to one year prior to participation in the ICCCM model.

• H1b: Adult patients with Type 2 diabetes, who received care at the ICCCM (intervention) site, had better patient engagement (number of missed visits (no show encounters/same day cancellations), annual influenza immunizations, and annual eye examinations) after one year than a sample of matched patients with Type 2 diabetes who received standard primary care within the same health system over that same year.

• H2a: Adult patients with Type 2 diabetes had better health care utilization (fewer hospitalizations, fewer hospital days, and fewer emergency room visits) after one year's participation in the ICCCM model in comparison to one year prior to participation in the ICCCM model.

• H2b: Adult patients with Type 2 diabetes who received care at the ICCCM (intervention) site had better health care utilization (fewer hospitalizations, fewer hospital days, and fewer emergency room visits) after one year than a sample of matched patients with Type 2 diabetes who received standard primary care within the same health system over that same year.

• H3a: Adult patients with Type 2 diabetes had better clinical indicators (percent of patients with Hgb A1C levels > 9.0; change and difference in Hgb A1C, weight, and systolic and diastolic blood pressure, systolic blood pressure < 140, diastolic blood pressure < 90) after one year's participation in the ICCCM model in comparison to one
year prior to participation in the ICCCM model.

- **H3b**: Adult patients with Type 2 diabetes who received care at the ICCCM (intervention) site will have better clinical indicators (percent of patients with Hgb A1C levels > 9.0; change in Hgb A1C, weight, and systolic and diastolic blood pressure, systolic blood pressure < 140, diastolic blood pressure < 90) for one year than a sample of matched patients with Type 2 diabetes who received standard primary care within the same health system over that same year.

**Study Design**

This study used a retrospective, longitudinal, matched design employing secondary data. It was retrospective in that the data were extracted from the EHR from June 2013 through June 2016. The data were longitudinal in that the data points were extracted at three different time points from June 2013 to June 2016. It was a matched comparison in that participants in the treatment group were matched using propensity scores to control for confounding variables of age, gender, race, insurance, baseline A1C, and comorbidities. It was a study using secondary data in that the data were already collected for another purpose and then were extracted based on specified data extraction rules (see Table 3, Data Extraction Rules for Sample #3 and Table 4, Dependent Variable Data Extraction Rules). The research design framework is presented in Figure 4, which describes the treatment group that received the ICCCM model of care and the standard model of care. Figures 5 and 6 provide the design schematic and the design notation.
Figure 5. Research design schematic

Treatment Group:

Patient outcomes in ICCCM → ICCCM Redesign - Innovation → Patient outcomes in ICCCM

Comparison Group:

Patient outcomes in comparison sites → Patient outcomes in comparison sites

Time 2 | Time 1 | Time 3

Figure 6. Research design notation

<table>
<thead>
<tr>
<th>1 yr prior to BL</th>
<th>BL</th>
<th>Intervention</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 yr post BL (ICCCM)</td>
<td>T2</td>
<td>T1</td>
</tr>
<tr>
<td>N (Matched)</td>
<td>T2</td>
<td>T1</td>
</tr>
</tbody>
</table>

**Human Subjects Protection**

Data were extracted by a research analyst in the health system into tables based on the data extraction rules (See Data Extraction Tables 3 and 4). The data were stored on a protected server provided by the Institutional Review Board (IRB). The health system Institutional Review Board approved this study through expedited review in August of 2017 and reapproved this study in August of 2018.

**Sample**

Consistent with Wagner’s The Care Model, the sample will be described in terms of the community, health system and individual participants.
Community. The community served is a large Midwestern city and its surrounding counties. In 2013, the community in which the ICCCM clinic was located had an estimated median household income of $41,794 and a median resident age of 35.1 years (City-Data, 2016). For community citizens aged 25 and over, 76.7% had at least a high school education and 15.5% had a bachelor’s degree or higher (City-Data, 2016). Approximately 75% were black and 53.4% were female (City-Data, 2016). The community in which the satellite clinic was located, had an estimated median household income of $57,823 and a median resident age of 40.3 years (City-Data, 2017). For community citizens age 25 and over, 85.8% had at least a high school education with 25.8% having a bachelor’s degree or higher (City-Data, 2017). Approximately 65.5% were white, 27.1% were Hispanic, and only 1.9% were black with 52.6% being female (City-Data, 2017).

The community in which each of the other clinics are located are all within the large Midwestern city or the surrounding counties. These clinics vary in median household income, median resident age, educational level, race and sex. Consequently, rather than matching clinics, participants were propensity matched (See Matched Sample).

Diabetes, hypertension, obesity and hypercholesterolemia were among the top health problems identified by respondents on the health needs assessment survey (Loyola University Health System, 2013a). This report also demonstrated that there are substantial disparities in unemployment rates, educational levels and socioeconomic status as well as health status in this population (Loyola University Health System, 2013a). The respondents surveyed identified the following barriers to health: decreased access to preventive and specialty care, coordination of healthcare, nutritional education, healthy food desserts, few safe places to play, and economic instability (Loyola University Health System, 2013a).
**Health system.** This health system provided primary care to a six-county metropolitan area in the Midwest (Loyola University Health System, 2013b). This large Jesuit academic medical center had 29 clinic locations throughout this metropolitan area. Of these clinics, 15 were primary care clinics.

**ICCCM clinic sites.** The ICCCM clinic was a family practice medicine clinic with one satellite clinic in a large Midwestern collar county community. These primary practice clinics provided care to patients of all ages by 13 family medicine physicians, one internal medicine physician, and two nurse practitioners (personal communication, Sandra Brehm, Director & Clinic Manager, 5/4/2017). These two clinics provided primary care to patients in high-need geographic community areas.

**Patient Sample**

The initial intervention sample was a convenience sample of patients with Type 2 diabetes from both intervention clinics who participated in the I-CARE-PATH model of care. The comparison group was comprised of propensity score matched patients with Type 2 diabetes from one of the 13 comparison primary care clinics within this academic medical center.

Inclusion criteria for the ICCCM intervention were adult (> 18) patients with type II diabetes who were active patients of one of the two intervention clinics who had been identified by the nurse care coordinators. The nurse care coordinators identified eligible patients by searching the Phytel database, a population management software tool, for all patients with Type 2 diabetes in these two clinics whose last A1C was between 8–10. Patients with an A1C greater than 10 were eligible to participate in the ICCCM only if they expressed a desire to manage their diabetes or were recommended by their primary care physician. In addition, primary care
physicians identified patients that they felt would benefit from care coordination (called a “gut check”).

Intervention participants for this study included the ICCCM patients. These were identified as patients assigned and actively followed by care coordinators, with a start date (T1) identified by the care-coordination entry into the problem list. An additional inclusion criterion was a diagnosis of type 2 diabetes for over one year prior to the T1 date; that is, prior to the T2 date.

Exclusion criteria for the intervention group were those patients with Type 2 diabetes who either did not have care-coordination entered into the problem list, were newly diagnosed with type 2 diabetes at T2 or after T2, expired prior to T3, dropped from the study prior to T3, or were pregnant the year prior to or during the care-coordination intervention (June 2013–June 2016). If care coordination was not entered in the problem list, no T1 date could be identified so these intervention patients were excluded. Pregnancy was an exclusion since A1C levels can be inaccurate due to the increased red blood cell turnover pregnant women experience, therefore patients who are pregnant rely more on glucose testing than A1C levels (American Diabetes Association [ADA], 2016). All patients provided from the available care coordinators list who met inclusion and exclusion criteria were included in the intervention group in this study (n=204).

Matched patients had to meet the same inclusion/exclusion criteria. However, they also had to be seen by either a family practice or internal medicine primary care physician within one of the 13 comparison clinics during the same period of time as their matched intervention counterpart (June 2014-June 2016). Therefore, matched patients were also excluded if they did not have a primary care physician within the health care system for the period from T1 to T3,
had expired prior to the T3 date, or were newly diagnosed or diagnosed after the matched T1 date. Potential match’s medical records (n = 371) were reviewed to ensure that they had a primary care physician contact within 6 months of T1 and T3 and to ensure that they were not pregnant during this time (see matched control sample Chapter 4). Potential matches were not excluded if they had missing data elements.

**Matched Sample**

Each participant was propensity-score-matched to a comparison participant to optimize the sample while ensuring a representative sample (Lanehart et al., 2012; Lanza, Moore, & Butera, 2013). A determination of the best possible match for each of the Type 2 diabetic intervention patients was made by statistically evaluating gender, race, ethnicity, language, age (Xing et al., 2015), insurance coverage (Medicare, Medicaid, private insurance payer, uninsured/self-pay as primary payer of services) (Jack et al., 2009), baseline A1C, and comorbidities based on the Charlson Comorbidity index diagnoses (D’Hoore, Sicotte, & Tilquin, 1993; Xing et al., 2015). In addition, it was determined that an estimate of the number of years since diagnosed with diabetes could be extracted from the administrative data, therefore this was also included in the match. Race and insurance coverage were matched to control for socioeconomic status. The insurance coverage match used the categories of Medicare, Medicaid, private insurance payer, uninsured/self-pay as primary payer of services (Jack et al., 2009). Since it is easier to achieve a greater reduction in A1Cs that are higher at baseline making regression to the mean a study limitation, baseline A1Cs were matched (The California Medi-Cal Type 2 Diabetes Study Group, 2004). Since the severity of chronic conditions increases over time, age was matched. Comorbidity was matched using the Charlson Comorbidity Index diagnoses using ICD-9 codes (D’Hoore et al., 1993) individually (rather than the index number). Specifically,
patients were matched for the following ICD-9 code diagnoses: cancer, metastases, dementia, cerebrovascular disease, diabetes with chronic complications, HIV, peptic ulcer disease, rheumatic disease, renal disease, liver disease either mild or moderate/severe, myocardial infarction, hemiplegia or paraplegia, chronic pulmonary disease and peripheral vascular disease using the algorithms described by Quan, et al. in 2005. Although only 4 patients in the intervention group required a translator, language was matched based on English verses non-English speaking as the primary language.

Data Sources

Data for this study were collected at all clinics and entered in the electronic medical record by the patient care tech (PCT), medical assistant (MA), licensed practical nurse (LPN), registered nurse (RN), and/or physician or administrative desk staff (service representative). EpicCare (Epic Systems, Verona, WI) is a common electronic health record system that began in the ambulatory clinic setting of this academic medical center in 2004. All of the clinics had been using Epic successfully since 2004 to document all patient care services provided and for decision support purposes. Epic is a robust electronic health record relational database used for data entry at the point of service. Epic manages clinical data (entered at the point of care by the appropriate provider), financial administrative data (entered by administrative personnel), and healthcare encounter information (entered by both administrative personnel and service associates). Data from the Epic EHR is downloaded daily into Clarity (Clarity Software, United Kingdom), a business management software tool, and Phytel (IBM Phytel, United States), a population management software tool. The care coordinators used Phytel to extract patient information related to primary care. Phytel provided the data (care history, relevant lab data, and care needs based on protocols; e.g., screenings) that the care coordinator used for decision
support. The Epic data were further downloaded into the data warehouse where it was extracted by the data analyst using data extraction rules (See Data Extraction Tables 3 and 4).

**Research Study Variables**

In this study, the intervention, or ICCCM, was the independent variable while the dependent variables were the patient engagement indicators (missed visits (no show encounters/same day cancellations), influenza immunizations, and annual eye examinations); healthcare utilization indicators (number and length of hospitalizations, number of emergency room visits); and the clinical indicators (Hgb A1C, weight, systolic and diastolic blood pressure). Each will be defined below.

**Independent variable: ICCCM intervention.** The ICCCM was a primary care, nurse-led interprofessional collaborative care-coordinated team model of care. Key characteristics included location of team members in the same clinic for convenient, daily communication; an equal voice in decisions for all team members; and the opportunity for all team members to help plan and improve the model. Three interprofessional collaborative practice teams were created, and each team included a nurse care coordinator, social worker, dietitian, and primary care physician. Since each clinic housed all employed team members including the primary care physician, each patient had all his/her care needs met at one time in the same clinic and team members communicated concerns daily with other team members. The patient population targeted was patients with Type 2 diabetes with high A1C levels (≥ 8.0 and < 10). Patients who met criteria were assigned a team.

**Model development.** A number of steps were taken to develop the interprofessional collaborative teams within this primary care clinic. These incremental steps were documented as
they occurred in the I-CARE-PATH meeting minutes. The following is a description of those steps taken in designing the intervention (Burkhart, et al., 2019).

*Step 1.* Develop a leadership team. This team included key leadership members from the schools, the clinic and the health system. Key members of this team were the health system upper management, Principle Investigator of the grant, Dean, and attorneys. This leadership team created the infrastructure and policy to link the health system and school initiatives. Key activities of the leadership team included contract negotiation and developing job descriptions.

*Step 2.* Create transformational teams including key members of the school, clinic, information technology department, and health system. This transformational team facilitated the system redesign by providing process evaluation and redesign, general oversight of the care redesign in the clinics, troubleshooting problems, and identifying opportunities to integrate the processes between the health system and the University schools/programs.

*Step 3.* Create interprofessional teams at the two clinics. Members of this team included providers and staff at the clinics, registered nurses, social worker, dietitian, physician, psychologist, licensed practical nurses, medical assistants, patient care technicians, desk staff, office manager, and clinic coordinator. The key activities of this team included participating in interprofessional training and providing feedback to further develop training materials.

*Step 4.* Identify the patient population to be care-coordinated. A phase-in system was used that began with the identification of Type 2 diabetic patients with A1Cs either between 8-10 or those with A1Cs > 10 who were motivated to manage their diabetes. A population management software linked to the electronic health record was used to identify current patients meeting the A1C criteria. In addition, patients who might benefit from care-coordination were identified by their clinic primary care provider. This was called the “gut-check.”
Step 5. Create patient panels for each interprofessional team (registered nurse care coordinator (RNCC), nurse practitioner care coordinator (NPCC), physician, social worker (SW), and dietitian (RD)). These interprofessional teams met monthly.

Step 6. Develop and establish multiple patient communication strategies. These communication strategies included telephone encounters, face-to-face meetings, group visits and group workshops. Telephone encounters were used to establish or strengthen relationships, coordinate care, and foster patient accountability and empowerment. Specifically, telephone encounters were used for touching base, following up on medication changes or, prescription refills, and ordering supplies.

Face-to-face meetings occurred during clinic visits to maximize the time the patient was in the clinic. These meetings were individualized based on patient needs and could include the social worker, dietitian and/or care coordinator as needed. Similarly, group visits made use of the time the patient was in the clinic. At these clinic visits, based on patient needs, a team member might join the physician during the visit or schedule a visit immediately after the physician clinic visit.

Group workshops were provided as outreach workshops for groups of patients to provide diabetes education, meal planning, and smoking cessation support. Patients could sign up for a single specific workshop or for a class series. Finally, support groups were offered to help empower patients to support each other in integrating healthy behaviors into their lives.

Step 7. Develop and follow a process for patient outreach for care-coordination. This included developing and following a process for initial contact/recruitment, on-going contact and discharge from care-coordination. Communication and care plans were individualized based on patient needs. This workflow included a process for adding patients to the care-coordination
worklist, removing patients from the care-coordination worklist, and telephone scripts for telephone communication.

Step 8. Establish monthly multidisciplinary care-coordination team meetings including the care coordinator, physician, social worker and dietitian. These teams met to review patient care plans for a select group of patients (approximately five each for both the RNCC and the NPCC). The RNCC and NPCC selected the patients to be discussed based on patient selection guidelines. The care coordinator maintained a multi-team meeting spreadsheet with the latest patient data (last and next appointments, last A1C, last lipid profile, statin dose/name as applicable, last microalbumin, names and doses of angiotensin-converting enzyme inhibitor (ACE) and angiotensin II receptor blockers (ARB), as well as any other important lab values). The Better Outcomes for Older adults Through Safe Transitions (Boost) tool was used to guide these monthly care-coordination meetings, as the tool incorporates medical, social and environmental determinants of health associated with hospital readmission (Society of Hospital Medicine, 2016). These include needs associated with medications, psychological issues, principal diagnosis of diabetes and other chronic conditions, physical limitations, health literacy, support system, prior hospitalizations, and palliative care (Society of Hospital Medicine, 2016). These meetings provided an opportunity for the healthcare team to review and optimize patient care plans, which were discussed and aligned with the patient’s health goals at the subsequent appointment. The team discussed each case and concurrently documented care planning during these meetings. An EHR screen was developed by the nurse informaticist to guide meeting workflow and document assessments and care plans. In addition, a timekeeper ensured that time was used wisely with six minutes per patient allotted for the discussion.
Step 9. Establish daily communication patterns within the team. At the beginning of each day, each physician met with the team member who “roomed” the patient (LPN, PCT, or medical assistant) to review the plan of the day for all scheduled patients. This was the morning “huddle.” If a care-coordinated patient was scheduled for that day, the care coordinator also met with the patient. Sometimes the care coordinator joined the physician during the visit, and sometimes the care coordinator met with the patient after the physician visit, depending on workflow. If the patient needed to meet with the dietitian or social worker, every attempt was made to incorporate that meeting during or immediately after the physician visit.

The daily nurse workflow was redesigned to integrate care-coordination. The following items describe the care coordinators’ (CC) workflow redesign.

- Checked email and calendar.
- Responded to phone messages and triaged calls from patients.
- EPIC communication occurred continuously throughout the day including:
  - responded hourly to in-basket messages
  - responded to patient emails
  - refilled patient medications
  - entered referrals
- Checked MDs’ folders throughout the day for authorizations, faxes.
- Checked physician team members’ hospital discharged patients from the EPIC inpatient lists.
- Called back care-coordinated patients only.
- Checked Team PCP schedule for future pre-visit lab work.
- Care-coordination (CC) activities:
Checked Team PCPs clinic schedule for any visits by care-coordinated patients.

- Informed PCPs' RN that the CC would like to speak to care-coordinated patients before or after the clinic visit.
- Requested impromptu care-coordination meetings as needed.

Weekly face-to-face care-coordination visits.

- Each CC had approximately two face-to-face patient visits per week.
- Each visit was approximately 1 hour.

Prepared for the multidisciplinary team meeting with each Team PCP.

Participated in Multidisciplinary Team meetings.

Attended care-coordination-related meetings

Followed up with care-coordinated patients.

- Contacted new care-coordination patients.

- Updated care-coordination documentation in EPIC and Phytel.

- Checked calendar/agenda for following day.

- Prepared monthly care-coordination dashboards.

**Step 10.** Provide community outreach and collaboration with community partners.

Relationships were built with schools and community centers to offer wellness programs. Specific initiatives included coordination of health fairs at pre-schools and high school, active participation in the community consortium charged with changing the environment for sustainable health outcomes for the township, and offering health wellness programs through the local community center.

**Step 11.** Established a workgroup to troubleshoot issues and learn from the health system redesign. This team was called $C^2$ and included the care coordinators, social worker, and
dietitian. They met every two weeks to troubleshoot problems, proactively identify strategies to support interprofessional collaborative practice and streamline workflow. In addition, this team developed initial designs for marketing, patient education materials, and welcome packages. This team helped create the organizational culture of support and collegiality.

*Step 12.* Ensured that the EHR supports, captures and measures outcomes of the new health system redesign. Documentation that aligned with the health care redesign model followed the new model’s workflow so that providers could easily document and capture data which could later be used for decision support (Haas et al., 2016). The EHR supported the provider workflow.

The nurse informaticist met regularly with the healthcare team to discuss workflow and optimize documentation needs. Documentation flowsheets included:

- outreach encounter documentation
- telephone encounter documentation
- monthly meeting documentation
- care coordinator-led team meetings utilizing the 8 Ps of the BOOST tool to accurately include the social determinants of health
- asynchronous encounter documentation to capture email data from the portal system

In addition, the nurse informaticist served on institutional committees in which she helped to ensure that documentation was designed to support future care-coordination efforts and extract summary reports that reflected the work of care-coordination.

*Team training in interprofessional practice to enhance productive interactions.* Team training was provided that focused on Interprofessional Education (IPE) competencies including values, roles, communication, and teamwork (Interprofessional Education Collaborative, 2016).
Each competency was addressed through didactic on-line modules, case analysis, and simulation. Care coordinators also attended motivational interviewing training. In addition, new team members received four (PCT/MA) to six and a half (nurses) hours of EPIC training (personal communication Mary Lou Knytych, EHR Inpatient Trainer, June 27, 2017).

**Dependent variables.** Dependent variables are listed below, along with their conceptual definition, and data collection methods. These definitions and data extraction rules are summarized in Table 4.

**Patient engagement.** Patient engagement is the concept of how interested and activated a patient is to maintain his/her own health. The underlying assumption is that those who are more engaged in their healthcare will show up to appointments, take recommended healthcare advice (influenza immunizations) and schedule preventive care. In this study, patient engagement was operationalized using the following variables.

*Missed appointments (no show visits and same-day cancellations).* A missed (no show and same-day cancellation) visit at this health care facility was defined as a visit that was not completed because the patient did not show up or call to reschedule on the day of the scheduled visit.

Same-day cancellations were scheduled encounters that were canceled on the same calendar date as the scheduled appointment.

Both no show visits and same-day cancellations were operationalized as the total number of missed visits from the Epic Encounters Database. Per protocol, these data were entered into the Epic Encounter Database by the service representative on the day of the scheduled visit. All service representatives were trained to follow Epic protocol by the healthcare institution.
Influenza immunization. Influenza immunizations were provided to prevent patients from contracting influenza. At the time of this study, the Centers for Disease Control recommended Influenza immunizations for all patients with diabetes who did not have a life-threatening allergy to the vaccine itself or any of the vaccine ingredients (Centers for Disease Control and Prevention [CDC], 2016a). Since this was an annual immunization, this variable was operationalized as a dichotomous variable (received or not received) for each time period (T2-T1, T1-T3). Vaccinations provided by the clinic or within the health system automatically populated the EHR. If the vaccination was administered outside the health system, the patient provided written or oral verification. If the patient provided oral verification without a written report, the patient's estimated exam date was documented.

Dilated retinal eye examination. An annual dilated retinal eye examination was recommended for patients with Type 2 diabetes. This variable was operationalized as a dichotomous variable (received or not received) for each time period (T2-T1, T1-T3). Eye examinations provided within the health system automatically populated the EHR. If the exam occurred outside the health system, the administering clinic submitted a written report to the primary care clinic. If the patient provided oral verification without a written report, the patient’s estimated exam date was documented.

Health care utilization. Health care utilization was a measure of how many high cost visits (emergency room and hospital) were being provided to each patient. Health care utilization was operationalized as count measures of the total number of hospital visits, emergency room visits, and total number of hospital days between each time-point.

Emergency department visits. These were any visits to the emergency room that did not result in any hospital encounter status. It was operationalized as a visit from the Epic encounter
database and was initiated when the patient checked into the emergency department by the
service representative.

*Hospitalizations.* Hospitalizations were any overnight stay in the hospital that were
classified as inpatient, inpatient hospice, or observation. Observation stays could include
overnight stays, which were expected to be less than two midnight stays but occasionally did last
longer than two midnights. Consequently, observation status visits were counted in the total
number of hospital visits. Short-term outpatient stays (outpatient-in-a-bed) were generally < 8
hours and usually reserved for patients who need post-procedure monitoring. Short-term
outpatient visits (outpatient-in-a-bed) were excluded. Rehabilitation visits were also excluded,
they were not acute care visits.

Hospitalizations were operationalized when the provider entered the order for the type of
stay, which generated a Hospital Account Record (HAR). Each visit has a distinct HAR.

To ensure the number of visits was not exaggerated, the highest level of care visit was
counted. If an encounter for the emergency department occurred on the same calendar day as an
encounter for a hospital stay, only the hospitalization was counted.

It was also possible that patients were admitted to the sister community hospital and
transferred to the academic tertiary care hospital, which would result in two HARs for billing
purposes. To ensure that these transfers were not extracted as two visits, if a hospital or
emergency department visit discharge date equaled the academic medical centers admission ED
or hospital observation or inpatient date, only the highest level of care HAR was counted.
However, the total number of days from admission to the sister community hospital to discharge
from the academic hospital was counted.
Every encounter the patient had with a clinician in the healthcare system is logged in Epic under an encounter number. No hospitalizations or emergency department visits to this health care system were missed in the data extraction. However, encounter information was only available from the EHR if these visits occurred at this academic medical center’s facilities or its sister community hospital’s facilities. Therefore, it was possible that some patients had visits outside these facilities. It was assumed that since the patients had been matched, an equal number of patients in both groups would be seeking outside services. This was a validity concern but was consistent with the manner that healthcare utilization had been addressed in the literature since it was not yet possible to obtain this information from all healthcare facilities throughout the nation.

**Clinical indicators.** Clinical indicators were quantitative health measures that were included in the National Committee for Quality Assurance’s (NCQA) Healthcare Effectiveness Data and Information Set (HEDIS). The clinical indicators that were extracted for this study included glycosylated hemoglobin or Hgb A1C, weight, and systolic and diastolic blood pressure.

**Glycosylated hemoglobin/A1C.** Glycosylated hemoglobin or A1C is a test that measures the amount of glucose that has adhered to the hemoglobin protein molecule of the red blood cell. Once adhered, it remains for approximately 120 days or the life of the red blood cell. Glycosylated hemoglobin provides a measure of average plasma blood glucose concentration for the previous three months. At both the ICCCM and all the primary standard care clinics, venipuncture for this test was performed either by a trained phlebotomist or an RN. This variable was operationalized as a lab value. To ensure reliability, both the ICCCM clinic and the standard care clinics used the same lab testing method for glycosylated hemoglobin or A1C. The A1C test
was performed using a Bio-Rad Variant II Turbo analyzer employing high performance liquid chromatography. This method complied with both accreditation requirements of the College of American Pathologists and the Clinical Laboratory Improvement Amendments of 1988 (Personal communication with Dr. Stephen Kahn, Professor and Vice Chair, Clinical Services, Pathology, 5/19/16.) It was therefore a valid measure of Hgb A1C. The normal lab value for this test was 4.0–6.0%.

**Weight.** Weight is the force of an object—in this case, the patient’s body due to gravity. It was measured in pounds at each clinic visit (both the ICCCM and the primary standard care clinics) using an upright standard digital scale, which was calibrated at least annually and as needed. At all clinics, weights were obtained by the LPN, MA, or PCT. Although actual weights were encouraged, if a patient refused to be weighed at a clinic visit, either verbal weights were entered, or no weight was entered. In both instances, the type of weight was documented as verbal or declined. To ensure validity, only actual weights were included in this study. In addition, since weight is dependent on fluid balance, no weights from emergency room, urgent care, or hospital visits were used. Per protocol, weights were documented in Epic by the clinician obtaining the weight at the point of service. Finally, to ensure reliability, weights were obtained in all clinics using an upright digital scale that was calibrated annually and as needed.

**Systolic and diastolic blood pressure.** Systolic blood pressure is the measure of the arterial pressure during left ventricular contraction or the pressure exerted by the blood on the arterial wall when the heart beats. Diastolic blood pressure is the pressure exerted by the circulating blood on the arterial wall between heart beats when the heart is at rest. Both systolic and diastolic blood pressure measurements were recorded in the EHR nursing flowsheet by the person performing the measure at the point of care. Since blood pressure could be measured
several times in each visit, over several visits, and while hospitalized or in the emergency department, an algorithm was developed to identify how to determine what blood pressure measures were used and how to average those measures (Burkhart et al., 2016). For more information on this dependent variable and the data extraction rules see the dependent variable data extraction rules in Table 4.

Blood pressure was measured using either a manual cuff or an automated blood pressure machine by the PCT/MA/LPN at each visit for all the clinics. Blood pressures were entered into the electronic nursing flowsheet at the point of care. PCTs/MAs and LPNs were required to have demonstrated proficiency in measuring blood pressure prior to performing this skill. In addition, in some instances, RNs, physicians, or advanced practice nurses might measure the patient’s blood pressure.

To support validity for this study, if more than one blood pressure was recorded for a clinic visit, only the last blood pressure value was extracted, as patients may have elevated blood pressures due to stress or exercise immediately prior to the visit. To ensure reliability, the automatic blood pressure machines were checked by the biomedical department annually and as needed. Manual blood pressure cuffs were replaced and verified with a second cuff as needed.

**Data Extraction**

Data were extracted exclusively from the data warehouse. The data warehouse received data from the Clarity download of the Epic EHR. Table 3 describes the data extraction rules to identify the ICCCM and matched samples.
## Table 3. Extraction Rules for Sample

### Data Extraction Rules Phase 1: Sample Identified

<table>
<thead>
<tr>
<th>ICCCM Sample</th>
<th>Data Extraction Rules</th>
</tr>
</thead>
</table>
| Identified by Care coordinator from Phytel lists of patients (obtained from clinic) | • Extract date patient entered into problem list by care coordinator–this date = timepoint 1 (T1)  
• Assign each patient with unique ICCCM identification number |

### T1 data: Data documented at first visit closest to T1 (within 6 months prior to or after T1)

- Gender
- Race
- Ethnicity
- Age
- Language
- Financial class (Medicare, Medicaid, private insurance payer, uninsured/self-pay as primary payer of services)
- A1C
- Comorbidities: the following diagnoses pulled from the ICD-9 codes: cancer, metastases, dementia, cerebrovascular disease, diabetes with chronic complications, HIV, peptic ulcer disease, rheumatic disease, renal disease, liver disease either mild or moderate/severe, myocardial infarction, hemiplegia or paraplegia, chronic pulmonary disease and peripheral vascular disease

### Identify Timepoint 2 (T2)

For each ICCCM patient, T2 = One year prior to T1 date.

### Identify Timepoint 3 (T3)

For each ICCCM patient, T3 date = one year after T1 date.

### Matched Sample (matching as appropriate for closest match while optimizing sample size i.e. propensity scoring)

- Extract all patients in General Medicine or family practice clinics with Type 2 diabetes documented in administrative ICD-9 codes who were active patients between June 2013 -June 2016 (“Match-1 sample” dataset)
- For each Match-1 sample, extract sex, race, age, insurance, baseline A1C, Charlson Comorbidity diagnoses from the administrative data set ICD-9 codes: cancer, metastases, dementia, cerebrovascular disease, diabetes with chronic complications, HIV, peptic ulcer
disease, rheumatic disease, renal disease, liver disease either mild or moderate/severe, myocardial infarction, hemiplegia or paraplegia, chronic pulmonary disease and peripheral vascular disease

- Assign each matched patient with unique identification number

First the population who received ICCCM was identified from the clinic care coordinator’s lists. The date that care coordination was added to each patient's problem list was extracted as T1. T2 and T3 were automatically one calendar year prior to T1 and one calendar year after T1 respectively. For clinical indicators, the variable closest to the T1, T2 and T3 dates were extracted. If no value was available within six months of the T1, T2 or T3 date, no data were extracted. To ensure at least one full year’s data after the intervention began, all the patients had to have a T1 date after June 1, 2014 when the intervention began but prior to February 1 of 2016 as the ICCCM model was changed in February 2017.

For each patient in the ICCCM group, the values for Hgb A1C; weight; systolic and diastolic blood pressure were extracted as described in the dependent variable data extraction rules table for each of the three time points (see dependent variable data extraction rules, Table 4). All influenza vaccinations; eye examinations; number of missed visits (no shows (NS) and same-day cancellations); hospital days and visits and emergency department visits were recorded that occurred between T2 (one year prior to the intervention) and T3 (one year post intervention). The data was then verified with the EHR and quality control checks of the data were performed prior to matching. These checks include descriptive statistics and frequency distributions of key variables to ensure that the ranges of the variables were plausible.
<table>
<thead>
<tr>
<th>Table 4. Dependent Variable Data Extraction Rules Table</th>
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<tbody>
<tr>
<td><strong>Variable</strong></td>
</tr>
<tr>
<td><strong>Patient Engagement</strong></td>
</tr>
</tbody>
</table>
| Missed Visits (No Show (NS) Visits + Same Day Cancellations) | ● Did not come to scheduled appointment  
● Did not call to cancel or reschedule  
● Patient cancels on same day of appointment or comes late to scheduled appointment and cannot be seen so the appointment must be cancelled  
● Appointment date = Cancellation date | ● Extract all canceled clinic visits and NS visits between T2 and T1 (NS 1)  
● Extract all canceled clinic visits and NS visits between T1 and T3 (NS 2)  
● For NS1 and NS2, count all visits in which the appointment date = cancellation date or the visit is a NS (Count 1 NS1, Count 1 NS2)  
● Label as #NS Pre ICCCM visits (T2-T1) & #NS Post-ICCCM visits (T1-T3) | ● Extract all canceled clinic visits and NS visits between T1 and T3 (NS 3)  
● For NS 3, count all visits in which the appointment date = cancellation date or this visit is a NS (Count 1 NS3)  
● Label as #NS Match visits (T1-T3) |
| **Influenza immunizations** | **Influenza immunization injection** | ● For T2-T1, extract date of influenza immunization  
● For T1-T3, extract date of influenza immunization  
● For each time period, if date is blank, assign 0 to influenza immunization  
● For each time period, if date is not blank, assign 1 to influenza immunization | ● For T1-T3, extract date of influenza immunization  
● For T1-T3 time period, if date is blank, assign 0 to influenza immunization  
● For T1-T3 time period, if date is not blank, assign 1 to influenza immunization |
| **Dilated eye examinations** | **Dilated eye examination from ophthalmology** | For each time period (T2-T1, & T1-T3) separately:  
● Extract date of all dilated eye/ophthalmologist examination  
● For each time period, if | For T1-T3:  
● Extract date of all dilated eye/ophthalmologist examination  
● If date is blank, assign 0 to dilated eye |
date is blank, assign 0 to dilated eye examination
• For each time period, if date is not blank, assign 1 to dilated eye examination

- If date is not blank, assign 1 to dilated eye examination

Healthcare Utilization

Hospitalizations - Number of hospitalizations & Number of days hospitalized

- Overnight stays in the hospital with inpatient, inpatient hospice or observation status at academic medical center or at affiliated community hospital
- Excludes Outpatient-in-a-bed, and rehab encounters
- If patient transfers from affiliated hospital to academic hospital, count as 1 visit

For each time period (T2-T1, & T1-T3) separately:

- Count all Inpatient, or Inpatient Hospice and Observation HARs from both academic and affiliated community hospital (HAR count)
- If affiliated community hospital discharge date from inpatient, inpatient hospice, observation or emergency department = admission date to academic hospital, count as 1 HAR only (add 1 to HAR count)
- To determine # of hospital days, subtract date of discharge from date of admission and add 1 for each inpatient, observation, and inpatient hospice visit

For T1-T3:

- Count all Inpatient or Inpatient Hospice and Observation HARs from both academic and affiliated community hospital (HAR count)
- If affiliated community hospital discharge date from inpatient, inpatient hospice, observation or emergency department = admission date to academic hospital, count as 1 HAR only (add 1 to HAR count)
- To determine # of hospital days, subtract date of discharge from date of admission and add 1 for each inpatient, observation, and inpatient hospice visit

Emergency Department (ED) Visit

Any visit to the ED in which patient checks in, is billed as ED visit and visit did not result in a hospital admission

For each time period (T2-T1, & T1-T3) separately:

- Count all Emergency Department (ED) visit HARs (ED count)
- If ED visit from affiliated community hospital was transferred to ED at academic hospital, count as only one ED visit—Discharge date ED

For T1-T3:

- Count all Emergency Department (ED) visit HARs (ED count)
- If ED visit from affiliated community hospital was transferred to ED at academic hospital, count as only one ED visit—Discharge date ED community hospital =
community hospital = admission ED date academic medical center = 1 ED visit

- If ED visit from community hospital was transferred to ED at academic hospital resulting in an inpatient or observation visit in academic hospital, do not count ED visit—Discharge date ED community hospital = inpatient/observation admission date academic medical center = 0 ED visit, 1 HAR visit

admission ED date academic medical center = 1 ED visit

- If ED visit from community hospital was transferred to ED at academic hospital resulting in an inpatient or observation visit in academic hospital, do not count ED visit—Discharge date ED community hospital = inpatient/observation admission date academic medical center = 0 ED visit, 1 HAR visit

---

**Clinical Indicators**

<table>
<thead>
<tr>
<th>Indicator</th>
<th>Description</th>
<th>Instructions</th>
</tr>
</thead>
</table>
| Hgb A1C   | Test that measures the amount of glucose that has adhered to the hemoglobin protein molecule of the red blood cell. | For each T1, T2 and T3 date:  
- Extract date of and value of A1C closest to each date  
- If no A1C exists within 6 months of each date, leave data point blank |
| Weight    | Force an object (the patient’s body) exerts due to gravity | For each ICCCM participant extract T1, T2 and T3 weight:  
- Extract weight closest to each date (T1, T2 and T3) and the date of weight  
- If weight extracted is verbal weight, do not extract and extract next closest actual weight and date of weight  
- If weight is from hospital or ED visit, do not extract  
- If no weight exists within 6 months of each date, leave data point blank |
|           |             | For each Match participant extract T1 and T3 weight:  
- Extract weight closest to each date (T1 and T3) and the date of weight  
- If weight extracted is verbal weight, do not extract and extract next closest actual weight and date of weight  
- If weight is from hospital or ED visit, do not extract  
- If no weight exists within 6 months of each date, leave data point blank |
<table>
<thead>
<tr>
<th>Systolic blood pressure</th>
<th>Measure of the arterial pressure during left ventricular contraction or the pressure exerted by the blood on the arterial wall when the heart beats</th>
</tr>
</thead>
<tbody>
<tr>
<td>For each ICCCM participant extract T1, T2 and T3 B/P:</td>
<td>• Extract systolic B/P taken closest to each date and the date taken</td>
</tr>
<tr>
<td></td>
<td>• Delete blood pressure measures from urgent care, outpatient surgery, ED, or hospital visits</td>
</tr>
<tr>
<td></td>
<td>• If more than one blood pressure is measured on the same date, the last systolic B/P taken will be used</td>
</tr>
<tr>
<td></td>
<td>• If no B/P exists within 6 months of each date, leave data point blank</td>
</tr>
<tr>
<td>For each matched participant extract T1 and T3 B/P:</td>
<td>• Extract systolic B/P taken closest to each date and the date taken</td>
</tr>
<tr>
<td></td>
<td>• Delete blood pressure measures from urgent care, outpatient surgery, ED, or hospital visits</td>
</tr>
<tr>
<td></td>
<td>• If more than one blood pressure is measured on the same date, the last systolic B/P taken will be used</td>
</tr>
<tr>
<td></td>
<td>• If no B/P exists within 6 months of each date, leave data point blank</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Diastolic blood pressure</th>
<th>Pressure exerted by the circulating blood on the arterial wall between heart beats when the heart is at rest.</th>
</tr>
</thead>
<tbody>
<tr>
<td>For each T1, T2 and T3 date:</td>
<td>• Extract diastolic B/P taken closest to each date and the date taken</td>
</tr>
<tr>
<td></td>
<td>• Delete blood pressure measures from urgent care, outpatient surgery, ED or hospital visits</td>
</tr>
<tr>
<td></td>
<td>• If more than one blood pressure is measured on the same date, the last diastolic B/P taken will be used</td>
</tr>
<tr>
<td></td>
<td>• If no B/P exists within 6 months of each date, leave data point blank</td>
</tr>
<tr>
<td>For each T1 and T3 date:</td>
<td>• Extract diastolic B/P taken closest to each date and the date taken</td>
</tr>
<tr>
<td></td>
<td>• Delete blood pressure measures from urgent care, outpatient surgery, ED or hospital visits</td>
</tr>
<tr>
<td></td>
<td>• If more than one blood pressure is measured on the same date, the last diastolic B/P taken will be used</td>
</tr>
<tr>
<td></td>
<td>• If no B/P exists within 6 months of each date, leave data point blank</td>
</tr>
</tbody>
</table>

After the data for the ICCCM participants had been verified, a series of data extractions were conducted to identify a matched participant for each ICCCM participant. First to identify the matched population, all patients who had Type 2 diabetes in their diagnostic codes were
extracted (Match–1 sample). Then, from this sample, patients who had a visit within six months of all the ICCCM participants T1 range were included (Match–2 sample). For the Match-2 sample, the gender, race, ethnicity, language, age, insurance, A1C at matched date (baseline A1C), date of diabetes diagnosis, and comorbidities were extracted. From the Match–2 sample, the closest three propensity matched score participants were identified and ranked. The propensity match was based on gender, race, ethnicity, language, age, insurance, A1C at T1, date of diabetes diagnosis and comorbidity between the ICCCM participant and the patient from a comparison primary care clinic within the same health system. The EHR of the top three potential matches was searched to determine if all inclusion/exclusion criteria had been met. The closest match who met all inclusion/exclusion criteria was identified as the match for the corresponding intervention patient. If no suitable match could be found, the intervention patient was deleted from the data for the matched portion of the study, resulting in a loss of 33 participants for the Hypotheses 1b, 2b, and 3b. As shown in Table 5, the 33 patients were demographically similar to the 171 intervention patients who had matches except that they were more likely to be non-English speaking.

Table 5. ICCCM Intervention Sample/33 Unmatched Patients' Demographics

<table>
<thead>
<tr>
<th>Age</th>
<th>Total Number</th>
<th>Percent</th>
<th>Total Number</th>
<th>Percent</th>
<th>Chi Square</th>
<th>Significance</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt;55</td>
<td>55</td>
<td>27.0</td>
<td>11</td>
<td>33.3</td>
<td></td>
<td></td>
</tr>
<tr>
<td>55-65</td>
<td>71</td>
<td>34.8</td>
<td>11</td>
<td>33.3</td>
<td></td>
<td></td>
</tr>
<tr>
<td>&gt;65</td>
<td>45</td>
<td>22.1</td>
<td>11</td>
<td>33.3</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Gender</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>0.72</td>
<td></td>
</tr>
<tr>
<td>Female</td>
<td>99</td>
<td>57.9</td>
<td>18</td>
<td>54.5</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>72</td>
<td>42.1</td>
<td>15</td>
<td>45.5</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Race</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>0.69</td>
<td></td>
</tr>
<tr>
<td>African-</td>
<td>108</td>
<td>63.2</td>
<td>20</td>
<td>60.6</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Next, for each of the corresponding matched patients, the values for Hgb A1C; weight; systolic and diastolic blood pressure; influenza vaccination; eye examination; number of no shows and same-day cancellations; hospital admission and discharge dates and emergency department visits were extracted (similarly to their matched counterpart) as described in the dependent variable data extraction rules table for both time-points (see Table 4). These data were downloaded into an Excel spreadsheet and imported into REDCap (Harris et al., 2009) and from REDCap into SPSS (IBM SPSS Statistics for Windows, Version 25.0, 2017, SPSS, Armonk, NY).

**Data Cleaning**

To ensure data integrity, all participants' data were compared to the EHR data to determine accuracy of the data extraction. Next data cleaning was conducted by analyzing frequency distributions of all variables and descriptive statistics. When outliers were identified, these variables were reverified with the EHR.

**Missing Data**

If there were no data for any of the three time points for any participant in the ICCCM group, that participant was excluded for that variable. Missing data were identified using
descriptive statistics. Missing data were not replaced, but rather, the participant was excluded from that data variable statistic.

**Power**

For this study, based on a quality improvement project, it was estimated that a total of 130 patients participated in ICCCM at the main clinic and its satellite clinic between October 2014 and June 2015. A power analysis using G*Power for a two-tailed, two group t-test, with a beta of 0.2 and alpha of 0.05 demonstrated that the smallest effect size that this study could detect was 0.35 if all 130 patients in the ICCCM group were successfully matched to another control group primary care clinic patient (Faul, Erdfelder, Buchner, & Lang, 2009). This would be for 260 patients or 130 in each group.

Based on the literature, this sample size would have enough power to answer the research questions. A review of the data on hemoglobin A1Cs indicated that this was not unlikely for this variable. Afzali, Karnon, Gray, and Beilby (2012) estimated a need for 84 participants to detect an absolute difference of 0.5% in mean A1C. This was based on a standard deviation of 1.44% with an alpha of 5% and 80% power (Afzali, Karnon, Gray, & Beilby, 2012). Shojania et al.’s meta-regression demonstrated a mean reduction in A1C as high as 0.67% for interventions that included team-based care and 0.52% for interventions that included case management (2006).

Clark, Snyder, Meek, Stutz, and Parkin (2001) found in their pre-/post-analysis of a team system intervention that the percentage of patients receiving the dilated eye examination at the end of one year increased from 53.9% to 80.3% for an effect size of 0.264, requiring 176 participants. The percent of patients achieving a blood pressure of < 140/90 increased from 38.9% to 66.8% for an effect size of 0.279, requiring 156 total participants (Clark, et al., 2001). Gabbay et al. (2006) found that the difference in the percent of patients receiving the pneumonia
vaccination increased from 6% in the control group to 50% in the nurse case management intervention group for an effect size of 0.44, requiring 57 total participants. Using McNemar’s test for the dichotomous study variables, the sample size required to detect a difference for a two-tailed test was 56 participants (28 in each group) with an effect size of 0.26. Consequently, the study was determined to be well powered for the dichotomous variables. However, no published information regarding the effect size needed for no show and same day cancellation visits was found.

**Data Analyses**

Data were reviewed upon entry into REDCap to ensure that the data matched with the data pulled in from the excel spreadsheet.

Descriptive statistics of the matching variables (gender, race, age, ethnicity, language, insurance, baseline A1C, length of time with DM, Charlson comorbidities previously listed, (see Table 3)) were presented to ensure that the patients were indeed well matched. Propensity diagnostics (standard mean differences) were evaluated to ensure the groups were similar at baseline (T1).

For all the dichotomous variables, McNemar's nonparametric test was used. However, since the propensity match demonstrated imbalance in baseline A1C and renal disease, generalized estimating equations were run to statistically control for those two variables.

Assumptions of normality, homogeneity of variance and, independence were assessed for the continuous variables to ensure that parametric statistical methods could be used. Since these assumptions were violated for all continuous variables, nonparametric statistics were used. Since the continuous healthcare utilization variables and missed visits had a Poisson distribution, they violated a normal distribution; therefore, a Wilcoxon signed ranked test was used to evaluate the
healthcare utilization and missed visit count variables. Since the intervention patients were from a family practice clinic and in some cases were related to each other (spouses, or parent/child), the assumption of independence was also violated; therefore, the Wilcoxon signed rank test was also used for these variables. Again, since the propensity match demonstrated imbalance in baseline A1C and renal disease, mixed models, general linear models with a binomial probability distribution and a logit link function were run to statistically control for those two variables.

However, since the general linear mixed model is a parametric test, the Wilcoxon signed rank test was also run to ensure there was no discrepancy in the results. The only continuous variable in which significance was affected by the baseline A1C and renal disease was missed visits. Therefore, missed visits in the ICCCM/propensity matched group were categorized into no missed visits or 1 or more missed visits and a generalized estimating equation test was run to statistically control for the covariates.

The data analysis table below (see Table 6) provides the hypotheses being tested, the variable definitions, and the statistical test planned.

<table>
<thead>
<tr>
<th>Hypothesis</th>
<th>Variable Definitions</th>
<th>Statistical Test</th>
</tr>
</thead>
<tbody>
<tr>
<td>Informed, empowered patient and family/patient engagement</td>
<td></td>
<td></td>
</tr>
<tr>
<td>1) After participating in the ICCCM for one year, Type 2 diabetic patients will have significantly increased patient engagement as demonstrated by fewer Missed (No Show visits and same day cancellation) visits than prior to participation.</td>
<td>Pre-ICCCM # No show/same day cancellations per participant between T1 &amp; T2</td>
<td>Change scores calculated for pre and post ICCCM timepoints</td>
</tr>
<tr>
<td></td>
<td>Post-ICCCM # Missed visits per participant between T1 &amp; T3</td>
<td>Wilcoxon Signed Rank Test</td>
</tr>
<tr>
<td>2) After participating in ICCCM for one year, Type 2 diabetic participants will have increased patient engagement as demonstrated</td>
<td>Post-ICCCM: # Missed visits between T1 &amp; T3 in ICCCM</td>
<td>General linear mixed model with binomial probability distribution and logit link function to control for variables with &gt;0.2 standardized mean</td>
</tr>
<tr>
<td></td>
<td>Post-Match: # Missed visits between T1 &amp; T3 in Match</td>
<td></td>
</tr>
</tbody>
</table>
by significantly fewer missed (No Show visits and same day cancellation) visits than matched participants receiving standard care.

difference in propensity match and **Wilcoxon Signed Rank Test** – due to discrepant results, variable was dichotomized into missed visits = none or ≥ 1 and **Generalized estimating equation** (GEE) was used to statistically control for unbalanced propensity matched covariates

3) After participating in the ICCCM model of care for one year, Type 2 diabetic participants will have a significantly greater number of received influenza immunizations than prior to participation.

| Pre-ICCCM: # ICCCM participants who received influenza immunizations between T1 & T2 |
| Post-ICCCM: # ICCCM participants who received influenza immunizations between T1 & T3 |

**McNemar’s test**

4) After participating in ICCCM for one year, Type 2 diabetic participants will have significantly greater increase in the number of received influenza immunizations than matched participants receiving standard care.

| Influenza immunizations is a dichotomous variable – either received or not received for the year |
| Post-ICCCM change: # ICCCM participants receiving influenza immunization between T1 & T3 |

**Generalized estimating equation** (GEE) to statistically control for unbalanced propensity matched covariates

5) After participating in the ICCCM model of care for one year, Type 2 diabetic participants will have a significantly greater number of received dilated eye examinations than prior to participation.

| Dilated eye examination is a dichotomous variable – either received or not received for the year |
| Pre-ICCCCM: # ICCCM participants who received dilated eye examinations |

**McNemar's test**
| 6) After participating in the ICCCM model of care for one year, Type 2 diabetic participants will have a significantly greater increase in the number of received eye examinations than matched participants receiving standard care. |
|---|---|---|
| Post-ICCCM: # ICCCM participants who received dilated eye examinations between T1 & T3 | Dilated eye examination is a dichotomous variable – either received or not received for the year | Generalized estimating equation (GEE) to statistically control for unbalanced propensity matched covariates |
| Post-Match: # matched participants who received dilated eye examinations between T1 & T3 |

### Productive Interactions/ Healthcare Utilization

| 7) After participating in ICCCM for one year, Type 2 diabetic participants will have significantly fewer hospitalizations than prior to participation. |
| Pre-ICCCM # hospitalizations per participant between T1 & T2 | Change scores calculated for pre and post ICCCM timepoints | Wilcoxon Signed Rank test |
| Post-ICCCM # hospitalizations per participant between T1 & T3 |

| 8) After participating in ICCCM for one year, Type 2 diabetic participants will have significantly fewer hospitalizations than matched participants receiving standard care. |
| Post-ICCCM Visits: # hospitalizations between T1 & T3 | General linear mixed model with binomial probability distribution and logit link function to control for variables with >0.2 standardized mean difference in propensity match and Wilcoxon Signed Rank Test |
| Post-Match Visits: # hospitalizations between T1 & T3 |

<p>| 9) After participating in ICCCM for one year, Type 2 diabetic participants will have significantly fewer emergency department visits than prior to participation. |
| Pre-ICCCM Visits: # emergency department visits per participant between T1 &amp; T2 | Change scores calculated for pre and post ICCCM timepoints | Wilcoxon Signed Rank test |
| Post-ICCCM Visits: # emergency department visits per participant between T1 &amp; T3 |</p>
<table>
<thead>
<tr>
<th>Outcome Measures</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>10</strong>) After participating in ICCCM for one year, Type 2 diabetic participants will have significantly fewer emergency department visits than matched participants receiving standard care.</td>
</tr>
<tr>
<td><strong>11</strong>) After participating in ICCCM for one year, Type 2 diabetic participants will have significantly fewer hospital days than prior to participation.</td>
</tr>
<tr>
<td><strong>12</strong>) After participating in ICCCM for one year, Type 2 diabetic participants will have significantly fewer hospital days than matched participants who receive standard care.</td>
</tr>
<tr>
<td><strong>13</strong>) After participating in ICCCM for one year, Type 2 diabetic participants will have significantly lower A1C levels than prior to participation.</td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td><strong>14</strong>) After participating in ICCCM for one year, a significantly lower number of patients will have A1C levels &gt; 9.0 than prior to participation.</td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td><strong>15</strong>) After participating in ICCCM for one year, Type 2</td>
</tr>
<tr>
<td>16) After participating in ICCCM for one year, Type 2 diabetic participants will have a significantly lower number of patients with A1C &gt; 9.0 than matched participants receiving standard care.</td>
</tr>
<tr>
<td>---</td>
</tr>
<tr>
<td>A1CT1 – A1CT3</td>
</tr>
</tbody>
</table>

Population subset: Only participants in either ICCCM or Match group with BMI's >25 or weight > 185 lb at T1 will be included.

<table>
<thead>
<tr>
<th>17) After participating in ICCCM for one year, Type 2 diabetic participants with a BMI &gt; 25 or weight &gt; 185 lb at T1 will have a significantly greater weight decrease than prior to participation.</th>
<th>Change: Pre ICCCM weight T1 Post ICCCM weight T3 Difference: Pre-ICCCM: Weight (Wt) change per participant - WtT2 – WtT1</th>
<th>Wilcoxon Signed Rank Test</th>
</tr>
</thead>
<tbody>
<tr>
<td>Post-ICCCM: Wt change per participant - WtT1 – WtT3</td>
<td>Change scores will be calculated for pre and post ICCCM timepoints</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>18) After participating in ICCCM for one year, Type 2 diabetic participants with a BMI &gt; 25 or a weight &gt;185 lb at T1 will have a significantly greater weight decrease than matched participants receiving standard care.</th>
<th>Post-ICCCM: Weight change per participant – WtT1 – WtT3</th>
<th>General linear mixed model with binomial probability distribution and logit link function to control for variables with &gt;0.2 standardized mean difference in propensity match and Wilcoxon Signed Rank Test</th>
</tr>
</thead>
<tbody>
<tr>
<td>Post-Match: Weight change per participant - WtT1 – WtT3</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Population subset: Only patients with hypertension coded in administrative data set will be included in this subset.

<table>
<thead>
<tr>
<th>19) After participating in ICCCM for one year, Type 2 diabetic participants with hypertension will have a significantly greater percentage of participants with Systolic B/P &lt; 140.</th>
<th>Pre-ICCCM: Percent of participants with Systolic B/P &lt; 140</th>
<th>McNemar's test</th>
</tr>
</thead>
<tbody>
<tr>
<td>Post-ICCCM: Percent of participants with Systolic B/P</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Statement</td>
<td>Methodology</td>
<td></td>
</tr>
<tr>
<td>----------------------------------------------------------------------------------------------------------------</td>
<td>-------------------------------------------------------------------------------------------------------</td>
<td></td>
</tr>
<tr>
<td>20) After participating in ICCCM for one year, Type 2 diabetic participants with hypertension will have a</td>
<td>Post-ICCCM: Percent of participants with Systolic B/P &lt; 140</td>
<td></td>
</tr>
<tr>
<td>significantly greater percentage of participants with systolic blood pressure &lt; 140 than matched participants</td>
<td>Post-Match: Percent of participants with Systolic B/P &lt; 140</td>
<td></td>
</tr>
<tr>
<td>receiving standard care.</td>
<td>Generalized estimating equation (GEE) to statistically control for unbalanced propensity matched</td>
<td></td>
</tr>
<tr>
<td></td>
<td>covariates</td>
<td></td>
</tr>
<tr>
<td>21) After participating in ICCCM for one year, Type 2 diabetic participants with hypertension will have a</td>
<td>Change:</td>
<td></td>
</tr>
<tr>
<td>significantly greater decrease in systolic blood pressure than prior to participation.</td>
<td>Pre ICCCM systolic b/p T1</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Post ICCCM systolic b/p T3</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Difference:</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Pre-ICCCCM: Systolic b/p change per participant – Sys b/p T2 – Sys b/p T1</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Post-ICCCM: Systolic b/p change per participant – Sys b/p T1 – Sys b/p T3</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Change/difference scores</td>
<td></td>
</tr>
<tr>
<td></td>
<td>will be calculated for pre and post ICCCM timepoints</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Wilcoxon Signed Rank Test</td>
<td></td>
</tr>
<tr>
<td>22) After participating in ICCCM for one year, Type 2 diabetic participants with hypertension will have a</td>
<td>Post-ICCCM: Systolic b/p change per participant – Sys b/p T1 – Sys b/p T3</td>
<td></td>
</tr>
<tr>
<td>significantly greater decrease in systolic blood pressure than matched participants receiving standard care.</td>
<td>Post-Match: Systolic b/p change per participant – Sys b/p T1 – Sys b/p T3</td>
<td></td>
</tr>
<tr>
<td></td>
<td>General linear mixed model</td>
<td></td>
</tr>
<tr>
<td></td>
<td>with binomial probability distribution and logit link function to control for variables with &gt;0.2</td>
<td></td>
</tr>
<tr>
<td></td>
<td>standardized mean difference in propensity match and</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Wilcoxon Signed Rank Test</td>
<td></td>
</tr>
<tr>
<td>23) After participating in ICCCM for one year, Type 2 diabetic participants with hypertension will have a</td>
<td>Pre-ICCCM: Percent of participants with Diastolic B/P &lt; 90</td>
<td></td>
</tr>
<tr>
<td>significantly greater percentage of participants with diastolic blood pressure &lt; 90 than prior to participation.</td>
<td>Post-ICCCM: Percent of participants with Diastolic B/P &lt; 90</td>
<td></td>
</tr>
<tr>
<td></td>
<td>McNemar's test</td>
<td></td>
</tr>
<tr>
<td>24) After participating in ICCCM for one year, Type 2 diabetic participants with hypertension will have a</td>
<td>Post-ICCCM: Percent of participants with Diastolic B/P &lt; 90</td>
<td></td>
</tr>
<tr>
<td>significantly greater percentage of participants with</td>
<td>Post-Match: Percent of participants with Diastolic B/P</td>
<td></td>
</tr>
<tr>
<td>Generalized estimating equation (GEE) to statistically control for unbalanced propensity matched covariates.</td>
<td>Generalized estimating equation (GEE) to statistically control for unbalanced propensity matched</td>
<td></td>
</tr>
<tr>
<td></td>
<td>covariates</td>
<td></td>
</tr>
</tbody>
</table>
| 25) After participating in ICCCM for one year, Type 2 diabetic participants with hypertension will have a significantly greater decrease in diastolic blood pressure than prior to participation. | Change: Pre ICCCM diastolic b/p T1  
Difference: Pre-ICCCM: Diastolic b/p change per participant – Dias b/p T2 – Dias b/p T1  
Post-ICCCM: Diastolic b/p change per participant – Dias b/p T1 – Dias b/p T3 | Change/difference scores will be calculated for pre and post ICCCM timepoints  
Wilcoxon Signed Rank Test |
|---|---|---|
| 26) After participating in ICCCM for one year, Type 2 diabetic participants with hypertension will have a significantly greater decrease in diastolic blood pressure than matched participants receiving standard care | Post-ICCCM: Diastolic b/p change per participant – Dias b/p T1 – Dias b/p T3  
Post-Match: Diastolic b/p change per participant – Dias b/p T1 – Dias b/p T3 | General linear mixed model with binomial probability distribution and logit link function to control for variables with >0.2 standardized mean difference in propensity match and Wilcoxon Signed Rank Test |
CHAPTER FOUR

RESULTS

The study aim is to determine whether a nurse-led interprofessional collaborative care-coordination model (ICCCM) will demonstrate improved patient engagement, use of fewer emergency and hospital encounters, and have better clinical outcomes both prior to the intervention and in comparison to a matched cohort.

Study Sample

The following sections will describe the intervention sample, the matched control sample, and the propensity match.

Intervention Sample

The ICCCM intervention pre/post sample consisted of 204 patients with type II diabetes from two intervention clinics for one year and who had been primary care patients for one year prior to the intervention redesign. As shown in Table 6, the majority of patients were English speaking, insured African American females who were under 55. In addition, 11 patients were deleted from the sample as they were not patients for a full year prior to the intervention so pre/post analysis was not possible. Although these 11 patients were less likely to have private insurance and more likely to have Medicaid coverage, Chi square test results revealed that none of the differences between these two groups were statistically significant (Table 7).
Table 7. ICCCM Intervention Sample/11 Disqualified Patients’ Demographics for Pre-/Post-Analysis

<table>
<thead>
<tr>
<th>Intervention patient population</th>
<th>11 patients without data year prior to intervention</th>
<th>Chi Square Significance</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Total Number</td>
<td>Percent</td>
</tr>
<tr>
<td>Age</td>
<td></td>
<td></td>
</tr>
<tr>
<td>&lt;55</td>
<td>94</td>
<td>46.1</td>
</tr>
<tr>
<td>55-65</td>
<td>67</td>
<td>32.8</td>
</tr>
<tr>
<td>&gt;65</td>
<td>43</td>
<td>21.1</td>
</tr>
<tr>
<td>Gender</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Female</td>
<td>117</td>
<td>57.4%</td>
</tr>
<tr>
<td>Male</td>
<td>87</td>
<td>42.6%</td>
</tr>
<tr>
<td>Race</td>
<td></td>
<td></td>
</tr>
<tr>
<td>African-American</td>
<td>128</td>
<td>62.7%</td>
</tr>
<tr>
<td>White</td>
<td>54</td>
<td>26.5%</td>
</tr>
<tr>
<td>Other</td>
<td>22</td>
<td>10.8%</td>
</tr>
<tr>
<td>Language</td>
<td></td>
<td></td>
</tr>
<tr>
<td>English</td>
<td>188</td>
<td>92.2%</td>
</tr>
<tr>
<td>Non-English</td>
<td>15</td>
<td>7.4%</td>
</tr>
<tr>
<td>Insurance</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Private</td>
<td>123</td>
<td>60.3%</td>
</tr>
<tr>
<td>Medicare</td>
<td>59</td>
<td>28.9%</td>
</tr>
<tr>
<td>Medicaid</td>
<td>19</td>
<td>9.3%</td>
</tr>
<tr>
<td>Uninsured/Other</td>
<td>3</td>
<td>1.5%</td>
</tr>
</tbody>
</table>

**Matched Control Sample**

For each of the 204 patients who qualified and completed one year of the intervention, a propensity score match using nearest neighbor match without replacement was performed (Lanza, Moore, & Butera, 2013). Potential matches of patients with type 2 diabetes were extracted from the other 13 primary care clinics within this health system. Matched variables included age, race, gender, ethnicity, language, financial class, comorbidities based on the Charlson comorbidity index, years with diabetes, and baseline A1C. Each of the intervention
participants was matched to three potential matches, who were ranked 1-3 with 1 being the closest match possible and 3 being the third closest possible match. One intervention patient had no potential matches. A chart review was conducted to ensure all matched participants met inclusion/exclusion criteria (potential matches n=609). If the best (first) match qualified, the other two were deleted and not evaluated (no chart review conducted). Of the 609 potential matches, 171 qualified, 242 were not evaluated as a better match qualified and 196 were disqualified based on inclusion/exclusion criteria. The reasons for disqualification were not having a primary care physician within the health system (n=75), being a primary care patient of one of the two intervention clinics (n=51), being diagnosed after T1 (n=43), having no encounters during the two year timespan for data collection (n=20), expired during data collection T3 (n=3), were pregnant (n=2), or newly diagnosed during data collection (n=2).

**Propensity match.** The following table (Table 8) demonstrates the standard mean difference between the ICCCM group and the matched control group.

<table>
<thead>
<tr>
<th></th>
<th>Number in ICCCM</th>
<th>Percent ICCCM</th>
<th>Number in Match (Control Group)</th>
<th>Percent Match (Control Group)</th>
<th>Standard mean difference</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Age</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>&lt; 55</td>
<td>58</td>
<td>33.9</td>
<td>58</td>
<td>33.9</td>
<td>0</td>
</tr>
<tr>
<td>55-65</td>
<td>64</td>
<td>37.4</td>
<td>59</td>
<td>34.5</td>
<td>0.06</td>
</tr>
<tr>
<td>&gt;65</td>
<td>49</td>
<td>28.7</td>
<td>54</td>
<td>31.6</td>
<td>0.06</td>
</tr>
<tr>
<td><strong>Race</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>AA</td>
<td>108</td>
<td>63.2</td>
<td>113</td>
<td>66.1</td>
<td>0.06</td>
</tr>
<tr>
<td>White</td>
<td>46</td>
<td>26.7</td>
<td>49</td>
<td>28.7</td>
<td>0.04</td>
</tr>
<tr>
<td><strong>Gender</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Female</td>
<td>99</td>
<td>57.9</td>
<td>100</td>
<td>58.5</td>
<td>0.01</td>
</tr>
<tr>
<td>Male</td>
<td>72</td>
<td>42.1</td>
<td>71</td>
<td>41.5</td>
<td>0.01</td>
</tr>
<tr>
<td><strong>Ethnicity</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hispanic</td>
<td>29</td>
<td>16.9</td>
<td>22</td>
<td>12.9</td>
<td>0.12</td>
</tr>
<tr>
<td>Non-Hispanic</td>
<td>141</td>
<td>82.5</td>
<td>146</td>
<td>85.4</td>
<td>0.08</td>
</tr>
<tr>
<td>Language</td>
<td>Match Mean</td>
<td>Match Variance</td>
<td>Standard Difference</td>
<td></td>
<td></td>
</tr>
<tr>
<td>----------------</td>
<td>------------</td>
<td>----------------</td>
<td>---------------------</td>
<td></td>
<td></td>
</tr>
<tr>
<td>English</td>
<td>161</td>
<td>94.2</td>
<td>163</td>
<td>94.8</td>
<td>0.05</td>
</tr>
<tr>
<td>Non-English</td>
<td>10</td>
<td>5.8</td>
<td>8</td>
<td>4.7</td>
<td>0.05</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Financial Class</th>
<th>Match Mean</th>
<th>Match Variance</th>
<th>Standard Difference</th>
</tr>
</thead>
<tbody>
<tr>
<td>Insurance</td>
<td>102</td>
<td>59.6</td>
<td>108</td>
</tr>
<tr>
<td>Medicaid</td>
<td>18</td>
<td>10.5</td>
<td>13</td>
</tr>
<tr>
<td>Medicare</td>
<td>48</td>
<td>28.1</td>
<td>48</td>
</tr>
<tr>
<td>Other</td>
<td>3</td>
<td>1.8</td>
<td>2</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Comorbidity</th>
<th>Match Mean</th>
<th>Match Variance</th>
<th>Standard Difference</th>
</tr>
</thead>
<tbody>
<tr>
<td>cancer</td>
<td>16</td>
<td>9.4</td>
<td>17</td>
</tr>
<tr>
<td>COPD</td>
<td>44</td>
<td>25.7</td>
<td>46</td>
</tr>
<tr>
<td>CVD</td>
<td>38</td>
<td>22.2</td>
<td>39</td>
</tr>
<tr>
<td>Dementia</td>
<td>4</td>
<td>2.3</td>
<td>7</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>DM End organ Disease</th>
<th>Match Mean</th>
<th>Match Variance</th>
<th>Standard Difference</th>
</tr>
</thead>
<tbody>
<tr>
<td>HIV</td>
<td>130</td>
<td>76</td>
<td>124</td>
</tr>
<tr>
<td>Mild liver disease</td>
<td>45</td>
<td>26.3</td>
<td>50</td>
</tr>
<tr>
<td>Severe liver disease</td>
<td>2</td>
<td>1.2</td>
<td>3</td>
</tr>
<tr>
<td>Metastases</td>
<td>1</td>
<td>0.6</td>
<td>1</td>
</tr>
<tr>
<td>MI</td>
<td>19</td>
<td>11.1</td>
<td>13</td>
</tr>
<tr>
<td>Plegia</td>
<td>10</td>
<td>5.8</td>
<td>7</td>
</tr>
<tr>
<td>PVD</td>
<td>39</td>
<td>22.8</td>
<td>44</td>
</tr>
<tr>
<td>Renal</td>
<td>38</td>
<td>22.2</td>
<td>22</td>
</tr>
<tr>
<td>Rheumatic</td>
<td>6</td>
<td>3.5</td>
<td>6</td>
</tr>
<tr>
<td>Peptic Ulcer</td>
<td>10</td>
<td>5.8</td>
<td>10</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Years w DM</th>
<th>Match Mean</th>
<th>Match Variance</th>
<th>Standard Difference</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt; 6.5</td>
<td>52</td>
<td>30.4</td>
<td>60</td>
</tr>
<tr>
<td>6.5 - 8.5</td>
<td>89</td>
<td>52</td>
<td>99</td>
</tr>
<tr>
<td>&gt; 8.5</td>
<td>30</td>
<td>17.5</td>
<td>12</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>ICCCM Mean</th>
<th>ICCCM Variance</th>
<th>Match Mean</th>
<th>Match Variance</th>
<th>Standard Difference</th>
</tr>
</thead>
<tbody>
<tr>
<td>Baseline A1C</td>
<td>9.13</td>
<td>3.34</td>
<td>7.88</td>
<td>3.44</td>
</tr>
</tbody>
</table>

The baseline matching characteristics used for the propensity match were compared to determine the adequacy of the match. An adequate match has a standard mean difference
between the two groups of less than 0.2 (Austin, 2009; Lanza, Moore, & Butera, 2013). As Table 8 demonstrates, there are 3 characteristics that were not able to be matched adequately—the number of years since diagnosed with diabetes, Baseline A1C, and renal disease diagnosis. The number of years since diagnosed with diabetes was based on the first-time diabetes was coded at this healthcare system. Given that this value often coincided with the date the patient initiated care at this health system, it is unlikely that the time period accurately reflects the date of diabetes diagnosis. Therefore, this variable was eliminated from the match. However, the other two characteristics indicate the match is not from the same population; therefore, it was necessary to control statistically for the differences in these variables using a mixed models analysis.

Table 8 also demonstrates the actual number and percent of patient demographics in the intervention group compared to the propensity matched group. As recommended by Austin (2009, 2007), standardized differences were used to evaluate the match balance since unlike t-tests, standardized differences are not affected by sample size. All the demographic characteristics were included in the propensity match. It is not recommended to run significance tests for these characteristics but rather standardized differences are recommended as they are neither a characteristic of a hypothetical population nor affected by the sample size (Austin, 2007; Imai, King, & Stuart, 2008).

**Data Analysis per Hypothesis**

The following describes the results per hypothesis.

**Data Analysis: Hypothesis 1a**

- **H1a:** Adult patients with Type 2 diabetes had better patient engagement (number of missed (no show encounters/same day cancellations), annual influenza immunizations,
and annual eye examinations) after one year's participation in the ICCCM model in comparison to one year prior to participation in the ICCCM model.

**Missed (no show/same day cancellation) visits.** The data maintained a very right skewed poisson distribution. Consequently, a parametric statistical test could not be used to test this hypothesis. Since the Wilcoxon signed ranks test looks at the rank or the difference in medians rather than standard deviations, it is robust to outliers. Therefore, the Wilcoxon signed rank test, a nonparametric test, was used. Three assumptions were met to ensure that this test could be used (Laerd Statistics, 2015b). The first assumption met was that the dependent variable, missed (no show visits/same day cancellations) visits, was measured at an interval or ratio level (Laerd Statistics, 2015b). The second assumption met was that the independent variable (the intervention) was measured for two related groups, in this case pre and post intervention (Laerd Statistics, 2015b). The final assumption was that the differences in the distribution of these two groups were normally distributed (Laerd Statistics, 2015b). When looking at the differences distribution, this proved to be true for the total number of missed (no show visits/same day cancellations) visits even though the data itself was not normally distributed.

<table>
<thead>
<tr>
<th>N</th>
<th>Post Total Missed Office Visit - Pre Total Missed Office Visit</th>
</tr>
</thead>
<tbody>
<tr>
<td>Post &lt; Pre Missed Office Visit</td>
<td>65</td>
</tr>
<tr>
<td>Post &gt; Pre Missed Office Visit</td>
<td>73</td>
</tr>
<tr>
<td>Post = Pre Missed Office Visit</td>
<td>66</td>
</tr>
</tbody>
</table>

As shown in Table 9, there was no statistically significant difference between the number of missed appointments one year prior to participating in the ICCCM and one year after
participating in the ICCCM. Therefore, the ICCCM study failed to reject the null hypothesis: there was no difference in missed appointments pre and post ICCCM intervention.

**Influenza immunizations.** McNemar's test was used to determine if this hypothesis was accepted or rejected. The following assumptions were met for performing McNemar's test: 1) there is one dichotomous dependent variable (received flu shot) from a related group (both from the same group pre and post intervention) and 2) the participants in each group are mutually exclusive; in this case no one both received the flu shot and did not receive the flu shot (Laerd Statistics, 2015a).

Table 10. Difference in Receiving Annual Influenza Immunization Pre- and Post-ICCCM

<table>
<thead>
<tr>
<th>Pre (T2-T1) influenza immunization</th>
<th>Post (T1-T3) influenza immunization</th>
<th>Total N</th>
</tr>
</thead>
<tbody>
<tr>
<td>No</td>
<td>89 (43.6%)</td>
<td>204</td>
</tr>
<tr>
<td></td>
<td>Yes (15.7%)</td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>30 (14.7%)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Yes (26.0%)</td>
<td></td>
</tr>
</tbody>
</table>

As shown in Table 10, although there was a slight increase in influenza immunization post intervention, there was no statistically significant difference between the groups ($p = 0.90$). Consequently, the ICCCM study failed to reject the null hypothesis for influenza immunizations: there was no difference in receiving an influenza immunization pre and post ICCCM intervention.

**Dilated eye examinations.** Since all the assumptions of McNemar's test were met, McNemar's test was also used for the statistical analysis of dilated eye examinations.

Table 11. Difference in the Number of Eye Examinations Pre- and Post-ICCCM

<table>
<thead>
<tr>
<th>Pre(T2-T1) eye examination</th>
<th>Post (T1-T3) eye examination</th>
<th>Total N: 204</th>
</tr>
</thead>
<tbody>
<tr>
<td>No</td>
<td>75 (36.8%)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Yes (18.1%)</td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>32 (15.7%)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Yes (29.4%)</td>
<td></td>
</tr>
</tbody>
</table>

As shown in Table 11, although there was an increase in eye examinations post intervention, the
difference was not statistically significant ($p = 0.63$). Consequently, the ICCCM study failed to reject the null hypothesis for dilated eye examinations: there was no difference in receiving a dilated eye examination pre and post ICCCM intervention.

**Data Analysis: Hypothesis 1b**

- **H1b:** Adult patients with Type 2 diabetes, who received care at the ICCCM (intervention) site, had better patient engagement (number of missed (no show encounters/same day cancellations), annual influenza immunizations, and annual eye examinations) after one year than a sample of matched patients with Type 2 diabetes who received standard primary care within the same health system over that same year.

A generalized estimating equation with a binary logistic function was used for the categorical variables of influenza immunizations and eye examinations to statistically control for the covariates of renal disease and baseline A1C. This generalized estimating equation was also used for missed visits after this variable was dichotomized. Then, based on the output from the generalized estimating equation, an adjusted odds ratio was calculated (Table 12). All matched pairs were included in the sample (n=171) for all three dichotomized variables.

**Table 12. Odds Ratio of Patient Engagement Variables in ICCCM Group vs. Matched Group Adjusted for BL A1C and Renal Disease**

<table>
<thead>
<tr>
<th>Variable</th>
<th>Unadjusted Mean</th>
<th>Adjusted Mean</th>
<th>Odds Ratio</th>
<th>95% Adjusted Confidence Interval</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>ICCCJM Group</td>
<td>Matched Group</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Missed Appointments</td>
<td>0.36</td>
<td>0.46</td>
<td>0.753</td>
<td>-0.739 to 0.170</td>
</tr>
<tr>
<td></td>
<td>0.34&lt;sup&gt;b&lt;/sup&gt;</td>
<td>0.41&lt;sup&gt;b&lt;/sup&gt;</td>
<td>I(Reference)</td>
<td></td>
</tr>
<tr>
<td>Influenza Immunization</td>
<td>0.40&lt;sup&gt;a&lt;/sup&gt;</td>
<td>0.51&lt;sup&gt;a&lt;/sup&gt;</td>
<td>0.693</td>
<td>-0.798 to 0.064</td>
</tr>
<tr>
<td></td>
<td>0.43&lt;sup&gt;b&lt;/sup&gt;</td>
<td>0.53&lt;sup&gt;b&lt;/sup&gt;</td>
<td>I(Reference)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>ICCCJM Group</td>
<td>Matched Group</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<sup>a</sup> Significance: $p < 0.05$; <sup>b</sup> Significance: $p = 0.05$.
Dilated eye examination

<table>
<thead>
<tr>
<th>Group</th>
<th>ICCCM</th>
<th>Matched Group</th>
</tr>
</thead>
<tbody>
<tr>
<td>Post Total Missed Office Visit - Pre Total Missed Office Visit</td>
<td>0.47</td>
<td>0.57&lt;sup&gt;b&lt;/sup&gt;</td>
</tr>
</tbody>
</table>

<sup>a</sup> Significant at p = 0.033  <sup>b</sup> Baseline A1C Covariate fixed at 8.5006

**Missed (No Show/Same Day Cancellation) Visits.** The Wilcoxon signed rank test was used for missed visits since missed visits had a Poisson distribution and did not meet the normality assumption of a parametric test (Table 13). However, since the Wilcoxon signed rank test cannot adjust for covariates, a general linear model with regular linear regression with normally distributed outcome was run despite not meeting the assumptions of a parametric test. This was necessary to determine if baseline A1C and/or renal disease had a significant effect on the outcome. This general linear model was a multivariable adjusted model to assess if the baseline A1C and/or renal disease made a difference. Using this model, it was determined that the statistical significance changed due to these covariates indicating that these variables attenuated the effect of the outcome of missed visits (Table 14). Therefore, missed visits was transformed to a categorical variable with either no missed visits or 1 or more missed visits and a generalized estimated equation as previously described was used to analyze this categorical variable.

**Table 13. Difference in the number of Missed Office Visits Between ICCCM and Matched Group**

<table>
<thead>
<tr>
<th>Group</th>
<th>N</th>
<th>Post Total Missed Office Visit - Pre Total Missed Office Visit</th>
</tr>
</thead>
<tbody>
<tr>
<td>ICCCM &lt; Control</td>
<td>58</td>
<td></td>
</tr>
<tr>
<td>ICCCM &gt; Control</td>
<td>81</td>
<td></td>
</tr>
<tr>
<td>ICCCM = Control</td>
<td>32</td>
<td>-2.266</td>
</tr>
</tbody>
</table>

As shown in Table 13, there was a statistically significant difference between the number of missed appointments with the matched control group having a statistically significant
decreased number of missed visits than the ICCCM group \((p = .02)\). Therefore, based on this data, the null hypothesis was rejected. Surprisingly, the matched control had a statistically significant fewer missed visits compared to the ICCCM group. However, since it was not possible to control for the Baseline A1C or renal disease, this data was also run as a mixed model despite being a Poisson distribution, which did not meet the assumptions of normality of the mixed model.

Table 14. Missed Visits Controlling for Renal Disease and Baseline A1C*

<table>
<thead>
<tr>
<th>Number of Missed Visits</th>
<th>Covariates added to model</th>
<th>Group</th>
<th>Mean t-statistic</th>
<th>Significance</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>none</td>
<td>ICCCM</td>
<td>1.94</td>
<td>2.101</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Control</td>
<td>1.42</td>
<td></td>
</tr>
<tr>
<td>Renal disease</td>
<td>ICCCM</td>
<td>2.22</td>
<td>1.732</td>
<td>0.08</td>
</tr>
<tr>
<td></td>
<td>Control</td>
<td>1.79</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Baseline A1C</td>
<td>ICCCM</td>
<td>1.85</td>
<td>1.334</td>
<td>0.18</td>
</tr>
<tr>
<td></td>
<td>Control</td>
<td>1.50</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Renal disease &amp; BL A1C</td>
<td>ICCCM</td>
<td>2.13</td>
<td>0.995</td>
<td>0.32</td>
</tr>
<tr>
<td></td>
<td>Control</td>
<td>1.87</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

*Baseline A1C controlled at 8.5006

As shown in Table 14, when adjusted for either baseline A1C and/or renal disease, missed visits were no longer statistically significant demonstrating that the null hypothesis was no longer able to be rejected. Since the mixed model assumptions had not been met, to accurately determine the statistical significance of missed visits while controlling for baseline A1C and renal disease, this data was dichotomized.

As shown in Table 12, these results demonstrate that after adjusting for the covariates of renal disease and controlling baseline A1C at 8.5006, the odds of the intervention group having no missed visits (no show/same day cancellations) was 0.753 times lower than that of the control group. Although these data show the control group with fewer missed visits, this difference was
not statistically significant \( \chi^2 (1, N = 171) = 1.503, p=0.22, \text{CI} [-0.739, 0.170] \). Therefore, the ICCCM study failed to reject the null hypothesis: there was no difference between the number of missed (no show/same day cancellation) visits in the intervention group compared to the propensity matched group.

**Influenza immunizations.** As shown in Table 12, after adjusting for the covariates of renal disease and controlling baseline A1C at 8.5006, the odds of the intervention group receiving their annual influenza immunization was 0.693 times lower than the control group. However, this difference was not statistically significant: \( \chi^2 (1, N = 171) =2.792, p =0.10, 95\% \text{ CI} [-0.798, 0.064] \). Therefore, the ICCCM study failed to reject the null hypothesis: there was no difference between the number of annual influenza immunizations in the intervention group compared to the propensity matched group.

**Dilated eye examinations.** As shown in Table 12, after controlling for covariates with the baseline A1C controlled at 8.5006, the odds of the intervention group receiving their annual eye examination was 0.552 times lower than the control group. This difference was statistically significant - \( \chi^2 (1, N = 342) =6.378, p =0.01, 95\% \text{ CI} [-1.058, -0.133] \) in that the patients in the ICCCM clinic were less likely to have an annual eye examination. Therefore, the ICCCM study rejected the null hypothesis, and the matched control group was more likely to have an annual eye examination.

**Data Analysis: Hypothesis 2a**

- **H2a:** Adult patients with Type 2 diabetes had better health care utilization (fewer hospitalizations, fewer hospital days, and fewer emergency room visits) after one year's participation in the ICCCM model in comparison to one year prior to participation in the ICCCM model.
As expected, all three variables, number of hospitalizations, emergency room visits and number of hospital days maintained a very right skewed poisson distribution. Consequently, a parametric statistical test could not be used to evaluate the data. Therefore, the Wilcoxon signed rank test, a nonparametric test was used. As previously explained, all three assumptions were met to ensure that this test could be used (Laerd Statistics, 2015b).

**Number of hospitalizations.** As shown in Table 15, the difference in the number of hospitalizations pre- and post- ICCCM was evaluated using the Wilcoxon signed test.

<table>
<thead>
<tr>
<th></th>
<th>N(%)</th>
<th>Post Hospitalizations – Pre Hospitalizations</th>
</tr>
</thead>
<tbody>
<tr>
<td>Post &lt; Pre</td>
<td>33(16.2%)</td>
<td></td>
</tr>
<tr>
<td>Post &gt; Pre</td>
<td>31(15.2%)</td>
<td>Z</td>
</tr>
<tr>
<td>Post = Pre</td>
<td>140(68.6%)</td>
<td>-0.177</td>
</tr>
</tbody>
</table>

Although there was a slight decrease in number of hospitalizations post intervention, this difference was not significant, \( z = -0.177, p = 0.86 \). Therefore, the ICCCM study failed to reject the null hypothesis: there was no difference in the number of hospital visits pre and post intervention.

**Number of emergency room visits.** As shown in Table 16, the difference in the number of emergency room visits pre- and post- ICCCM was evaluated using the Wilcoxon signed test.

<table>
<thead>
<tr>
<th></th>
<th>N(%)</th>
<th>Post ER visit - Pre ER visit</th>
</tr>
</thead>
<tbody>
<tr>
<td>Post ER visit &lt; Pre ER visit</td>
<td>27(13.2%)</td>
<td></td>
</tr>
<tr>
<td>Post ER visit &gt; Pre ER visit</td>
<td>40(19.6%)</td>
<td>Z</td>
</tr>
<tr>
<td>Post ER visit = Pre ER visit</td>
<td>137(67.2%)</td>
<td>-1.108</td>
</tr>
</tbody>
</table>

Although more patients sought treatment in the emergency room after the intervention than before, there was no statistically significant difference between the two groups \( p = 0.27 \). Therefore, the ICCCM study failed to reject the null hypothesis: there was no difference in the number of emergency room visits pre and post intervention.
Number of days hospitalized. As shown in Table 17, the difference in the number of days hospitalized pre- and post- ICCCM was evaluated using the Wilcoxon signed test.

<table>
<thead>
<tr>
<th>N(%)</th>
<th>Wilcoxon sign Test</th>
</tr>
</thead>
<tbody>
<tr>
<td>Posthosp days &lt; Prehosp days</td>
<td>34(16.7%)</td>
</tr>
<tr>
<td>Posthosp days &gt; Prehosp days</td>
<td>35(17.2%)</td>
</tr>
<tr>
<td>Posthosp days = Prehosp days</td>
<td>135(66.2%)</td>
</tr>
</tbody>
</table>

The difference in the number of days hospitalized pre and post ICCCM participation was not statistically significant (p = 0.64). Therefore, the ICCCM study failed to reject the null hypothesis: there was no difference in the number of hospital days pre and post intervention.

Data Analysis: Hypothesis 2b

- H2b: Adult patients with Type 2 diabetes who received care at the ICCCM (intervention) site had better health care utilization (fewer hospitalizations, fewer hospital days, and fewer emergency room visits) after one year than a sample of matched patients with Type 2 diabetes who received standard primary care within the same health system over that same year.

All three healthcare utilization variables demonstrated significant outliers in the Poisson distribution, violating the assumptions for the use of parametric statistics. Therefore, the Wilcoxon Signed Rank test was used to determine the effect of the ICCCM model on the intervention group when compared to a propensity matched group of patients for the healthcare utilization variables. As previously described, a general linear model was also run to control for the covariates for baseline A1C and renal disease despite not meeting all of the assumptions, since the Wilcoxon Signed Rank test does not provide a method of controlling for variables (see
Table 18). Neither the direction nor the significance of the results differed between the general linear model and Wilcoxon Signed Test for the three utilization outcome variables. Consequently, the decision was made to use the Wilcoxon Signed Rank test for these variables.

Table 18. Healthcare Utilization Controlling for Renal Disease and Baseline A1C*

<table>
<thead>
<tr>
<th></th>
<th>Group</th>
<th>Mean</th>
<th>t-statistic</th>
<th>Significance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of Hospitalizations</td>
<td>ICCCM</td>
<td>0.77</td>
<td>-1.191</td>
<td>0.24</td>
</tr>
<tr>
<td></td>
<td>Control</td>
<td>0.62</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Number of Emergency Room Visits</td>
<td>ICCCM</td>
<td>0.40</td>
<td>0.341</td>
<td>0.73</td>
</tr>
<tr>
<td></td>
<td>Control</td>
<td>0.37</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Number of Hospital Days</td>
<td>ICCCM</td>
<td>3.86</td>
<td>-0.850</td>
<td>0.40</td>
</tr>
<tr>
<td></td>
<td>Control</td>
<td>3.28</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

*Baseline A1C controlled at 8.5006

**Number of hospitalizations.** As shown in Table 19, although three more participants in the intervention group had more hospitalizations than the matched control group, this difference between the two groups was not statistically significant ($p = 0.59$). Consequently, the ICCCM study failed to reject the null hypothesis: there was no difference in the number of hospitalizations between the intervention group and propensity matched group.

**Emergency room visits.** As shown in Table 19, although nine more ICCCM participants had more emergency room visits than the matched control group, this difference between these two groups was not statistically significant ($p = 0.24$). Consequently, the ICCCM study failed to reject the null hypothesis: there was no difference in the number of emergency room visits between the ICCCM group and propensity matched group.

**Number of days hospitalized.** As shown in Table 19, although five more ICCCM participants had a greater number of hospital days than the propensity matched control group, this difference was not statistically significant ($p = 0.48$). Consequently, the ICCCM study failed
to reject the null hypothesis: there was no difference in the number of hospital days between the intervention group and the propensity matched control group.

Table 19. Difference in Healthcare Utilization in ICCCM Intervention Group and Matched Group

<table>
<thead>
<tr>
<th></th>
<th>N(%)</th>
<th>ICCCM hospitalizations - Matched hospitalizations</th>
</tr>
</thead>
<tbody>
<tr>
<td>ICCCM hospitalizations &lt; Matched hospitalizations</td>
<td>29(17.0%)</td>
<td></td>
</tr>
<tr>
<td>ICCCM hospitalizations &gt; Matched hospitalizations</td>
<td>32(18.7%)</td>
<td>Z</td>
</tr>
<tr>
<td>ICCCM hospitalizations = Matched hospitalizations</td>
<td>110(64.3%)</td>
<td>-0.536</td>
</tr>
<tr>
<td>ICCCM ER visits &lt; Matched ER visits</td>
<td>28(16.4%)</td>
<td>ICCCM ER visits – Matched ER visits</td>
</tr>
<tr>
<td>ICCCM ER visits &gt; Matched ER visits</td>
<td>37(21.6%)</td>
<td>Z</td>
</tr>
<tr>
<td>ICCCM ER visits = Matched ER visits</td>
<td>106(62.0%)</td>
<td>-1.168</td>
</tr>
<tr>
<td>ICCCM hosp days &lt; Matched hosp days</td>
<td>29(17.0%)</td>
<td>ICCCM hosp days – Matched hosp days</td>
</tr>
<tr>
<td>ICCCM hosp days &gt; Matched hosp days</td>
<td>34(19.9%)</td>
<td>Z</td>
</tr>
<tr>
<td>ICCCM hosp days = Matched hosp days</td>
<td>108(63.2%)</td>
<td>-0.703</td>
</tr>
</tbody>
</table>

**Data Analysis: Hypothesis 3a**

- **H3a:** Adult patients with Type 2 diabetes had better clinical indicators (percent of patients with Hgb A1C levels > 9.0; change in Hgb A1C, weight, and systolic and diastolic blood pressure, systolic blood pressure < 140, diastolic blood pressure < 90) after one year's participation in the ICCCM model in comparison to one year prior to participation in the ICCCM model.

**Clinical Indicators.** The clinical indicator data were continuous data, which assumed a normal distribution. However, since the ICCCM group were from a family practice clinic, there
were patients who were related and living in the same household (i.e. spouses, or parent/child). Therefore, it could not be assured that these patients met the parametric assumption of independence (Field, 2009). Consequently, since the assumptions of a parametric test were violated, nonparametric tests for all clinical indicators were used. After verifying assumptions, McNemar's test was used to analyze all categorical variables (i.e. A1C > 9, systolic blood pressure < 140, diastolic blood pressure < 90), and the Wilcoxon signed rank test was used for all continuous variables (change in absolute numeric value pre and post ICCCM) (Laerd Statistics, 2015a; Laerd Statistics, 2015b).

**A1C.** The A1C was measured as both dichotomized with A1C > 9.00 or ≤ 9.00 and as a continuous variable. Both the change in A1C from just prior to the ICCCM to one year of participation and the difference between the A1C one year prior to the ICCCM and one year after the initiation of the ICCCM intervention were analyzed.

*Categorical analysis of A1C.** McNemar's test evaluated the difference between the number of patients with A1C levels > 9.00 pre and post entering the ICCCM intervention. Of the initial 204 participants, 182 participants had data from one year prior to the ICCCM entry and one year post ICCCM entry.

Table 20. Difference in Number of High A1C (9.0) Pre- and Post-ICCCM

<table>
<thead>
<tr>
<th>Pre(T1) A1C Grouped</th>
<th>Post (T3) A1C Grouped</th>
<th>Total N</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>N ≤9.00 (%)</td>
<td>N &gt; 9.00 (%)</td>
</tr>
<tr>
<td>≤9.00</td>
<td>83 (45.6%)</td>
<td>13 (7.1%)</td>
</tr>
<tr>
<td>&gt; 9.00</td>
<td>41 (22.5%)</td>
<td>45 (24.7%)</td>
</tr>
</tbody>
</table>

As shown in Table 20, there was a statistically significant difference among the groups (\(p = 0.001\)) indicating that more patients improved their A1C after participating in the ICCCM intervention. Consequently, the null hypothesis was rejected.
Absolute change in A1C. The change in A1C pre and post the ICCCM intervention violated the independence assumption for parametric tests. Therefore, the Wilcoxon signed rank test was used. The change between A1C just prior to starting in the ICCCM and one year post ICCCM (T1 & T3) was evaluated for the 182 participants. As shown in Table 21, there was a significant change in A1C over the year with $z = -5.650$, $p < 0.001$. Consequently, the null hypothesis for the difference between the change in A1C pre and post intervention equaling zero was rejected and more patients had statistically significant lower A1C after the ICCCM intervention than before the intervention.

Table 21. Change in A1C Pre- and Post-ICCCM Intervention

<table>
<thead>
<tr>
<th>A1C change between timepoints (Pre ICCCM – Post ICCCM)</th>
<th>Z</th>
<th>Significance</th>
</tr>
</thead>
<tbody>
<tr>
<td>A1C pre ICCCM &lt; A1C post ICCCM</td>
<td>-5.650</td>
<td>&lt; 0.001</td>
</tr>
<tr>
<td>A1C pre ICCCM &gt; A1C post ICCCM</td>
<td></td>
<td></td>
</tr>
<tr>
<td>A1C pre ICCCM = A1C post ICCCM</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Absolute difference in A1C. The difference between A1C for the year prior to ICCCM and A1C for the year after ICCCM initiation was evaluated for the 164 participants with data at all three timepoints using the Wilcoxon signed test. As shown in Table 22, there was a significant difference ($p < 0.001$). Consequently, the null hypothesis for the difference in A1C pre and post intervention equaling zero was rejected and more patients had statistically significant lower A1C in the year after the intervention than in the year before the intervention.

Table 22. Difference in A1C Pre -and Post-ICCCM Intervention

<table>
<thead>
<tr>
<th>Difference in A1C over one year</th>
<th>N(%)</th>
<th>Z score</th>
<th>Significance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Difference Post ICCCM A1C (T1-T3) &lt; Difference Pre ICCCM A1C (T2-T1)</td>
<td>53(32.3%)</td>
<td>-4.470</td>
<td>&lt; 0.001</td>
</tr>
</tbody>
</table>
Difference Post ICCCM A1C (T1-T3) > Difference Pre ICCCM A1C (T2-T1) 110(67.1%)

Difference Post ICCCM A1C (T1-T3) = Difference Pre ICCCM A1C (T2-T1) 1(0.6%)

T1A1C = at ICCCM intervention; T2A1C = 1 year pre ICCCM intervention; T3 A1C = 1 year post ICCCM intervention

**Weight.** Participants (n=171) were selected for this variable only if they were overweight when entering the ICCCM intervention (T1): their BMI was greater than 25 or if they had no BMI and their weight was greater than 185 pounds (Centers for Disease Control and Prevention [CDC], 2016b). The decision to use 185 pounds was determined as it was unlikely for anyone, male or female to have a height more than 6 feet and the BMI for a patient with a weight of 185 pounds and height of 6 feet is 25.1 or overweight. However, 44 of these participants either were not overweight or did not have a weight both pre and post and 1 additional patient did not have a weight one year prior to ICCCM. Consequently, the final analysis included 160 participants for change in weight and 159 for difference in weight.

**Absolute change in weight.** As shown in Table 23, the change in weight pre ICCCM and post ICCCM was statistically significant (p = 0.02). Consequently, the null hypothesis for the change in weight pre and post intervention equaling zero was rejected and more patients had statistically significant lower weights in the year after the intervention than before the intervention.

<table>
<thead>
<tr>
<th>Weight</th>
<th>N(%)</th>
<th>Z score</th>
<th>Significance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Post ICCCM wt &lt; Pre ICCCM wt (wt loss)</td>
<td>88(55%)</td>
<td>-2.280</td>
<td>p = 0.02</td>
</tr>
<tr>
<td>Post ICCCM wt &gt; Pre ICCCM wt (wt gain)</td>
<td>62(38.8%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Post ICCCM wt = Pre ICCCM wt (no change)</td>
<td>10(6.3%)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Absolute difference in weight. Next the difference in weight pre and post intervention for the overweight participants with weight information at all three timepoints (N= 159) was then calculated and compared using the Wilcoxon signed rank test. As shown in Table 24, the difference in weight for the full year prior to ICCCM compared to the year after ICCCM was not statistically significant. Consequently, the ICCCM study failed to reject the null hypothesis. Participants who were overweight at baseline had no statistically significant difference in weight for the year after the intervention compared to the year before the intervention. Therefore, although overweight patients overall had a statistically significant decrease in weight between T1 and T3, the change in the difference in weight for the year prior to the intervention compared to post intervention was not statistically significant.

Table 24. Difference in Weight Pre- and Post-ICCCM Intervention

<table>
<thead>
<tr>
<th>Weight change between timepoints (Yr after intervention (T1-T3) – Yr prior to intervention (T2-T1))</th>
<th>Z score</th>
<th>Significance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Post wt loss (T1-T3) &lt; pre wt loss (T2-T1)</td>
<td>79(49.7%)</td>
<td>-.269  p = 0.79</td>
</tr>
<tr>
<td>Post wt loss (T1-T3) &gt; pre wt loss (T2-T1)</td>
<td>78(49.1%)</td>
<td></td>
</tr>
<tr>
<td>Post wt loss (T1-T3) = pre wt loss (T2-T1)</td>
<td>2(1.3%)</td>
<td></td>
</tr>
</tbody>
</table>

Blood pressure. Participants were selected for this variable only if they carried the diagnosis of hypertension at T1 (n=183) in the administrative data set (ICD codes). Blood pressure was measured in 3 ways: 1) change in blood pressure, 2) difference in blood pressure, 3) dichotomized blood pressure. The change (pre ICCCM (T1) and post ICCCM (T3)) and the difference (year prior to the intervention (T2-T1) and the year post intervention (T1-T3) in the systolic and diastolic blood pressure values of these hypertensive participants were compared using the Wilcoxon signed rank test. A total of 180 participants had blood pressure results for
both two (change in blood pressure) and three (difference in blood pressure) timepoints. Therefore, 180 participants of the 183 potential participants with hypertension were included in the analysis of both change and difference in blood pressure. Next, these participants were separated into groups based on systolic blood pressure less than 140 or greater than or equal to 140 and diastolic blood pressure less than 90 or greater than or equal to 90. Since this is dichotomous nonparametric data, McNemar’s test was used for this analysis after verifying assumptions.

**Absolute change in systolic blood pressure.** As shown in Table 25, the change in the value of systolic blood pressure immediately pre and post ICCCM was not statistically significant ($p = 0.48$). Consequently, the null hypothesis for the change between post ICCCM systolic blood pressure and pre ICCCM systolic blood pressure being the same was supported. There was no difference in systolic blood pressure pre and post intervention.

<table>
<thead>
<tr>
<th>Systolic Blood Pressure</th>
<th>N(%)</th>
<th>Z score</th>
<th>Significance</th>
</tr>
</thead>
<tbody>
<tr>
<td>T3 systolic b/p &lt; T1 systolic b/p</td>
<td>79(43.9%)</td>
<td>-0.709</td>
<td>$p = 0.48$</td>
</tr>
<tr>
<td>T3 systolic b/p &gt; T1 systolic b/p</td>
<td>92(51.4%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>T3 systolic b/p = T1 systolic b/p</td>
<td>9(5.0%)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Absolute change in diastolic blood pressure.** As shown in Table 26, the change in diastolic blood pressure immediately pre and post ICCCM was not statistically significant ($p = 0.66$). Consequently, the null hypothesis for the change between post ICCCM diastolic blood pressure and pre ICCCM diastolic blood pressure being the same was supported. There was no difference in diastolic blood pressure pre and post intervention.
Table 26. Change in Diastolic Blood Pressure Pre-and Post-ICCCM

<table>
<thead>
<tr>
<th>Diastolic Blood Pressure</th>
<th>Z score</th>
<th>Significance</th>
</tr>
</thead>
<tbody>
<tr>
<td>T3 diastolic b/p &lt; T1 diastolic b/p</td>
<td>88(49.2%)</td>
<td>-0.440</td>
</tr>
<tr>
<td>T3 diastolic b/p &gt; T1 diastolic b/p</td>
<td>77(42.8%)</td>
<td></td>
</tr>
<tr>
<td>T3 diastolic b/p = T1 diastolic b/p</td>
<td>15(8.4%)</td>
<td></td>
</tr>
</tbody>
</table>

**Absolute difference in systolic blood pressure.** As shown in Table 27, the difference in systolic blood pressure for the year prior to ICCCM compared to the year post ICCCM was not statistically significant (\( p = 0.478 \)). Consequently, the null hypothesis for the difference between systolic blood pressure one year before ICCCM and one year after ICCCM equaling zero was supported. There was no difference in systolic blood pressure one year pre ICCCM compared to one year post ICCCM.

Table 27. Difference in Systolic Blood Pressure Values for Years Pre- and Post-ICCCM

<table>
<thead>
<tr>
<th>Difference in Systolic Blood Pressure</th>
<th>N(%)</th>
<th>Z score</th>
<th>Significance</th>
</tr>
</thead>
<tbody>
<tr>
<td>T1-T3 &lt; T2-T1</td>
<td>89(49.7%)</td>
<td>-0.709</td>
<td>( p = 0.48 )</td>
</tr>
<tr>
<td>T1-T3 &gt; T2-T1</td>
<td>86(47.8%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>T1-T3 = T2-T1</td>
<td>5(2.8%)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Absolute difference in diastolic blood pressure.** As shown in Table 28, the difference in diastolic blood pressure values for the year prior to ICCCM compared to the year post ICCCM was not statistically significant (\( p = 0.92 \)). Consequently, the null hypothesis for the difference between diastolic blood pressure one year before ICCCM and one year after ICCCM equaling zero was supported. There was no difference in diastolic blood pressure one year pre ICCCM compared to one year post ICCCM.
Table 28. Difference in Diastolic Blood Pressure Values for Years Pre- and Post-ICCCM

<table>
<thead>
<tr>
<th>Difference in change of Diastolic Blood Pressure</th>
<th>Z score</th>
<th>Significance</th>
</tr>
</thead>
<tbody>
<tr>
<td>T1-T3 &lt; T2-T1</td>
<td>87(48.3%)</td>
<td>-0.096</td>
</tr>
<tr>
<td>T1-T3 &gt; T2-T1</td>
<td>85(47.5%)</td>
<td></td>
</tr>
<tr>
<td>T1-T3 = T2-T1</td>
<td>8(4.5%)</td>
<td></td>
</tr>
</tbody>
</table>

*Dichotomized systolic blood pressure.* As shown in Table 29, the difference in the pre/post number of participants with systolic blood pressure <140 compared to ≥ 140 was not statistically significant (p = 1.00). Consequently, the number of participants with a systolic blood pressure less than 140 one year after ICCCM was no different than the number of participants with a systolic blood pressure less than 140 pre ICCCM. Therefore, the null hypothesis was not rejected. There was no difference in systolic blood pressure less than 140 pre and post intervention.

Table 29. Grouped Systolic Blood Pressure Pre- and Post-ICCCM

<table>
<thead>
<tr>
<th>Pre(T1) Systolic BP</th>
<th>Post (T3) Systolic BP</th>
<th>Total N</th>
<th>Significance</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt; 140</td>
<td></td>
<td>179</td>
<td></td>
</tr>
<tr>
<td>N &lt;140 (%)</td>
<td>N ≥ 140 (%)</td>
<td>80 (44.7%)</td>
<td>33 (18.4%)</td>
</tr>
<tr>
<td>≥ 140</td>
<td></td>
<td>33 (18.4%)</td>
<td>33 (18.4%)</td>
</tr>
</tbody>
</table>

*Dichotomized diastolic blood pressure.* As shown in Table 30, the difference in the pre/post number of participants with diastolic blood pressure <90 compared to ≥ 90 was statistically significant (p = 0.04). Consequently, the number of participants with a diastolic blood pressure less than 90 post ICCCM was greater than the number of participants with a diastolic blood pressure less than 90 pre ICCCM. Therefore, the null hypothesis was rejected. There was a statistically significant improvement in the number of participants with a diastolic blood pressure less than 90 post ICCCM compared to pre ICCCM.
Table 30. Grouped Diastolic Blood Pressure Pre- and Post-I CCCM

<table>
<thead>
<tr>
<th>Pre(T1) Diastolic BP</th>
<th>Post (T3) Diastolic BP</th>
<th>Total N</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt; 90</td>
<td>N &lt;90 (%)</td>
<td>N ≥ 90 (%)</td>
</tr>
<tr>
<td>&lt; 90</td>
<td>143 (79.9%)</td>
<td>7 (3.9%)</td>
</tr>
<tr>
<td>≥ 90</td>
<td>18 (10.1%)</td>
<td>11 (6.1%)</td>
</tr>
</tbody>
</table>

Data Analysis: Hypothesis 3b

- H3b: Adult patients with Type 2 diabetes who received care at the ICCCM (intervention) site will have better clinical indicators (percent of patients with Hgb A1C levels > 9.0; change in Hgb A1C, weight, and systolic and diastolic blood pressure, systolic blood pressure < 140, diastolic blood pressure < 90) for one year than a sample of matched patients with Type 2 diabetes who received standard primary care within the same health system over that same year.

Again, since the assumption of independence was likely violated, nonparametric tests were used to evaluate all clinical indicators. A generalized estimating equation controlling for baseline A1C and renal failure was used to analyze the dichotomized variables of A1C > 9.0, systolic blood pressure < 140 and diastolic blood pressure < 90 at T3. A general linear mixed model for quantitative variables was run to determine the effect of the ICCCM model on the intervention group and a propensity matched group of patients for the continuous variables of change in A1C, weight, systolic and diastolic blood pressure while controlling for the dichotomous covariate renal disease and the continuous covariate baseline A1C. Since the data did not meet all the assumptions of the parametric test, the Wilcoxon Signed Rank test was also run to ensure there was no discrepancy in the results after controlling for the covariates using a parametric test and the nonparametric test. Finally, since both the general linear mixed model and generalized estimating equations are robust to missing data and the level of missing data was not high, matches with data points for only one of the two groups (intervention or control) were
kept in the statistical model (Field, 2009). Hence the number of participants in some instances is
different between the groups. The results of the generalized estimating equations (Table 31) and
the general linear mixed model (32) for all the clinical variables are shown in the tables below.

Table 31. Odds Ratio of ICCCM Group vs. Matched Group in Categorized A1C, Systolic B/P,
Diastolic B/P Adjusted for BL A1C and Renal Disease

<table>
<thead>
<tr>
<th>Variable</th>
<th>Group</th>
<th>N</th>
<th>Unadjusted Mean</th>
<th>Adjusted Mean</th>
<th>Odds Ratio</th>
</tr>
</thead>
<tbody>
<tr>
<td>HGB A1C level &gt; 9.0</td>
<td>ICCCM Group</td>
<td>155</td>
<td>0.37</td>
<td>0.19&lt;sup&gt;a&lt;/sup&gt;</td>
<td>1.802</td>
</tr>
<tr>
<td></td>
<td>Matched Group</td>
<td>163</td>
<td>0.16</td>
<td>0.12&lt;sup&gt;a&lt;/sup&gt;</td>
<td>1 (Reference)</td>
</tr>
<tr>
<td>Systolic B/P &lt; 140</td>
<td>ICCCM Group</td>
<td>150</td>
<td>0.61</td>
<td>0.61&lt;sup&gt;b&lt;/sup&gt;</td>
<td>0.799</td>
</tr>
<tr>
<td></td>
<td>Matched Group</td>
<td>149</td>
<td>0.68</td>
<td>0.66&lt;sup&gt;b&lt;/sup&gt;</td>
<td>1 (Reference)</td>
</tr>
<tr>
<td>Diastolic B/P &lt; 90</td>
<td>ICCCM Group</td>
<td>150</td>
<td>0.89</td>
<td>0.91&lt;sup&gt;b&lt;/sup&gt;</td>
<td>1.147</td>
</tr>
<tr>
<td></td>
<td>Matched Group</td>
<td>149</td>
<td>0.89</td>
<td>0.90&lt;sup&gt;b&lt;/sup&gt;</td>
<td>1 (Reference)</td>
</tr>
</tbody>
</table>

<sup>a</sup> Baseline A1C Covariate fixed at 8.5013
<sup>b</sup> Baseline A1C Covariate fixed at 8.5007

Table 32. Change in Clinical Indicators Between ICCCM Group and Matched Group Unadjusted
and Adjusted for Baseline A1C and Renal Disease

<table>
<thead>
<tr>
<th>Variable</th>
<th>Group</th>
<th>N</th>
<th>Unadjusted Mean</th>
<th>Adjusted Mean</th>
<th>t</th>
<th>Sig.</th>
<th>Lower Bound</th>
<th>Upper Bound</th>
<th>95% Confidence Interval</th>
</tr>
</thead>
<tbody>
<tr>
<td>Change in A1C</td>
<td>ICCCM Group</td>
<td>152</td>
<td>0.66</td>
<td>0.79&lt;sup&gt;a&lt;/sup&gt;</td>
<td>2.948</td>
<td>.003</td>
<td>0.176</td>
<td>0.881</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Matched Group</td>
<td>156</td>
<td>0.04</td>
<td>0.26&lt;sup&gt;a&lt;/sup&gt;</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Change in Weight</td>
<td>ICCCM Group</td>
<td>165</td>
<td>2.72</td>
<td>2.37&lt;sup&gt;b&lt;/sup&gt;</td>
<td>1.490</td>
<td>.14</td>
<td>-0.863</td>
<td>6.234</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Matched Group</td>
<td>165</td>
<td>0.34</td>
<td>-0.32&lt;sup&gt;b&lt;/sup&gt;</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Change in Systolic B/P</td>
<td>ICCCM Group</td>
<td>169</td>
<td>-0.48</td>
<td>-0.19&lt;sup&gt;c&lt;/sup&gt;</td>
<td>0.26</td>
<td>-7.366</td>
<td>1.993</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Matched Group</td>
<td>169</td>
<td>1.41</td>
<td>2.50&lt;sup&gt;c&lt;/sup&gt;</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Change in Diastolic B/P</td>
<td>ICCCM Group</td>
<td>169</td>
<td>-0.21</td>
<td>-0.38&lt;sup&gt;c&lt;/sup&gt;</td>
<td>0.45</td>
<td>-3.839</td>
<td>1.717</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Matched Group</td>
<td>169</td>
<td>0.751</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
HGB A1C level > 9.0. As shown in Table 31, these results demonstrate that after adjusting for the covariates of renal disease and controlling baseline A1C at 8.5013, the odds of the intervention group having an A1C > 9.0 after one year (T3) was 1.8 times higher than that of the control group. However this difference was not statistically significant \(X^2 (1, N = 318) = 2.798, p = 0.09, CI [-1.01, 1.279]\). Therefore, the null hypothesis was not rejected: there was no difference between the number of patients with an A1C > 9.0 after one year in the intervention group compared to the propensity matched group.

However, the unadjusted results (Table 32), demonstrated a significant difference between the number of patients with an A1C > 9.0 after one year in the intervention group compared to the propensity matched group \(X^2 (1, N = 318) = 20.160, p<0.001, CI [0.631, 1.609]\). The unadjusted odds of the intervention group were 3.065 times more likely to have an A1C >9 after the intervention than the matched comparison group. However, at baseline there were also more patients that had an A1C > 9.0 in the intervention group (N = 80) than the matched comparison group (N = 31). Consequently, as shown in Table 33, adjusting for baseline A1C attenuated the difference in A1C >9 between the ICCCM and matched comparison groups.

Table 33. Odds Ratio of ICCCM Group vs. Matched Group With and Without Adjustments in Categorized A1C > 9

<table>
<thead>
<tr>
<th>Covariates added to model</th>
<th>Group Mean</th>
<th>Odds Ratio</th>
<th>95% Confidence Interval</th>
</tr>
</thead>
<tbody>
<tr>
<td>HGB A1C level &gt; 9.0</td>
<td>ICCCM</td>
<td>0.37</td>
<td>3.065</td>
</tr>
<tr>
<td></td>
<td>Control</td>
<td>0.16</td>
<td>1 (Reference)</td>
</tr>
<tr>
<td>Renal disease</td>
<td>ICCCM</td>
<td>0.36</td>
<td>3.099</td>
</tr>
<tr>
<td></td>
<td>Control</td>
<td>0.15</td>
<td>1 (Reference)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Wald Chi-Square</th>
<th>Significance</th>
</tr>
</thead>
<tbody>
<tr>
<td>20.160</td>
<td>p &lt; 0.001</td>
</tr>
<tr>
<td>19.778</td>
<td>p &lt; 0.001</td>
</tr>
</tbody>
</table>
### Change in A1C

As shown in Table 3, 308 total participants were included in this analysis. The results indicate that the intervention group had a statistically significant higher mean change in A1C from pre (T1) to post (T3) ICCCM with the covariate of baseline A1C controlled at 8.5117 $t(308) = 2.948$, $p=0.003$, indicating that the intervention group had a statistically significant larger improved change in A1C from pre-post (T1-T3) than the control group. Therefore, for hypothesis 3b, the change in A1C was significantly improved in the intervention group. Therefore, the null hypothesis was rejected; there was a statistically significant improved change in A1C for the intervention group pre to post (T1 to T3) ICCCM compared to the propensity matched group.

### Weight change

As shown in Table 3, 330 participants were included in this analysis. The results indicate that although the intervention group did have a lower mean change in weight from pre (T1) to post (T3) ICCCM with the covariate of baseline A1C controlled at 8.5773, the difference was not statistically significant $t(256) = 1.490$, $p=0.14$. Therefore, the null hypothesis was not rejected, there was no difference between the weight change in the intervention group compared to the propensity matched group.

### Systolic blood pressure < 140

As shown in Table 31, after adjusting for the covariates of renal disease and controlling baseline A1C at 8.5007, the odds of the intervention group having a systolic blood pressure < 140 at one-year post ICCCM (T3) was 0.799 times lower than that of the control group. However, this difference was not statistically significant $X^2 (1, N = 299) = 0.746$, $p = 0.39$, CI [-0.734, 0.285]. Therefore, the null hypothesis was not rejected: there

<table>
<thead>
<tr>
<th>Baseline A1C</th>
<th>ICCCM</th>
<th>Control</th>
<th>1 (Reference)</th>
<th>2.514</th>
<th>$p = 0.11$</th>
</tr>
</thead>
<tbody>
<tr>
<td>Control</td>
<td>0.13a</td>
<td>1</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Renal disease &amp; BL A1C</th>
<th>ICCCM</th>
<th>Control</th>
<th>1 (Reference)</th>
<th>2.798</th>
<th>$p = 0.09$</th>
</tr>
</thead>
<tbody>
<tr>
<td>Control</td>
<td>0.12a</td>
<td>1</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

$^a$Baseline A1C=8.5013
was no difference between the number of patients with a systolic blood pressure < 140 after one year (T3) in the intervention group compared to the propensity matched group.

**Change in systolic blood pressure.** As shown in Table 32, 338 participants were included in this analysis. The results demonstrate that the intervention group had a lower mean change in systolic blood pressure from pre (T1) to post (T3) ICCCM with the covariate of baseline A1C controlled at 8.4893. However, the difference was not statistically significant \( t(338) = -1.129, p = 0.26, CI [-7.366, 1.993] \). Therefore, for hypothesis 2b, the null hypothesis was not rejected: there was no difference between the systolic blood pressure change in the intervention group compared to the propensity matched group.

**Diastolic blood pressure < 90.** As shown in Table 31, after adjusting for the covariates of renal disease and controlling baseline A1C at 8.5007, the odds of the intervention group having a diastolic blood pressure < 90 after one year of ICCCM (T3) was 1.147 times higher than that of the control group. However, this difference was not statistically significant \( X^2 (1, N = 299) = 0.141, p = 0.71, CI [-0.579, 0.854] \). Therefore, the null hypothesis was not rejected: there was no difference between the number of patients with a diastolic blood pressure < 90 after one year (T3) of ICCCM in the intervention group compared to the propensity matched group.

**Change in diastolic blood pressure.** As shown in Table 32, 338 participants were included in this analysis. The results demonstrate that the intervention group had a lower mean change in diastolic blood pressure from pre (T1) to post (T3) ICCCM with the covariate of baseline A1C controlled at 8.4893. However, the difference was not statistically significant \( t(338) = -0.751, p = 0.45, CI [-3.839, 1.717] \). Therefore, the null hypothesis was not rejected: there was no difference between the diastolic blood pressure change in the intervention group compared to the propensity matched group.
CHAPTER FIVE
DISCUSSION

This chapter is divided into six main sections: study limitations, discussion of results, theoretical linkages, implications for healthcare, future opportunities for research and conclusion.

Study Limitations

Study limitations incorporated 3 main areas (1) limitations due to the data collection process, (2) limitations inherent to secondary data and propensity matching and (3) historical biases.

Limitations Due to the Data Collection Process

Limitations due to the data collection process included (1) limitation associated with identifying the ICCCM population (2) the inability to measure variables (healthcare utilization, influenza immunizations and eye examinations) outside this healthcare system and (3) limiting the population to one healthcare system.

Limitations of care coordinator lists to identify ICCCM population. The care coordinator lists of patients varied over time in that patients dropped out of the study and/or clinic for various reasons. In the initial ICCCM study rollout, patients were not given the option of choosing to participate but were automatically placed on the care coordinators lists if they met criteria. This documentation process was later revised to only include patients who agreed to participate in care-coordination. Also, since the care coordinators deleted inactive patients from their lists, there may have been ICCCM patients who had completed a year of ICCCM but chose
to drop out of the study or relocated and changed primary care clinics after one year. It is unknown how many patients may have dropped from the study before or after completing a full year of ICCCM. To address this limitation, a chart review was conducted for all potential intervention participants to ensure that they met inclusion/exclusion criteria.

**Limitations of healthcare utilization received outside this healthcare system.**
Information about healthcare utilization (hospitalizations and emergency room visits) received outside this healthcare system was not available and could skew the results. In a systematic review, Hansen et al. (2011) estimated that this could account for as much as 20% error in number and length of hospitalizations. However, for this study, it was assumed that this would be similar between the pre and post period and across the comparison and intervention groups.

**Limitations of influenza vaccinations and dilated eye examinations received outside this healthcare system.** Similarly, a limitation for both influenza vaccinations and dilated eye examinations relates to documentation and care provision. Both can be provided at outside facilities and thus be underreported. The PCP and care coordinator have little control over whether and where patients obtain an ophthalmology examination. This is a limitation for all 15 PCP clinics (both the ICCCM and the propensity matched groups). Since all clinics within the health system utilized the same process for documenting both influenza immunizations and eye examinations provided at outside facilities, it was assumed that missed information would be equivalent between the pre/post and control/intervention arms of the study. All participants should be equally affected by this limitation unless it is mitigated by another variable (i.e., socioeconomic status).

**Limiting the population to one healthcare system.** This study examined patients within
one healthcare system within a large Midwestern city. A benefit is that the clinics followed the same policies and procedures and experienced similar organizational and regional cultures. Although site-specific differences were minimized, findings are not necessarily generalizable outside this healthcare system. Consequently, any transferability of the findings to other populations outside this healthcare system must be viewed with caution.

**Limitations Inherent to Secondary Data and Propensity Matching**

Health services research methods have limitations inherent to the process.

**Secondary data limitations.** Study variables were limited to those elements captured in the medical record. Therefore, some variables could not be measured like socioeconomic status (SES), making a proxy variable necessary. Proxy variables (e.g. insurance for SES) were chosen based on previous research (Jack et al., 2009).

**Socioeconomic status limitation.** Differences in socioeconomic status between the intervention group and propensity match were difficult to control and may have led to overt bias. The large ICCCM clinic served one of the poorest areas of the city, and the EHR does not provide an ideal variable to measure socioeconomic status (SES). This study aligned with other studies in the literature and used insurance coverage as a proxy for SES (Jack et al., 2009).

Also, insurance coverage is recorded for a single point in time for both the ICCCM and propensity matched group. Since insurance is generally tied to employment in the US and can change over the year, it is possible that patients with lower SES may be more likely to face insurance policy changes or be without insurance within a year's timeframe. The intervention population may have experienced more insurance fluctuation in comparison to the propensity match sample.
Missing data. The amount of missing data for this study was minimal. In fact, less than 5% of the data was missing for any of the three data groups: pre-intervention, post-intervention or matched comparison group. The data point most frequently missing was the A1C. Since lab work involves an additional charge, it is possible that not all patients in this population were able to afford additional expenses and thus were of a lower socioeconomic status than those with all data points. However, this amount of missing data is minimal.

Data timepoints. Using a six-month timeframe before or after the three timepoints is a limitation in that there was a wide timeframe in which to collect the data for both the matched and intervention groups. Since the same process was followed for both the ICCCM and the comparison groups with the data element closest to the timepoint being used, both groups were similarly affected.

Propensity match variable limitations. The most significant limitation of propensity matching is that the match is limited to variables chosen for matching; it is always possible that an unobserved unmatched variable could have accounted for the findings. An unmatched measure in the ICCCM study could account for significant differences between the groups. Matching on a greater number of variables minimizes this risk. In this study, to minimize bias, the propensity score variables were based on previous studies and included all demographic data, baseline A1C, number of years with diabetes and comorbidities as listed in the Charlson comorbidity scale (Xing et al., 2015; Jack et al., 2009; D’Hoore, Sicotte, & Tilquin, 1993). The Charlson comorbidity scale has been used to match chronic conditions in other research studies (D’Hoore, Sicotte, & Tilquin, 1993; Xing et al., 2015).
In the ICCCM match, an ideal match on renal disease, baseline A1C and the date of diabetes was not possible within this healthcare system. The date of diabetes diagnosis was only documented when coded in the administrative database, which could have been the date patients entered the healthcare system, rather than the date of original diagnosis. Consequently, it was decided that the date was likely inaccurate. Therefore, it was not used as a covariate. The other two variables were controlled statistically.

**Historical Bias Limitations**

Historical bias is always a consideration in research. In this study, the Patient Protection and Affordable Care Act had completed rollout but was still being adapted in healthcare systems throughout the US due to Medicaid expansion and 30-day readmission penalties.

**Care coordination for Medicaid patients.** During this period of time, Medicaid was expanded under the Affordable Care Act, and Medicaid patients in all clinics had their own care coordinators in addition to the care coordinator within the intervention arm of the study. Medicaid care coordinators learned from the ICCCM system and used the ICCCM tools for care coordination (personal communication Julia Havey, Sr. Systems Analyst, LUHS, 11/16/18). To address this issue, both the ICCCM and propensity matched samples were well-matched on Medicaid insurance (Standard mean difference (SMD) = 0.102). Therefore, the difference between ICCCM and traditional Medicaid care coordination was incorporated into the study.

**Transitional care coordination for Medicare patients.** To minimize readmissions, Medicare patients were provided a care coordinator upon hospital discharge. Medicare patients at the ICCCM clinic also followed the ICCCM model of care and the ICCCM care coordinator
worked with the transitional care coordinator. This issue was addressed by matching based on Medicare insurance (SMD = 0).

**Discussion of Results**

This study evaluated the benefit of an interprofessional, nurse-led collaborative care-coordination model of care for patients with type 2 diabetes in the ambulatory setting on patient engagement, healthcare utilization and clinical indicators. A summary of the findings is presented in Table 34 with significant findings bolded.

<table>
<thead>
<tr>
<th>Table 34. Summary of Statistical Findings</th>
</tr>
</thead>
<tbody>
<tr>
<td>Variable</td>
</tr>
<tr>
<td>-----------</td>
</tr>
<tr>
<td><strong>Patient Engagement</strong></td>
</tr>
<tr>
<td>Total Number of missed visits</td>
</tr>
<tr>
<td>Annual influenza immunizations</td>
</tr>
<tr>
<td>Annual dilated eye examinations</td>
</tr>
<tr>
<td><strong>Utilization</strong></td>
</tr>
<tr>
<td>Number of hospitalizations</td>
</tr>
<tr>
<td>Number of emergency room visits</td>
</tr>
<tr>
<td>Number of days hospitalized</td>
</tr>
<tr>
<td><strong>Clinical Indicators</strong></td>
</tr>
<tr>
<td>Percent of pts with HGB A1C &gt; 9 (T1-T3)</td>
</tr>
<tr>
<td>Change in HGB A1C (T1-T3)</td>
</tr>
<tr>
<td>Difference in A1C year pre vs year post (T2-T1 vs T1-T3)</td>
</tr>
<tr>
<td>Change in weight (T1-T3)</td>
</tr>
<tr>
<td>Difference in weight year pre vs year post (T2-T1 vs T1-T3)</td>
</tr>
<tr>
<td>Change in systolic b/p (T1-T3)</td>
</tr>
<tr>
<td>Difference in systolic b/p year pre vs year post (T2-T1 vs T1-T3)</td>
</tr>
<tr>
<td># with Systolic b/p at goal (&lt; 140) (T1-T3)</td>
</tr>
<tr>
<td>Change in diastolic b/p (T1-T3)</td>
</tr>
<tr>
<td>Difference in diastolic b/p year pre vs year post (T2-T1 vs T1-T3)</td>
</tr>
<tr>
<td># with Diastolic b/p at goal (&lt; 90) (T1-T3)</td>
</tr>
</tbody>
</table>

NA = Not applicable
As Table 3 indicates, this study found statistically significant improvements in several clinical indicators including A1C, weight, and diastolic blood pressure in the ICCCM participants. However, patient engagement indicators, including annual eye examinations and unadjusted missed visits, demonstrated a surprising inverse response to the intervention in comparison to the propensity match. Healthcare utilization did not show significant improvement for either the pre/post study arm for the ICCCM group or the propensity matched comparison group. The following discusses each outcome in more detail.

**Aim 1: Patient Engagement Results**

The ICCCM intervention had no effect on any of the patient engagement variables in the pre/post study. However, there were surprising findings per variable as discussed in the following sections.

**Missed visits.** Missed visits did not improve in the pre/post study as hypothesized, suggesting that missed visits are not related to care-coordination. This is consistent with the literature in that Wu et al. (2018) measured missed visits in a VA enhanced ImPACT team model and found no significant difference in missed visits between the pre/post or usual care/ImPACT model (Wu, Slightam, Wong, Asch, & Zulman, 2018).

*Missed visits may not be related to patient engagement.* There are many reasons that patients miss visits including scheduling problems, not feeling well at the designated time, forgetting the appointment, and having extraneous circumstances like car or transportations issues. Hwang et al. (2015) found that patients with a high number of missed visits correlated with patients who were younger, non-white, spoke limited English, had Medicaid or were uninsured, lived in areas with low median household incomes, and/or carried a diagnosis of
either alcohol use disorder or depression. Therefore, missed visits may not be a good proxy measure for patient engagement.

Missed visits may be more related to socio-economic or social determinants, rather than patient engagement. This is a plausible explanation since the unadjusted matched sample demonstrated fewer missed visits ($p = .02$), which is contrary to the expected finding. Hwang et al. (2015) found that lower socioeconomic status was significantly related to missed visits. Therefore, this study may not have adequately controlled for socioeconomic status, as insurance was the only available proxy measure. Further research is needed to identify a better proxy measure for patient engagement.

Missed visits may be affected by health status. Missed visits were affected by baseline A1C and the presence of renal disease. Unadjusted missed visits were significantly less in the matched group. However, after adjusting for baseline A1C and renal disease, there was no longer a significant difference in missed visits. Hwang et al. (2015) also found that patients with higher A1C's had greater numbers of missed visits when controlling for other patient characteristics. It is difficult to interpret these findings without further insight into the mindset of these participants, but it is noteworthy that severity of illness in the form of the covariates (i.e. renal disease and increased baseline A1C) appeared to attenuate the increased number of missed visits for the ICCCM group. Since these patients are more likely to feel unwell than patients without renal disease or with a normal A1C, missed visits could be related to how patients were feeling at the time of the missed visit. Patients with chronic illness may also feel overwhelmed by the number of clinic visits needed between specialists and primary care physicians. More research is
needed to further explore possible explanations for missed visits. In the meantime, it is important for providers to avoid blaming patients for missed visits due to lack of engagement.

**Influenza immunization.** Although there was no significant difference pre-post or compared to the matched sample, none of the influenza immunization rates (40.4% – 50.9%) approximated the HealthyPeople 2020 goal of a 70-90% influenza immunization rate (Office of Disease Prevention and Health Promotion [ODPHD], 2018). However, this low rate is consistent with the literature. In the 2013-2014 flu season, based on national vaccination coverage records, only 43.2% of adults (>19) received the influenza vaccination (Williams et al., 2016). In this study, care coordination did not affect these national trends.

**Optimizing influenza vaccination rates.** Current influenza vaccination rates are low in this population. This study demonstrates the need to identify strategies to improve this rate. Currently, patients with portal registrations receive an email blast every October encouraging the influenza vaccination. However, this strategy did not yield optimal results. A better understanding of patient behavioral choices about the influenza vaccination is needed.

**Patients may choose against influenza vaccination.** There are many reasons people choose not to receive the influenza immunization that could lead to low vaccination rates. In a secondary data study of the Behavioral Risk Factor Surveillance System (BRFSS) data, La et al. (2018) found that patients were more likely to have received the influenza vaccine if they were female, had increased age, higher level of education, higher annual household income and at least one chronic condition (La et al., 2018). High-need geographic communities generally are comprised of people with lower annual household incomes and lower levels of education.
Therefore, optimizing influenza vaccination rates in these high-need geographic communities may require different strategies for outreach.

A qualitative study focusing on why patients choose to receive or not receive the influenza immunization will be needed. Of particular interest, in the ICCCM arm, there were patients who changed their decision to receive or not to receive the vaccination as well as those who never received the vaccination during the 2-year study period. Therefore, a mixed method design using quantitative methods to identify these populations and qualitative methods to understand patient decision-making can identify the problems and provide opportunities to improve the influenza vaccination rate. This will be of paramount importance if the 2020 goal is to be actualized in this healthcare setting.

**Influenza immunizations documentation accuracy.** Without an integrated IT system (i.e. one that can interface with all clinics where patients receive vaccinations including Minute Clinics), it is difficult to assess the accuracy of the influenza immunization data. An integrated system would not only improve vaccination documentation accuracy but also provide an accurate assessment of interventions to increase vaccination rates. According to the CDC, in the 2014-2015 flu season 42.3% of influenza vaccinations were given in nonmedical settings (Centers for Disease Control and Prevention [CDC], 2018a). This would indicate that possibly a significant number of patients choose to receive the influenza vaccination at an outside site. With the increased number of Minute Clinics and work settings providing influenza vaccinations, this number has likely increased. The absence of an integrated IT system is a barrier to capturing accurate influenza vaccination rates. If primary care clinics are going to coordinate their patients care, it is important for them to understand what care is being received at other sites. This further
emphasizes the need for an integrated IT system, if the HealthyPeople 2020 influenza vaccination goals are to become reality.

**Eye examinations.** There was no significant difference in eye examinations in the pre/post study. This is consistent with the literature. In the Physician Group Demonstration Project, after 5 years, eye examinations significantly improved with no significant improvement after 2 years (Department of Health and Human Services, 2009; Kautter et al., 2012). It is possible that eye examinations is a longer outcome measure than hypothesized, which may explain the lack of significant improvement in the ICCCM group after one year. There were interesting additional findings related to examination patterns.

**PCP/care coordinator has minimal influence over dilated eye examinations.** The fact that care coordinators and PCPs have little control over whether a patient receives a dilated eye examination may influence these findings. Although care coordinators and PCPs can encourage an outside eye examination, since this service is not provided within the clinic, any control over the service is muted. The care coordinators’ role was to encourage patients to obtain an eye examination and to elicit and document any reported eye examinations at each clinic visit.

**Eye examination rates.** This study demonstrated that 45.1 -63.7% patients reported receipt or received the eye examination per the EHR. The matched comparison group met the HealthyPeople 2020 goal of a 58.7% eye examination rate (Office of Disease Prevention and Promotion [ODPHP], 2019). However, the ICCCM group was not meeting this goal either pre- or post-intervention.

**Matched comparison group had more eye examinations.** The matched comparison group did have significantly more eye examinations than the ICCCM group. It is unclear why. It
could be related to poorer eye health in the comparison group, SES or the length of the study. Retinopathy/eye disease was not part of the propensity match, so it is possible that the ICCCM and matched comparison group were not well balanced on this variable at baseline. It is possible that more matched patients were having visual acuity problems or were more concerned about eye health. It is also possible that matched patients could afford to pay for the eye examination, which is not necessarily included in health insurance coverage. Therefore, it is possible that SES or differences in insurance policies could have made the difference. Finally, as the PGP study demonstrated, it may take longer than one year to effect change in eye examinations (Department of Health and Human Services, 2009; Kautter et al., 2012). Further research is needed to better understand this result.

*All groups had more eye examinations than influenza vaccinations.* It is interesting that in both the pre/post and the ICCCM/matched comparison arms of the study, participants were more likely to receive an eye examination than an influenza vaccination. It is possible that these patients were already experiencing eye problems or that they were more concerned about eye disease than preventive measures. It is also possible that patients were more likely to remember and report their eye examinations, as eye examinations require more effort and may be more memorable than influenza immunizations. It is also possible that this figure was underreported in either or all groups, which further leads to the need for an integrated IT system to effectively care coordinate these patients. Regardless, this health behavior was unexpected and difficult to interpret without more research to understand this unexpected finding.

**Aim 2: Healthcare Utilization Results**

The ICCCM intervention did not improve any of the healthcare utilization variables.
Although the literature indicates that transitional care with nurse care-coordination has been effective in reducing hospitalizations and length of stay (Coleman, Parry, Chalmers, & Min, 2006; Naylor et al., 1994; Naylor et al., 1999; Naylor et al., 2004; Naylor et al., 2011a, Naylor et al., 2011b; Naylor et al., 2014; Hewner et al., 2014), this study did not support that care-coordination in the diabetes population affected hospitalization or emergency visits. This is consistent with the literature on care-coordination (Peikes et al., 2009; Nelson, 2012a; Nelson, 2012b; Hickam et al., 2013).

**Effect of time on healthcare utilization.** The only care-coordination study that reported a significant reduction in emergency room visits did so after 2 and 3 years with no reduction in hospitalizations (Gary et al., 2009). This suggests that care-coordination models may take a longer period of time to impact healthcare utilization.

Neither the TEAMcare intervention nor the diabetes care management team models—both of which were based on the Chronic Care Model and utilized a care team—demonstrated improved healthcare utilization after year 1 or year 2 (Katon et al., 2012; Kearns, 2017). In fact, Katon et al. (2012) looked at cost and found increased costs for healthcare utilization after both year 1 and year 2. Therefore, it is noteworthy this study did not demonstrate an increase in the number of hospitalizations, which is the most costly form of healthcare utilization.

It is likely that improved clinical outcomes do not impact healthcare utilization immediately. The complications of diabetes take years to develop, consequently it is likely unrealistic to anticipate that improving diabetes control will have an effect on healthcare utilization within one year. About one-fifth of the participants in each group were hospitalized in the year of study (19.3%- 21.5%). It is likely that it would take a significant amount of time for
an interprofessional collaborative care-coordination model to mitigate the number of emergency room visits and number of hospitalizations.

**Aim 3: Clinical Indicator Results**

Several clinical indicators were affected, including A1C, change in weight, and diastolic blood pressure. The following discusses each in more detail.

**A1C results.** The ICCCM group demonstrated a statistically and clinically significant improvement in A1C both pre-post care-coordination and in comparison to the matched sample. In fact, the A1C had an average statistically significant decrease of 0.8% between pre ICCCM and post ICCCM. This is consistent with the literature (Shojania et al., 2006; C. B. Taylor et al., 2003; Watts & Sood, 2016; Mullen & Kelley, 2006; Egginton et al. 2012, Ishani et al., 2011; Micklethwaite et al., 2012; W.J. Katon et al., 2010; Hickam et al., 2013). Furthermore, the literature is clear that improved A1C improves the microvascular complications of diabetes (American Diabetes Association, 2018). Consequently, this is a significant finding with potentially long-lasting benefits. Further research on this population would be needed to determine whether the ICCCM had an effect on the participants' A1C beyond one year.

Most of the literature on care-coordination in a type 2 diabetes population uses A1C as the gold standard for diabetes management studies, and most found statistically significant improvement in A1C (Egginton et al., 2012; Ishani et al., 2011; Katon, W. J. et al., 2010; Micklethwaite, Brownson, O'Toole, & Kilpatrick, 2012; Mullen & Kelley, 2006; Shojania et al., 2006; Taylor et al., 2003). In 2013, Hickam et al. found in their comparative effectiveness review that case management had a significant impact on glucose management. This study supports the
conclusion of Hickam et al. (2013) in that there was both a clinically significant and a statistically significant improvement in A1C in both pre/post evaluation and matched control.

Finally, it is noteworthy that the unadjusted percent of patients with A1C > 9 was significantly improved in the intervention group in comparison to the matched group \((p < 0.001)\). However, after adjusting for baseline A1C and renal disease, A1C > 9 was no longer significant \((p = 0.09)\). This may be a power limitation due to the low number of patients at baseline (T1) with an A1C > 9 in the control group (33) compared to the intervention group (80).

**Weight.** Although weight is not a common variable in care-coordination research studies, this study indicated a statistically significant improvement (average 2.2 pound weight loss) in the pre/post ICCCM arm of the study but did not have a significant effect in comparison to the matched control. This is particularly significant clinically, as this population would be expected to gain on average 2.2 pounds each year of their adult lives (Lowe, 2015). However, weight can fluctuate, making it difficult to interpret weight findings, which may be why few care-coordination studies used this variable. In fact, in this study, weight was very labile even after removing patients with documented bariatric surgery procedures with a large range in both weight loss or gain in all study groups. The total range for change in weight in the pre-ICCCM/post-ICCCM year and the matched comparison group year was from 78 to 113 pounds with weight gains as high as 55 pounds and losses as high as 67 pounds. This large weight fluctuation makes it difficult to interpret change in weight.

**Role of dietitian.** It is important to note that the patients in the ICCCM had direct access to the dietitian who was available during clinic appointments, for individualized one-on-one education appointments, group educational classes and cooking classes to meet the needs of this
population. The importance of including the dietitian to help improve outcomes in the diabetes population particularly weight and A1C cannot be understated. In care-coordination research studies, although the registered dietitian could have already been included in standard clinic practice, only one study was identified that mentioned the inclusion of a registered dietitian as part of the care-coordination intervention (Mickelthwaite et al., 2012).

Snaterse et al. (2016) systematic review and meta-analysis indicated that of the 9 (out of 18) nursing care-coordination randomized controlled trials that reported weight as an outcome measure, only one demonstrated a statistically significant weight loss (.9 kg) (Allison, Squires, Johnson, & Gau, 1999). More recently, Holtrop et al. (2017) found no improvement in weight after a nurse care management intervention for patients with type 2 diabetes. However, in the same study there was a statistically significant drop in weight (5% of body weight lost) in obese nondiabetic patients with the same intervention in the same clinics (Holtrop et al., 2017). It appears that there may be other mechanisms involved in weight loss and diabetes since the results were so different in these two populations.

The American Diabetes Association (ADA) states that people with type 2 diabetes with disordered eating behaviors tend to suffer binge eating, and people with type 2 diabetes treated with insulin intentionally missing doses of insulin (American Diabetes Association, 2018, p. S35). Either of these behaviors could lead to considerable weight changes. Some diabetic medications like metformin have been associated with weight loss and other medications particularly antidepressants, anticonvulsants including gabapentin are associated with weight gain (American Diabetes Association, 2018). Since medications were not evaluated in this study, it is possible that this may have had an impact on the weight fluctuation.
In addition, Lowe (2015) suggested that in the current obesogenic environment, obese adults would be expected to gain on average 1kg per year without any intervention. This further demonstrates the clinical significance of an average 2.2 pound weight loss during a time period when the expected weight change would be a 2.2 pound weight gain (Lowe, 2015). However, more research is needed to better understand both the significance of the weight loss as well as the weight variability phenomenon if the goal is to positively impact weight in patients with type 2 diabetes in the future.

**Blood pressure.** The following sections will discuss the significant blood pressure finding.

**Diastolic blood pressure at goal improved.** This study found a significant difference in the number of patients with diastolic blood pressure at goal (<90) in the pre/post data with no significant change in systolic blood pressure. The ADA set the blood pressure goal for patients with type 2 diabetes at <140/90 based on evidence of improved cardiac outcomes (American Diabetes Association, 2018). This finding is particularly significant, as there was little national improvement in blood pressure at goal for adults with type 2 diabetes between 2008 and 2012 indicating it is difficult to impact blood pressure (National Center for Health Statistics, 2016). Furthermore, increasing the number of participants with blood pressures at goal in this high-risk population is particularly important since controlled hypertension has been shown to reduce cardiovascular events caused by atherosclerotic heart disease (American Diabetes Association, 2018). The leading cause of both morbidity and mortality in diabetes is atherosclerotic heart disease (de Boer et al., 2017). Consequently, this finding of improved diastolic blood pressure at goal is not just statistically significant but also clinically important.
The literature on blood pressure and care-coordination is mixed but there have been some studies that demonstrated improved diastolic blood pressure (Gabbay et al., 2006; Ishani et al., 2011). Other studies found no effect on diastolic blood pressure (Micklethwaite, Brownson, O'Toole, & Kilpatrick, 2012; Snaterse et al., 2016).

Although unable to provide statistical significance due to the lack of a control group, Kautter (2012) found that the PGP reported improved numbers of patients with blood pressure < 140/90 over the five-year study. However, in looking at the raw percentages, half of the sites exhibited either no change or a decrease in the per cent of patients at goal after the first year (Kautter et al., 2012). This indicates that blood pressure may take longer to impact than one year.

The ICCCM team care-coordination approach to patient care provided personal attention to participants, which may have contributed to improved diastolic blood pressure. More research into the etiology of this change would be needed to fully understand the mechanism for this finding. Furthermore, as the PGP demonstrated, improvement in blood pressure goal for both systolic and diastolic blood pressure (< 140/90) may be a longer term effect of a care-coordination intervention. It is notable that this study demonstrated an improvement in one year. A longer study of this model is needed to illuminate the full impact of this intervention on blood pressure.

**Theoretical Linkages**

As shown in Figure 7, it was hypothesized that patient engagement would be the first effect of this new model of care. Participants would need to be engaged in their health behavior to impact any change in either healthcare utilization or clinical indicators. These health behavior changes would then impact how these participants use healthcare services. It was thought that
participants would choose to discuss health problems with their primary care clinic rather than use the emergency room or hospital. Then, also due to increased engagement in their health, participants would be motivated to improve their clinical indicators.

However, it is clear that clinical indicators demonstrated improvement after one year with no positive difference in the measured patient engagement factors or healthcare utilization. It is possible that these variables, missed visits, influenza vaccination rates and dilated eye examinations are not measuring patient engagement or that patient engagement is not an early effect but rather a later effect of a changing healthcare system. Furthermore, it is possible that participants become more engaged after they see and feel positive results and thus both patient engagement and healthcare utilization improve only after improvement in clinical indicators.

Figure 7. Expected order of outcomes

**Implications for Healthcare**

The sequelae of diabetes occurs most often in patients who cannot maintain good glycemic control (Skyler et al., 2009; The Diabetes Control and Complications Trial Research Group [DCCT], 1993; UK Prospective Diabetes Study Group, 1998). Consequently, the major goal of diabetes management is to assist patients in improving glycemic control. However, finding strategies like ICCCM that successfully assist patients with diabetes to improve control
has been challenging. Incorporating successful strategies, like the ICCCM into health system redesign is essential if the goal is to improve health in this high risk diabetes population.

**Using Population Health Strategies to Guide Health Care**

Population health is a data driven approach to improving the health outcomes of an entire group or population of people, rather than looking at each member of the population individually (Centers for Disease Control and Prevention [CDC], 2018b). It provides a snapshot of health outcomes and distributions of a specific population served. Goals for populations can then be set by clinics, hospitals, insurance providers, etc. to improve overall quality in the populations they serve. These goals can be set administratively by institutions that serve patients but are also generally based on current performance and national health guidelines. National health guidelines are based on current best evidence that are used to set public health policy (e.g., HealthyPeople 2020). The ICCCM model used population health strategies to effect change. The care coordinators identified the target population using the Phytel system and then targeted this population for the intervention. The ICCCM team-based, care-coordination model of care did significantly improve clinical indicators, A1C, weight and diastolic blood pressure of the type 2 diabetes population in a primary care clinic within a high-need geographical community.

**Using Interprofessional Collaborative Practice to Guide Health Care**

Essential to the ICCCM model was the collaborative care, team approach. Several IOM/National Academy of Health reports support the use of interprofessional collaborative practice as a healthcare goal (Institute of Medicine, 1999; Institute of Medicine, 2001). These reports emphasized the need for communication across disciplines and the need to include teamwork in healthcare redesign. The ICCCM model focused on working across disciplines and
with patients to improve care. The teams consisted of the nurse care coordinator, dietitian, social worker, and physician who met to refine system problems, and to discuss individual patient care plans. The goal was to ensure that everyone on the team was actively engaged in the care plan to help patients meet their personal health goals. This was achieved both through workflow modifications and team meetings. The ICCCM was a team approach to health system redesign in which each member of the team was equal and was essential to assist participants with their own healthcare problems.

Differentiating Transitional Care and Care Coordination

Transitional care models focus on crisis management for high risk patients over a short time period (i.e., post hospitalization) primarily through the use of telephone touches. Care-coordination focuses on a team (two or more participants including the patient) effort to organize the patient's care to ensure all resources needed are provided (Agency for Healthcare Research and Quality, 2014). Care-coordination further calls for communication between team members to ensure the optimal exchange of information between the patient and all other team members (Agency for Healthcare Research and Quality, 2014). Rather than using scheduled phone calls, care-coordination is built on providing both a trusting relationship to those ready to embrace change and strategies to help participants who struggle with their own healthcare maintenance. It involves strategizing with patients to help them meet their own goals. Past research has demonstrated focusing on the relationship in care-coordination can improve clinical outcomes (Peikes et al., 2012).

Care Coordination Team Members

The ICCCM model has demonstrated continued success with patients struggling with
type 2 diabetes. Each team member played a unique role in the model.

**RN care coordinator.** This unique team approach was led by the nurse care coordinator. The focus of this approach was on meeting the participants' needs rather than the needs of the health system. Nurses ensured that all team members communicated and that patients were the focus. Nurses led the team meetings and through the guidelines set by the ICCCM redesign, chose the patients from the population management system, Phytel who would best benefit from these team meetings. The nurse care coordinators met with patients to mutually identify health goals, communicated with patients regularly, and provided or coordinated the needed support to maximize behavior change. The RN built relationships with participants. Having a close trusting relationship with patients has been identified as an essential ingredient to impact patient behavior (Nelson, 2012a; Peikes et al., 2012). The combination of an on-going relationship with the participants, a modified workflow redesign for team communication, and nurse care coordinators working to their full capability contributed to improving patient outcomes in this model.

**Registered dietitian.** The dietitian on the team worked with individual participants and provided group education to promote healthy eating habits. The dietitian met individually and in team appointments to provide Medical Nutrition Therapy to patients. This included individualized dietary education which led to an individualized nutrition plan. This plan could include carbohydrate counting, or exchange lists to help the patient with food choices. In addition, the dietitian provided affordable, healthy group cooking classes to help participants learn simple cooking strategies to increase food choices and simplify meal planning. Through the development of a trusting relationship, the dietitian was able to have an impact on participants' eating habits. Few models included a registered dietitian. Although several case management
studies include a nurse certified diabetes educator (Watts & Sood, 2016) or dietitian-provided education (Mullen & Kelley, 2006), the only one that specifically mentioned the addition of the dietitian to the team was Micklethwaite et al. (2012) who found a significantly decreased A1C in a diabetes population but no difference in BMI, or blood pressure. Furthermore, Holtrop et al. (2017) demonstrated in their care management study, that achieving both weight loss and A1C improvement in the type 2 diabetes population was not possible with care management alone. The ICCCM study was able to accomplish both significantly improved A1C's, weight and diastolic blood pressure at goal. It is likely that this was only possible with the added expertise of the full team including the dietitian.

Social worker. The social worker was essential in this high-need geographic area as many of the ICCCM population experienced financial problems including loss of insurance, homelessness, and difficulty paying for medications. Social workers are uniquely qualified to address barriers to healthcare access. The social worker was able to find community resources to assist patients when times were difficult. This model further supports the American Diabetes Association "Standards of Medical Care in Diabetes-2018," which recommends including treatment for common social problems like "food insecurity, housing stability, and financial barriers" (American Diabetes Association, 2018, p. S9).

Expanding healthcare teams to include a dietitian and social worker did improve outcomes. Katon et al. (2012) also showed improvement with the addition of mental health providers. Low income communities have greater needs for support due to financial barriers leading to housing and insurance instability and food insecurity. Embracing ways of increasing
healthcare value to this population will be an essential ingredient for improving health outcomes in the future.

**Physician.** Having full physician support was essential for this model to be effective. The physician provided for the basic health care needs of these patients. Not only did the physicians fully support the team effort but they welcomed and encouraged this team model. In addition to daily communication, physicians met formally with the care-coordination teams monthly. Through these opportunities, physicians built a close trusting relationship with team members. The physician no longer had the primary responsibility for care-coordination, but rather was integrated into the process to ensure appropriate medical care, while other team members were responsible for coordination.

**High need patients.** Patients with poor diabetes control identified either through Phytel or the primary care physician were the focus of this intervention. Through motivational interviewing and goal setting, patients identified and set their own health goals making this intervention patient-centered. These patient-identified goals provided the direction for the health care team to address individualized needs for high-risk participants who were willing to change their behavior. This included individualizing solutions for participants with unique problems, including providing cooking classes, financial strategies, and behavior problems, while also insuring access to medication and equipment needed to control their diabetes and health.

**ICCCM Healthcare Implications Summary**

This interprofessional team model integrated interventions, targeted those with the greatest need (low-income patients with poorly controlled diabetes), and built relationships with patients to collectively improve health outcomes. Each member of the team contributed their
expertise and trusted each other to provide that expertise. This workflow encouraged a fluidity of communication among team members including the patient which was instrumental in meeting patient needs. The result was improved clinical outcomes.

Implications for Nursing Practice

Ambulatory care delivery is being rejuvenated with the changes in health policy due to healthcare reform, the Affordable Care Act, Precision Medicine, value-based care and population health (Paschke, 2017). Ambulatory care nursing is also changing rapidly with nurses being expected to "enhance patient safety and the quality and effectiveness of care delivery" and "provide the leadership necessary for collaboration and coordination of services" (Paschke, 2017, p 1). Due to the close alignment to the American Academy of Ambulatory Care Nursing (AAACN) standards, the ICCCM further demonstrates the importance of these competencies in ambulatory nursing (Haas, Swan, Haynes, 2014).

The AAACN stresses that ambulatory nurses must have leadership skills to lead a team approach to patient care (Paschke, 2017). In fact, RNs are responsible for providing the leadership needed for collaborative processes and coordination (Paschke, 2017). The current standards for care-coordination and transitional care were used to provide the guidance needed to develop the care-coordination role in the ICCCM (Haas et al., 2014). These nine competencies include self-management support, advocacy, education and engagement of patient and family, cross setting communication and transition, coaching and counseling of patients and families, nursing process, population health, teamwork and collaboration and patient-centered care-planning (Haas et al., 2014). The ICCCM included many nursing activities to meet these competencies including a care plan developed through motivational interviewing, which centered
on the patient's values, preferences and goals and provided solutions to socioeconomic issues, while negotiating services for the patient. Care coordinators coached the patient and family in self-advocacy and assessed patient and family readiness to learn as well as their understanding using educational methods like "teach back." Care coordinators collaborated with all health team members to ensure all understood the care plan developed with the patient. They used a population health tool (e.g. Phytel) for management of the diabetic clinic population not only to identify high-risk patients but also to ensure that all guidelines for patient care were being addressed. Teamwork was a core principle of the ICCCM and included a focus on the patient to identify the patients' goals and to ensure that care always remained targeted on the patient's personal health priorities.

**Implications for Healthcare Education**

It is widely recognized that to improve population health, interprofessional collaboration and teamwork are essential, therefore it is critical that students learn to coordinate care across disciplines to improve patient outcomes (Institute of Medicine, 2015). The ICCCM study demonstrated the importance of a team approach in ambulatory care. In the past, healthcare used a hierarchical model with the physician at the top of the tier (Institute for Transformational Interprofessional Education, 2015). However, the IOM has stressed the importance of educational institutions to collaborate with practitioners to promote interprofessional teamwork (Institute of Medicine, 2015). To achieve this, healthcare education must include opportunities for teamwork across all healthcare disciplines. Therefore, understanding how to effectively collaborate with physicians, nurses, dietitians, social workers, psychologists etc. is imperative to our current health system that relies on increasingly specialized fields. Furthermore, experiential
learning, a key to interprofessional education requires an environment that reflects interprofessional collaboration (Committee on the Learning Health Care System in America & Institute of Medicine, 2013).

Achieving high functioning teams does not happen without intent. The ICCCM model used TeamSTEPPS in training the provider teams to work together as equals (Agency for Healthcare Research and Quality, 2018). TeamSTEPPS provides a scientific curriculum designed to improve 'communication and teamwork skills' for the healthcare professional (Agency for Healthcare Research and Quality, 2018). Incorporating an evidence-based model like TeamSTEPPS into educational curriculum can facilitate this transition to future teamwork in healthcare (Agency for Healthcare Research and Quality, 2018).

Aligning with the IOM recommendation for collaboration with practitioners, the Institute for Transformational Interprofessional Education (ITIE) at Loyola University Chicago (LUC) was developed to promote interprofessional collaboration between practitioners and educators within LUC (Institute for Transformational Interprofessional Education, 2015). LUC and Loyola University Medical Center used the ITIE model to create the Interprofessional Collaborative Care-Coordination Model (ICCCM) within two ambulatory care clinics to provide an environment of experiential learning in collaborative practice. The ICCCM model concentrates on the 4 competencies of values and ethics, roles and relationships, communication and teamwork (Institute for Transformational Interprofessional Education, 2015; Interprofessional Education Collaborative Expert Panel, 2011). These are the core competencies developed by the Interprofessional Education Collaborative Expert Panel (2011) and embraced by ITIE (Institute for Transformational Interprofessional Education, 2015; Interprofessional Education
Numerous challenges were met in developing the ICCCM as both a practice clinic and an educational clinic. In fact, the greatest challenge was getting all stakeholders at all levels engaged in the process (Vlasses & Michelfelder, 2015). Working with both the university and the health system, two separate business entities to develop a clinic that met the goals of both education and practice, was challenging (Vlasses & Michelfelder, 2015). Equally important challenges faced were getting buy-in from all the physicians and practitioners in the ambulatory clinics, hiring, integrating, and training all personnel involved in the ICCCM, and both developing new tools and integrating existing tools to capture the model's outcomes in the information system (Vlasses & Michelfelder, 2015). The challenge of developing trust between all practitioners was also key to the program's success (Vlasses & Michelfelder, 2015). Despite the potential challenges, developing practice areas that provide hands on educational opportunities for healthcare students of diverse disciplines is needed to provide experiential learning.

Finally, teaching students the importance of continual workflow evaluation and redesign (Plan-Do-Study-Act (PDSA)) is imperative for continual improvement in healthcare systems (Agency for Healthcare Research and Quality, 2013). The ICCCM members met regularly to continually improve the model which was a continuous focus of all team members. This method of evaluation is essential to continually improving the healthcare system and will be an essential ingredient for new health professionals of all disciplines to have in their toolbelt.

**Implications for Health Policy**

The Patient Protection and Affordable Care Act (PPACA) is the current overriding
healthcare policy in the US (Congress.gov, 2010). It focuses on the Triple Aim – access, quality and cost (Bleich, 2013). Despite numerous legislative attempts to repeal it, the ACA remains the law of the land, and estimates are that about 20 million more Americans are now insured (Sommers & Epstein, 2017). Furthermore, The PPACA placed an emphasis on transitional care, care-coordination and care innovations to improve chronic care management (Newell, 2013).

This study is one of a few US care-coordination team studies to analyze a new care model to improve chronic care management. The ICCCM study demonstrates the value of an interprofessional collaborative care-coordination model to improve diabetes outcomes.

**Future Opportunities for Research**

This study, which evaluated an interprofessional collaborative care-coordination model in a diabetes population, is one of few US studies to evaluate a well-defined team model of care. The ICCCM study demonstrated the value of a care-coordinated team approach to diabetes management to improve A1C, weight and diastolic blood pressure. However, further research is needed to fully investigate the reason behind missed visits, weight fluctuation and patient engagement. Furthermore, the benefit of this team approach on patient satisfaction, long term health gains and provider satisfaction was not addressed in this study and will need to be a focus of future research. The following provides suggested directions for future studies.

**Longitudinal Study**

A longer longitudinal study of the ICCCM model needs to be conducted to fully evaluate the effectiveness of this model. One year is not enough to evaluate the effectiveness of this model on healthcare utilization or patient engagement. As the PGP demonstrated, it may not
even be enough time to effectively understand the benefits of the model on clinical indicators like blood pressure.

**Qualitative Research to Study Patient Perspective**

Qualitative research exploring what participants found helpful in their own self-management will be critical to fully understand the ICCCM results. Targeting patients who improved their A1C, weight and blood pressure can provide insight into the most effective elements of team-based care. In addition, targeting those who did not improve health outcomes will also provide a clearer picture of what elements did not provide needed support. Furthermore, using participatory action research can provide a clearer understanding of patient behavior and patient needs which will lead to the best supportive measures to assist patients to meet their own healthcare goals in their own environment. Changing behavior is extremely difficult. Understanding patients' perspectives of their needs in health behaviors is essential to improving population health. Patient behavior can only be fully understood with patient-focused qualitative studies.

**Patient Engagement Research**

Few studies were found that included the variables of missed visits, influenza immunizations or annual eye examinations. More research is needed to further understand what constitutes patient engagement and what variables measure patient engagement. Qualitative studies are needed to learn from patients as only patients truly know what strategies help them meet their goals and to identify other variables that measure or enhance patient engagement.

Preventing missed visits historically has been done using a carrot and stick approach, currently this health system is dismissing patients from the system if they miss six appointments
throughout the health system in an 18 month time period (personal communication Amber Baskin, Clinical Coordinator, family practice center, 12/21/18). Although it is clear that missed appointments are associated with certain patient demographics, it is unclear why these patients are missing appointments (Hwang, Andrew et al., 2015). Punishing patients particularly those with higher healthcare needs who may have other priorities like finding a place to sleep at night will not solve the problem of missed appointments, help patients in need, or improve population health (Chokshi, 2018). Rather, research to facilitate an understanding of these patients' problems, concerns and behaviors that led to missed appointments will provide meaningful solutions needed to rectify this ambulatory care problem. Furthermore, if the goal of healthcare is to promote health, and the underlying assumption is that patients with chronic conditions who do not show up for clinic visits are less likely to achieve optimal health, then finding solutions to this problem is imperative to achieving optimal health for this high need patient population.

**Team Care**

The US has few studies that incorporate a team approach to care management. Although many organizations including the ADA, the National Academies of Medicine, the Robert Wood Johnson Foundation and the World Health Organization have widely accepted a team approach to care as the gold standard and in fact recommends this approach, there have been few studies in the US that use a team approach (American Diabetes Association, 2018; Institute of Medicine, 2015; Robert Wood Johnson Foundation, 2011; World Health Organization, 2010). International studies that have combined collaborative healthcare teams with care-coordination can provide some guidance, but the US healthcare system is very different from the healthcare system of other countries. Consequently, these international studies cannot be directly transferred to a US
population. Therefore, there is a great need for more research on collaborative care-coordination models in the US. Furthermore, mixed methods research evaluating team management of care will be needed to fully assess the effectiveness of individual interventions, as well as optimal team makeup.

**Conclusion**

This is one of few studies to provide very specific details describing an ambulatory care model that measured the effect on patient engagement, healthcare utilization and clinical indicators for the type 2 diabetes population in a primary medicine clinic serving a low SES community. It provided an initial step to redesign primary care incorporating a patient-centered, interprofessional team approach to best meet the needs of this Type 2 diabetes patient population. Findings demonstrate significantly improved A1C, weight and diastolic blood pressure. Further research will be needed to critically evaluate how this care model affected patients' self-management skills. Furthermore, studying this model over time will reveal the sustainability in patient behavior, while enhancing our understanding of patient engagement and healthcare utilization. Health system, administrative and policy support will be critical to integrate preventive care in this acute care-focused US healthcare system.
APPENDIX A

NOTICE OF CONTINUING IRB APPROVAL/

ANNUAL REVIEW OF A RESEARCH PROJECT
NOTICE OF CONTINUING/ANNUAL REVIEW OF A RESEARCH PROJECT

Date: 06/26/2018

Investigator: Burkhart, Elizabeth
LU Number: 210082
TITLE: The effectiveness of an ambulatory care redesign on patient engagement, healthcare utilization, and clinical indicators

Dear Investigator,

Continuing (or Annual) Review #1 of the above-referenced research project was performed on 06/26/2018 by Expedited Review. The project was assigned a status of "Expedited Approval".

Details of this Board review can be accessed through the on-line Research Portal or by clicking the following link:

http://portal.luhs.org

If you have any questions regarding this review action, please call the IRB Secretary (708-216-4608) or Dr. Kenneth Micetich (708-327-3144).

Kenneth Craig Micetich, M.D.
Chairman
Institutional Review Board for the Protection of Human Subjects
Loyola University Health Sciences Division
APPENDIX B

INITIAL IRB APPROVAL 8/17

NOTICE OF FULL APPROVAL OF A RESEARCH PROPOSAL
NOTICE OF FULL APPROVAL OF A RESEARCH PROJECT

Investigator: Burkhart, Elizabeth
LU Number: 210082
Title: The effectiveness of an ambulatory care redesign on patient engagement, healthcare utilization, and clinical indicators

Date of Initial Review: 08/03/2017
Type of Review: Full Board
Meeting Date: 08/16/2017
Action of Initial Review: Full Approval

IRB Findings:
1. The study is of minimal risk and qualifies for expedited review 45CFR46.110, b-1, HHS Secretary Category # 5).
2. The requirement for consent is waived:
   a) the research could not practicably be done without the waiver;
   b) the waiver does not adversely affect the rights of the individual;
   c) the research involves no more than minimal risk;
   d) there is no information that would need to be provided to the individual.
   (45CFR46.116, d1-4).
3. The IRB finds that:
   (A) The use or disclosure of protected health information involves no more than minimal risk to the individuals;
   (B) The alteration or waiver will not adversely affect the privacy rights and the welfare of the individuals;
   (C) The research could not practicably be conducted without the alteration or waiver;
   (D) The research could not practicably be conducted without access to and use of the protected health information;
   (E) The privacy risks to individuals whose protected health information is to be used or disclosed are reasonable in relation to the anticipated benefits if any to the individuals, and the importance of the knowledge that may
reasonably be expected to result from the research.

(F) There is an adequate plan to protect the identifiers from improper use and disclosure;

(G) There is an adequate plan to destroy the identifiers at the earliest opportunity consistent with conduct of the research, unless there is a health or research justification for retaining the identifiers, or such retention is otherwise required by law;

(H) There are adequate written assurances that the protected health information will not be reused or disclosed to any other person or entity, except as required by law, for authorized oversight of the research project, or for other research for which the use or disclosure of protected health information would be permitted by this subpart.

4. The IRB finds that in # 3 above and the conditions of approval that the requirements detailed in 45CFR164.512i2 are met and the requirement for patient authorization waiver is met.

5. This letter should be shown to medical records to allow the retrospective chart review to begin.

6. Refer to conditions of approval.

Re-Review Date 08/03/2018

Informed Consent Document required? NO
Reason ICD not required

# of Participants 0
Participants Compensated? NO

IRB Number 210082080317
Date of Approval 08/03/2017
Frequency of Review Annual
Date of First Review 08/03/2018

Conditions of Approval:

1. Please review the information section of this approval letter. You are required to review and adhere to the conditions of approval as stated in this letter (refer to project summary) as well as the LUMC P-6 policy regarding access to and release of patient information for the purpose of research. For questions you may contact the IRB office at extension 64608.

2. Institutional policy requires that patient identifiable research data must be collected and stored in a secured location. The medical center provides a centralized
research server for this purpose. If you have not already done so, please e-mail Joseph Koral (x67904, jkoral@lumc.edu) and request an account for this server. In the request, please include all domain IDs of the individuals that require access to this resource. If you have questions regarding information system security please contact Dan Smith (x68207, dasmith@lumc.edu).

3. You are bound by the usual and customary medical, legal and ethical considerations governing the confidentiality of the medical record.

4. The data you collect may not be sold or given to any third party outside the scope of this submission unless it is to a journal for publication. Data to a journal for publication must be de-identified.

5. The chart reviewed is to be identified on the data collection form by a unique code number and the master list kept under lock and key. If you are not collecting data elements that can directly or indirectly identify the chart reviewed then this requirement is not relevant.

6. The link of the patient to the project is to be destroyed when it is no longer necessary.

ITEMS SUBMITTED FOR REVIEW

- 07/17/2017 abstract
- 07/31/2017 PhD Proposal
- 08/03/2017 Retrospective Review Template

YOU HAVE FULL APPROVAL AND YOUR PROJECT MAY BEGIN.

The following is for your information and will help you meet local and federal IRB requirements.

1. You must use the final IRB-approved version of the Consent Document. Spelling and grammatical changes may be made as necessary, but any other changes require prior review and approval.

2. You are required to maintain complete records of this project. Any changes in the protocol and the Consent Document must receive prior IRB approval. Use the online Research Portal's Project Amendment form to report changes. A change to the protocol necessary for the immediate safety and welfare of a research participant may be implemented prior to IRB review and approval.

3. Federal Regulations require that projects undergo periodic review of research activity at least once a year. This review must be substantive. The frequency of review and next scheduled date of periodic review for your project
can be found under the "Annual Review" tab in the Research Portal's IRB section.
You will receive notification 4-8 weeks prior to the scheduled date of review.
At that time, you must provide information regarding the status of the project.
If the information is not received, the project will be suspended.
It is important that you not let approval lapse.

4. The IRB must be notified any time that the project temporarily or permanently stops enrolling participants along with the reason. Use the online Closure form to submit these notifications.

5. Any notices or advertisements soliciting participation must receive prior IRB approval.
Use the online Amendment reporting form.

6. The IRB must be notified PROMPTLY of all serious and any unanticipated adverse events associated with the project (or the device or the drug). This includes any notification received of adverse events occurring at other performance sites. Further guidance on adverse event reporting may be found at the Office for Human Research Protections web site; [http://www.hhs.gov/ohrp/policy/AdvEvntGuid.htm](http://www.hhs.gov/ohrp/policy/AdvEvntGuid.htm#Q5)
Reportable events include, but are not limited to:
a) a serious adverse event (including events that produce injury or death, an event leading to hospitalization or lead to prolongation of a current hospital stay);
b) the enrollment of a patient on a study that is no longer enrolling participants;
c) pregnancy occurring on the study where the study excludes pregnancy;
d) any patient reporting a billing problem as a result of project participation;
e) any participant who has voiced a complaint about some aspect of the project or the consent document;
f) any unanticipated, untoward, or unexpected adverse event not covered above including rare adverse events or adverse events that occur at an unexpected rate

7. The IRB may suspend the project to new participant enrollment or may suspend the participation of current subjects if there is a perceived safety and/or regulatory issue.
8. Prospective consent must be obtained from all research participants.

9. The IRB may review your records relating to this project, including signed consent documents.

10. The Institutional Review Board of Loyola University Medical Center is appropriately constituted and has been granted Federal Wide Assurance Number FWA00017487.

11. If you are unsure of your reporting requirements or of what is expected of you during the conduct of this research, please call the IRB Office (708-216-4608) or Dr. Kenneth Micetich (708-327-3144).

12. The Loyola Institutional Review Board is appropriately constituted as stipulated in 45cfr46 and is compliance with Good Clinical Practice Guidelines insofar as those guidelines are consistent with the U.S. Food and Drug Administration regulations (21 CFR Parts 50 and 56) and the Department of Health and Human Services regulations (45 CFR 46) pertaining to the protection of human subjects in research.

Kenneth Craig Micetich, M.D.
Chairman
Institutional Review Board for the Protection of Human Subjects
Loyola University Health Sciences Division
REFERENCES


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Loyola University Health System. (2013b). *Loyola University health system community benefit report 2013.* Maywood, IL: Loyola University Health System.


Newell, M. (2013). The affordable care act: Shaking up the system provides opportunities for care management. Journal of Aging Life Care, Fall


VITA

Nancy Johansen Madsen earned both a Bachelor of Science in Nursing and a Bachelor of Arts in Scandinavian Studies from the University of Minnesota in 1980. She began her nursing career at the University of Minnesota on an inpatient medical-surgical unit. Dr. Madsen thrives on learning new things and has enjoyed a nursing career filled with new challenges and opportunities. She has enjoyed working as a charge nurse on two medical-surgical floors, a volunteer refugee nurse, staff nurse in pediatric intensive care and adult/pediatric crossover float pool, a nursing research supervisor and later as a research project director, and finally as a clinical documentation specialist. Dr. Madsen also received her Danish nursing license from Aalborg Sygehus Nord in Aalborg, Denmark where she worked on a third medical-surgical unit. Dr. Madsen received her medical-surgical certification in 2008.

In 2010, Dr. Madsen changed paths from direct patient care to clinical documentation. In this capacity, Dr. Madsen has become fascinated with health information, specifically how documentation is coded, measured and used to demonstrate the quality of patient care and improve population health. She has particularly enjoyed teaching health professionals both the importance as well as the method of accurate and complete documentation. In 2011, she received the Nurse Innovator Excellence Award at Loyola.

In 2012, Dr. Madsen began the BSN to PhD program at Loyola University Chicago. She has presented her research at the Midwest Nursing Research Society and the Ruth K. Palmer Symposium at Loyola University Chicago. Dr. Madsen served as the first PhD student
representative on the Marcella Niehoff School of Nursing (MNSON) PhD committee and as the Midwest Nursing Research Society emerging scholar liaison for MNSON. She is the 2016 Jonas Scholar for MNSON and has been inducted into Alpha Sigma Nu. Dr. Madsen looks forward to her next professional chapter, sharing her nursing knowledge as a faculty member.