THE EFFECTS OF AN ON-SITE HEALTH CENTER AND CARE COORDINATION ON TYPE-2 DIABETES OUTCOMES

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ABSTRACT

More than 30.3 million people in the United States (US) have diabetes with 90-95% having type-2 diabetes mellitus (T2DM). In 2017, the total costs of diabetes care were estimated at $327 billion and contributed to the $3.3 trillion in annual health care costs in the US. Of the chronic diseases, T2DM is the seventh leading cause of death in the US. Management of T2DM is complex and requires a multidisciplinary approach. The on-site health center promotes health through innovative care solutions using a patient centered model. Care coordination can potentially maximize the value of care delivery with improved health outcomes.

This scholarly project evaluated changes in T2DM outcomes at one on-site health center after enrollment into care coordination. A non-experimental, retrospective chart review was performed utilizing secondary data from health risk assessments (HRAs) and an electronic health record (EHR). The T2DM clinical variables evaluated at initial HRA and post-HRA surveys were: weight, body mass index (BMI), blood pressure (BP), blood glucose (FBS), hemoglobin A1c (HbA1c), microalbumin, low/high density lipoproteins (LDL, HDL), medication therapy with angiotensin-converting enzyme inhibitors (ACE) or angiotensin receptor blockers (ARB), and HMG-CoA reductase inhibitors (statins). Additional variables included number of health center visits, foot exams, and wellness, podiatry, and eye exam referrals.

Comparison of initial and post-HRA data were analyzed using a paired *t*-test. Data was used for comparison of organizational benchmarks and T2DM national standards. A total of 92

participants met the inclusion criteria. There were statistically significant improvements in HbA1c and microalbumin results. The post-HRA mean HbA1c was 7.5% (p=.045) and microalbumin was 17.8 (p=.006). There were near significant results for post-HRA mean DBP of 80.5 mmHg (p=.053) and FBS of 140.9 (p=.053). The American Diabetes Association (ADA) standards of diabetes care were met for BP control and lipid management, but not for HbA1c. Organizational benchmarks for foot exams, ACE or ARB medication therapy were met but not achieved for HbA1c. The implications to practice are on-site health centers can provide chronic disease management while potentially improving T2DM outcomes. Recommendations for further study include a cost benefit analysis of T2DM care at on-site health centers.

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Best regards,

Shalonda Felesa Wilson-Patterson

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Chapter I: Introduction

Diabetes mellitus is defined as a chronic disease in which the body is unable to appropriately convert, or breakdown food ingested into energy (CDC, 2017). One out of ten Americans have diabetes, with 90% to 95% diagnosed with type-2 diabetes mellitus (T2DM). In T2DM there is a progressive loss of pancreatic cell function leading to decreased insulin secretion. Insulin deficiency occurs due to the inability to produce enough insulin, utilize insulin effectively or have a resistance to insulin, which results in elevated blood glucose levels. If the elevated levels of blood glucose are left untreated or undiagnosed this leads to prediabetes and can progress to T2DM (CDC, 2017). Left unmanaged, further negative sequelae including kidney disease, heart disease, stroke, vision loss, and neuropathy may occur (CDC, 2017). T2DM care requires frequent monitoring, evaluation, and management. Innovative care delivery models for T2DM include on-site health centers to provide this continuity. The utilization of on-site health centers has demonstrated benefits by increasing diagnostic screening, early detection, and preventative care based upon evidence-based guidelines (O'Keefe & Anderson, 2017). Improved access to care for chronic disease management at on-site health centers may increase opportunities for assessment and diagnosis of T2DM, monitoring of diabetic control, and assessment of medication compliance thereby preventing complications and negative sequelae (O'Keefe & Anderson, 2017).

Statement of the Problem

The National Diabetes Statistics Report (CDC, 2017) describes the incidence of diabetes as approximately 1.4 million for newly diagnosed cases in United States (US) adults 18 years or older in the year 2015. Of these cases, more than half occurred in adults ages 45 to 64 years old, equally in males and females (CDC, 2017). The incidence of diabetes was higher in non-

Hispanic blacks (9.0 per 1,000 persons) and Hispanics (8.4 per 1,000 persons) when compared to non-Hispanic whites (5.7 per 1,000) (CDC, 2017).

The prevalence of diagnosed and undiagnosed diabetes is estimated at 9.4% of the US population, or 30.3 million people of all ages, of which 7.2 million or approximately 24% do not report or were not aware of having diabetes (CDC, 2017). The percentage of adults with diabetes increases with age with a prevalence of 25.2% for ages 65 years or older (CDC, 2017). The age adjusted prevalence of diagnosed and undiagnosed diabetes was higher for non-Hispanic blacks, Hispanics, and Asians when compared to non-Hispanic whites (CDC, 2017).

The incidence and prevalence of diabetes varies with level of education, which serves as an indicator of socioeconomic status. The incidence among individuals with less than a high school education was approximately two times greater (10.4 per 1,000 persons) than individuals with a high school education or higher (5.3 per 1,000 persons) (CDC, 2017). The prevalence by education level varied significantly with 12.6% of adults with a diabetes diagnosis with less than a high school education versus 9.5% of adults with at least a high school education, and 7.2% with more than a high school education (CDC, 2017).

Significance of the Problem

According to the Center for Disease Control's (CDC, 2017) National Center for Chronic Disease Prevention and Health Promotion (NCCDPHP) six in ten adults have a chronic disease in the US and four in ten have two or more chronic conditions. In the last 20 years, the number of adults diagnosed with diabetes has more than tripled and more young adults, teenagers and children are being diagnosed with diabetes (CDC, 2017). The mortality rate for diabetes in the US from 2013 to 2016 was 25.7 deaths per 100,000 population (CDC, 2017).

Diabetes and chronic disease management are one of the leading causes of the $3.3 trillion in annual health care costs in the US. The CDC (2017) states chronic diseases are the leading causes of death and disability in the US. Of the chronic diseases causing death and disability, T2DM ranks seventh as one of the leading causes of death in the US (CDC, 2017). T2DM is a complex metabolic disease process in which poor management or progression of the disease can result in significant comorbidities, such as cardiovascular disease, peripheral neuropathy, and poor wound healing. T2DM is the leading cause of kidney failure, lower-limb amputations, and adult blindness (CDC, 2017).

Papanicolas, Woskie, & Jha (2018) reported the US spent twice as much as other countries on health care, specifically 17.8% of the gross national product, although it performs poorly on many population health outcomes. The American Diabetes Association (ADA) estimated in 2017 the total costs of diabetes care at $327 billion, reflecting a 26% increase over a five-year period (2019). The average medical costs for diagnosed diabetics averages nearly $10,000 per year, reflecting a rate which is approximately 2.3 times higher than in the absence of the disease (ADA, 2019). Other variables leading to the increase in costs associated with T2DM include inability to work or increased absenteeism from the workplace, decreased productivity in the workplace, and an overall loss of productivity related to morbidity and mortality (ADA, 2019). As the debate regarding health care reform and spending continues, the issue of chronic disease management provides an example of the negative financial impact the US is currently experiencing.

T2DM requires a multifaceted approach to care management that includes primary care visits that routinely include physical examinations, laboratory testing, prescriptions, medication management, specialty referrals, and patient education. Primary care delivery is often provided

with inadequate care coordination and care is often fragmented or duplicated (Williams et al., 2019). According to the Agency for Healthcare Research and Quality (AHRQ), care coordination in primary care involves "deliberately organizing patient care activities and sharing information among all of the participants concerned with a patient's care to achieve safer and more effective care" (AHRQ, 2018, p. 1).

T2DM treatment requires diabetes self-management education (DSME) and diabetes self-management support (DSMS) regarding lifestyle modifications which include diet, exercise, and self-blood glucose monitoring (SBGM). Powers et al. (2015) defines DSME as an "ongoing process of facilitating the knowledge, skill, and ability necessary for diabetes self-care" and DSMS as "activities that assist people with diabetes in implementing and sustaining the behaviors needed to manage their condition on an ongoing basis" (p. 2101). Together DSME and DSMS provide the education and resources to increase patient understanding and management of their chronic condition.

Powers and colleagues (2015) examined the joint position statement of the ADA, the American Association of Diabetic Educators (AADE), and the Academy of Nutrition and Dietetics which collectively supported the importance of an initial DSME by a health care provider and resources for ongoing DSMS. The goals of the position statement were to improve patient care and education, improve the health of T2DM patients and overall population, and reduce the per capita costs of diabetes-associated complications (Powers et al., 2015).

Many individuals diagnosed with T2DM spend a third or more of their time at work, and it is often difficult to obtain the primary care services required to manage T2DM. The benefit of an on-site health center is improved productivity related to both reduced absences and

presenteeism, which occurs when employees comes to work impaired by illness and are unable to work to their full ability (Caloyeras, Liu, Exum, Broderick, & Mattke, 2014).

Standards of Care

The ADA reported only 14% of patients met the standards of care for diabetes in the three target goals of glycemic control, blood pressure (BP) control, and cholesterol control (ADA, 2019). The target goal of glycemic control is a HbA1c less than 7% with the recommendation for testing at least 2 times per year in patients meeting glycemic goal and every 3 months in patients not meeting glycemic goal or when the treatment regimen changes; the frequency of testing allows for clinical presentation, current treatment plan, and provider judgement (ADA, 2019). The target goal of BP for patients with T2DM is dependent upon level of cardiovascular risk. For patients with a low cardiovascular risk of less than 15%, the target BP is less than 140/90 mmHg; whereas a high cardiovascular risk greater than 15% has a target BP of less than 130/80 mmHg (ADA, 2019). The management of patients with T2DM and elevated BP includes initiation of drug classes aimed at reducing cardiovascular events, including angiotensin converting enzyme (ACE) inhibitors or angiotensin receptor blockers (ARBs) (ADA, 2019). The target goal of lipid management for patients with T2DM are LDL less than 100mg/dL and HDL greater than 40mg/dL for men and 50mg/dL for women (ADA, 2019).

On-Site Health Center

One of the Institute for Healthcare Improvement's (IHI) goals are to promote "The Triple Aim", which encompasses a framework to improve the patient experience of care by focusing on quality and satisfaction; improving the health of populations; and reducing the per capita cost of health care (IHI, 2020). The concept of "triple aim" describes the characteristics needed for

organizations that are committed to providing an integrated approach to health care delivery that includes a redesign of primary care delivery, a partnership with patients and their families, population health management, and fiscal management of the associated costs (Ryan, Brown, Glazier, & Hutchinson, 2016).

On-site health centers are institutions that integrate the goals of the "triple aim". According to the National Association of Worksite Health Centers (NAWHC) an on-site health center, also known as a worksite or workplace clinic is defined as "a setting where an employer offers one or more medical and wellness services, delivered by licensed providers, to all or a designated portion of its active population and other eligible individuals" (NAWHC.org, 2019). The goal of the on-site health center "is to provide easy access and immediate attention, at little or no cost, for a host of services and products that an employee would normally have to leave the worksite to obtain" (NAWHC.org, 2019).

The on-site health center addresses the goals of the "triple aim" by providing primary care service delivery that is accessible and convenient at low to no cost for participants; encouraging use of wellness programs that allow employees to be involved in their care; decreasing common illnesses and their severity; and augmenting management of chronic conditions such as T2DM that require regular visits and compliance monitoring. Through these initiatives, on-site health centers strive to improve overall patient outcomes (NAWHC.org, 2019).

Patients of the on-site health center are the employees and their families, specifically those who are covered by employer sponsored health benefits. As a benefit to the employees and their dependents the on-site health center services are provided at no additional cost and typically co-payment fees are waived. Employees have the additional benefit of being provided health

care services while remaining “on the clock”. The on-site health centers are usually staffed with one or two primary care providers with ancillary staff consisting of a registered nurse (RN), licensed practical nurse (LPN) and/or medical assistant (MA). Laboratory services and formulary specific medication dispensary are available at the on-site health center. Any employee can access the on-site health center by completing a health risk assessment and scheduling an appointment.

Care Coordination Program

The redesign of primary care delivery requires population health management together with care coordination. According to the AHRQ care coordination in primary care involves “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” (AHRQ, 2018, p. 2). Care coordination requires several key elements: a comprehensive risk or needs assessment, individualized care planning, access to needed services and equipment, communication and monitoring. The ADA (2019) recognizes the barriers to optimal care delivery that includes poorly designed and fragmented care coordination, particularly in the management of chronic diseases such as T2DM.

The care coordination program at the project site provides the framework for chronic disease management of employees with specific chronic conditions that impact employer health care costs. The care coordination program manages: T2DM, hypertension, and hyperlipidemia. For the purposes of this study the primary focus was patients with a T2DM diagnosis. The organizational outcomes for the on-site health center are to determine if employees with T2DM utilizing the on-site health center are meeting determined internal benchmarks and whether there is improvement in diabetes care management as reported by improvements in weight, BMI, BP,

blood glucose, HbA1c, microalbumin, LDL, and HDL. Organizational internal benchmarks include HbA1c less than 7% in a year, more than 50% of patients will receive an ACE or ARB prescription during the year, and more than 50% of patients will receive a foot exam during the year.

The care coordination program at the project site is managed by clinical staff, a designated nurse supported by a medical assistant, which seeks to identify gaps in care and assists with facilitating coordination of primary care services, laboratory services, wellness and specialty referrals, and patient education resources. The clinical staff reviews patient records diagnosed with T2DM, documents in the electronic health record (EH R) any potential gaps in care based upon current evidence-based guidelines. The clinical staff will attempt to schedule patients at the on-site health center who may need laboratory services performed, repeated, or follow-up visits to review and discuss lab results. The clinical staff will identify high risk patients in need of additional support and assist these patients with referrals for wellness services. The clinical staff communicates their findings, activities, and progress with health center providers to ensure gaps identified are addressed and closed.

Organizational Needs Assessment

An organizational needs assessment was completed utilizing Edgar Schein's "Levels of Culture Theory" which identifies three levels of analysis: artifacts, espoused beliefs and values, and basic underlying assumptions of the parent company of the on-site health center (Schein, 2017). The parent company was established in 2004 in the southeastern US and functions as a for-profit entity. The parent company has over 200 on-site health centers located in over 27 states across the US with more than 1,300 employees. The focus of the parent company is to integrate wellness and care management with primary care and chronic disease management at

lower costs and greater convenience. The parent company also offers preventative and occupational health management options focused on health promotion. For the purposes of this study, one on-site health center of this parent company was identified as the sample population and is located along the southeastern gulf coast of the US in a metropolitan area with 77,000 residents. The on-site health center sample population was comprised of 1,200 city and municipal employees to whom the parent company provides health insurance benefits which can be utilized at the on-site health center for primary care and care coordination services at no additional cost. The care coordination program has been in place for three years and employees who have been identified as T2DM have been enrolled for diabetes care management.

Artifacts

Schein (2017) describes the first level of culture, artifacts, as the organizational structures or processes that can be readily observed, heard, and felt and can be associated with the physical environment or the inherent or perceived values of the company. In terms of artifacts, the parent organization is in alignment with its mission statement, which seeks to inspire employers and employees to achieve well-being and health through innovative, quality, cost-effective healthcare solutions. The company artifacts include modeling of compassion for patients and enthusiasm for the delivery of quality health care.

Values

The second level of culture is espoused beliefs or values which are the ideals, goals and values shared by the parent company and throughout the on-site health center providers, staff, and clients (Schein, 2017). The mission statement serves as the overriding theme of employee performance in the workplace focused on achieving health and well-being while delivering care with enthusiasm and compassion. The vision statement serves as a guide for the parent company

to be an innovative pioneer of healthcare solutions, deliver superior health and financial outcomes by challenging traditional healthcare conventions. The company's core values include doing what is best for the patient as well as the employer and are readily apparent in the delivery of care to patients, families, and clients.

Assumptions

Schein (2017) refers to the third level of culture as basic underlying assumptions, which are the unconscious beliefs and values that may influence behavior in an organization. The care coordination program seeks to enhance the quality of care delivery and focuses on health and wellness, improved patient care experience, population health management, and decreasing health care costs. Using Schein's description, the basic underlying assumption of the parent company is that it is the nature of humans to want to be healthy and well and there is an interest by the client (employer) to facilitate and aid in keeping their employees and their families healthy and well. The employer assumes that by facilitating the availability of the on-site health center, employees will utilize the services and be guided towards well-being and healthier lifestyles. For the employer these outcomes will potentially manifest as decreased health care expenditures, decreased loss of productivity, and improvement in employee morale.

Research Question

There is increasing interest in on-site health centers and care coordination programs with a focus on health promotion, disease prevention, and lowering of health care costs. The PICOT acronym was used to formulate the evidence based clinical question for this project. The PICOT consists of patient population of interest, the intervention, the comparison or control group, the outcomes or consequences, and the time frame used for the intervention or duration of data collection (Moran, Burson, & Conrad, 2017). The PICOT question for this study was: In adult

patients with T2DM, what is the effect of an on-site health center and the care coordination program on T2DM outcomes? The T2DM outcomes evaluated were weight, BMI, BP, blood glucose, HbA1c, microalbumin, LDL, HDL, and indications for ACE or ARB, and statin medication therapy. The total number of health center visits, foot exams, and referrals for wellness, podiatry, and optical exams was obtained.

The sample of records reviewed included adult patients from 18 years and older who received primary care services and T2DM care coordination from January 1, 2018 through December 21, 2019 and completed a minimum of three health center visits. The evaluation period was from point of entry into primary care, which begins when the patient completes their HRA and schedules their first appointment at the on-site health center. Patient data collection was compiled retrospectively from initial HRA forward to the next annual HRA.

Theoretical Framework

The theoretical framework used for implementation of this project was the "Chronic Care Model" (CCM) (Coleman, Austin, Brach, & Wagner, 2009), which identified six essential elements of a health care system that encourage high-quality chronic disease care. These six elements include: the health system, delivery system design, decision support, clinical information systems, self-management support, and the community (Coleman et al., 2009). Each element has several evidence-based change concepts, which applied in combination, encourage interactions between providers and patients to improve active patient participation in their plan of care.

The first element "health system" encompasses patient safety and care coordination efforts. Organizations seeking to improve chronic disease outcomes are focused on preventing medical errors and lapses in communication that could impact care coordination. Changes

within these organizations typically begins with senior and upper management strategies which transform policies into relevant practice (Coleman et al., 2009). The elements of the CCM "delivery system design" and "clinical information systems" include care coordination and case management. Care coordination focuses on organizing patient and population health data to improve health care delivery and case management in order to deliver evidence-based care with regular follow-ups. Both care coordination and case management identify and share information using performance indicators to monitor and evaluate the progress of the health care team (Coleman et al., 2009). The elements "decision support and self-management support" share the focus of evidence-based guideline implementation for patient education to facilitate self-care and patient participation, both emphasizing the role of the patient in managing their health care (Coleman et al., 2009). The final element of the CCM "community" includes forming partnerships with entities outside of a health system, such as the ADA, to provide linkages to additional health care resources and patient education (Coleman et al., 2009).

The ADA has determined that the use of the CCM is an effective framework for guiding T2DM care delivery and chronic disease management (ADA, 2019). CCM core elements promote health systems with a quality-oriented culture, care delivery that is proactive, self-management support, evidence-based practice with care guidelines using clinical information systems, and community resources (ADA, 2019). The important aspect of T2DM chronic disease management and the CCM involves achieving the six "Quality Chasm" aims of the National Academy of Medicine, formerly known as Institute of Medicine (IOM). The "Quality Chasm" six aims - timely, safe, effective, efficient, equitable, and patient centered care – reinforce that high-quality referrals and care transition are primary goals of care coordination (IOM, 2001).

Definition of Terms

Care Coordination - organization of patient care activities to provide chronic disease management, optimize outcomes, and decrease complications while improving patient engagement in care.

Chart Reviews/Audits – assessment of patient medical record (electronic) to extract data regarding clinic visits, lab values, wellness encounters following official date of entry to care within the health center.

DSME – diabetes self-management education; process of facilitating the knowledge, skill, and ability necessary for diabetes self-care: patients actively record their visits/check-ups, exams, lab results, influenza/pneumonia shots, and self-blood glucose monitoring results using a score card.

DSMS - diabetes self-management support; activities that assist with implementing and sustaining behaviors needed to manage diabetes: trained wellness coaches who provide support via telehealth/phonic visits and provide a library of resources via smartphone applications (apps), print outs, or logs.

DSMES – a combination of both diabetes self-management education and diabetes self-management support.

Hemoglobin A1c (HbA1c) – blood test used to determine average blood glucose concentrations.

Health Risk Assessments (HRAs) – a questionnaire completed by patients providing health information and outlining their past medical history, social history, health risks, and lifestyle habits (smoking, exercise, use of seat belt); also includes clinical data of blood pressure, height, weight, waist circumference, and laboratory results.

Internal Benchmarks – Organizational quality measures based upon evidence-based practice

diabetes care management: percentage of patients with HbA1c <7 in a year, percentage of patients who received an ACE or ARB medication during the year, percentage of patients who received microalbumin testing in a year, and percentage of patients who received a foot exam during the year.

On-site Health Centers – project site is an on-site health center; also known as near site clinic, worksite clinic, workplace clinic, or wellness clinic; facility utilized by employees for acute/chronic primary care services financed by the employer.

Type-2 Diabetes Mellitus (T2DM) – Patients receiving an ICD-10 coding of T2DM; project site coding is E11.0 through E11.9 pertaining to T2DM.

Wellness Referral - patients who fail to meet the standard of care associated with T2DM, i.e. BMI, BP, blood glucose, HbA1c, LDL, or HDL are referred for wellness services which include an appointment with the wellness or health coach.

Chapter II: Review of the Literature

This literature review provides a summary and in-depth synthesis of the previous body of evidence that exists relative to on-site health centers, care coordination, and T2DM. The search strategy, methodologies involved, and a critique of existing studies compiled are presented which support the purpose of this study.

Introduction to Search Criteria

A review of the literature was completed using PubMed MEDLINE and the Cumulative Index to Nursing and Allied Health (CINAHL) databases. Articles were reviewed and assessed for relevance by evaluating the abstract and using specific criteria to include manuscripts relevant to this project. Inclusion criteria were limited to articles published between 2014 and 2020, English language, humans, and adults 18 years and over. Articles were excluded that included children, foreign languages, pregnant females, and adults over 75 years.

The PubMED MEDLINE search using the key terms from the PICOT: "on-site health center" AND "diabetes" yielded forty-one articles. Additional inclusion and exclusion criteria were selected for articles for review: articles published between 2014 and 2020, humans, English language, age adults 18+ years. The initial yield decreased to twenty-five articles. Of the remaining articles, one article by Dalal, Khoury, and Nyce (2014) was retrieved which specifically addressed on-site health center performance. An additional search with the same inclusion and exclusion criteria was performed utilizing the key terms "on-site clinic" AND "diabetes" which yielded seventy-two articles, of which one article by Tarride et al. (2018) was retained that addressed the effectiveness of T2DM screening in the workplace. An additional search using the key terms "workplace clinic" AND "diabetes" yielded one hundred twenty-five

articles of which eight articles were retained for review. The eight articles retained included four retrospective studies (Das et al., 2019; Levy & Thorndike, 2018; Ostovari, Yu, Yih, & Steele-Morris, 2017; Misra-Hebert, Hu, Taksler, Zimmerman & Rothberg, 2016), one prospective study (Burton, et al., 2015), one descriptive study (Padwal, 2017), one randomized study (Kramer et al., 2015), and one peer-reviewed study (Hafez et al., 2017). A final search using the terms "care coordination" AND "diabetes" yielded sixty-five articles of which three were retained for review. These articles included one retrospective study (McClendon, Wood, & Stanley, 2019), case study (Sepers et al., 2015), and pre/post intervention study (Zupa, Arena, Johnson, Thearle & Siminerio, 2019).

A CINAHL search using the term "on-site health center" provided five articles none of which met inclusion criteria. A second search using "care coordination" AND "type 2 diabetes" provided eighteen articles, one of which met the inclusion criteria and was relevant to this project. The article (Fitzgerald et al., 2017) was a qualitative data analysis of care coordination themes related to program implementation.

There were notable studies focused specifically on on-site or workplace health centers or clinics with the focus on T2DM management and outcomes. Similarly, there was a small sampling of studies regarding the impact of on-site or worksite health centers/clinics and care coordination efforts and outcomes. These outcomes were related to improvements in weight loss, BP, HbA1c, LDL, and HDL levels. In general, an increasing presence of on-site health centers exists, however there is limited research regarding on-site health centers and their effect on chronic disease management of T2DM (Dalal et al., 2014). This gap provides a foundation for further inquiry and evaluation of how on-site health centers could affect T2DM outcomes with properly implemented care coordination programs.

Critique and Synthesis of the Literature

The literature regarding T2DM and its management focuses on the cost of care management as well as the desired diabetes outcomes. There is growing interest in on-site health centers and the importance of care coordination programs to address chronic disease outcomes. The literature review will focus on these three central themes: T2DM care management outcomes, on-site health centers, and care coordination.

Type-2 Diabetes Mellitus Care Management Outcomes

General T2DM outcomes focus on two main goals: the delay or prevention of complications and maintaining or optimizing quality of life (ADA, 2019). The process starts at understanding the characteristics of the individual patient: demographics, clinical variables, comorbidities, current lifestyle, and level of motivation. The process continues with understanding the specific factors that may affect the patient's treatment plan and ensuring that the patient is actively engaged and agrees with the plan. Once the provider and patient agree to the plan it is implemented, monitored, and reviewed for necessary modifications or additional support (ADA, 2019). Patient preference is an integral component in this evidence-based practice approach.

Misra-Hebert and colleagues (2016) completed a retrospective cohort study evaluating whether employee financial incentives improved diabetes and cardiovascular risk factor control. This retrospective data analysis of EHR data linked to insurance claims data of participants with diabetes. An employee study cohort consisted of patients with a T2DM diagnosis with at least two HbA1c greater than 6.5% in two years or with an ICD-9 diagnosis of T2DM and a prescribed diabetes medication (Misra-Hebert et al., 2016). The employee cohort with T2DM was compared to a cohort of non-employees with diabetes and insurance. The intervention was

initially a fixed financial incentive of one hundred dollars for participating in a disease management and achieving the specified clinical goals. The incentive increased to include health insurance premium discounts linked to achieving clinical goals and program participation. The variables measured included evaluating for changes in weight, systolic BP, LDL, and HbA1c (Misra-Hebert et al., 2016). The sample population consisted of 1,092 employees with T2DM matched to non-employees with insurance.

The results of the Misra-Hebert et al. (2016) study showed employee participation increased as incentives increased and there were annual improvements in diabetes and cardiovascular risk factor control. Employees had a larger decline in HbA1c than non-employees and a larger decline in weight, however the systolic BP and LDL results were not statistically significant when comparing employee to non-employee cohorts (Misra-Hebert et al., 2016). A limitation of the study noted no more than fifty percent of employees agreed to participant and the study failed to address any relevant impact of incentives on chronic disease management of diabetes and/or implications for care coordination (Misra-Hebert et al., 2016).

A study by Sepers et al. (2015) measured the implementation, effects, and sustainability of delivering DSME and DSMS using a coordinated care approach at multiple patient centered medical home sites. The study implemented the American Association of Diabetes Educators (AADE) coordinated interventions which included DSME, DSMS, additional access to care services, and enhanced practice site resources focused on improving diabetes care (Sepers et al., 2015). The AADE focuses on 7 key self-care behaviors to coach and assist patients with setting goals and priorities known as “AADE & Self-Care Behaviors”. DSME focused on “AADE7 Self-Care Behaviors” in individual and group sessions supported with nutrition education and DSMS was provided in group sessions, which included cooking classes with diabetic recipes

(Sepers et al., 2017). Access to additional diabetes care included at home or work follow-up visits for missed appointments, outreach meetings, telephonic care services, and assistance with transportation to diabetes care appointments (Sepers et al., 2015). Practice sites resources were enhanced with an EHR to coordinate services; coordinated patient care teams consisting of a provider, nurse care coordinator, certified diabetic educator, and health behavior coach; and DSME trained community health workers for additional support (Sepers et al., 2015). The results of the study examined implementation, clinical outcomes, and sustainability of interventions. The findings revealed care coordination encompassed most of the services implemented and resulted in improvements of HbA1c, BMI, and blood glucose, while each practice site maintained some of the interventions focused on sustainability (Sepers et al., 2015). This study supports the need for practice sites to provide care coordination, DSME, and DSMS focused on improving diabetes outcomes.

Burton et al. (2015) performed a 12-month prospective analysis of employees participating in a 12-month worksite diabetes management program who were at risk for diabetes, determined as pre-diabetic or were diagnosed with diabetes. The employees were evaluated using a pre- and post-program survey with questions about their diabetes and behavioral health questions. The clinical screenings included height, weight, and waist circumference measurements; HDL, LDL, total cholesterol, blood glucose, and HbA1c testing (Burton et al., 2015). The surveys and clinical screenings were repeated at six months and twelve months. The 65 diabetic employees received self-efficacy support during the twelve months in the form of clinical staff, health coach, dietician, pharmacist, and counselor. The results showed a statistically significant improvement in employee knowledge of diabetes,

however the clinical screening tests for HbA1c from baseline and at six- and twelve-month intervals were not significant (Burton et al., 2015).

Zupa and colleagues (2019) examined the effectiveness of a diabetes educator focused and insurer based DSME intervention with coordination of primary care and care management of high-risk diabetics. The diabetes educator performed the DSME telephonically or in-person, in addition to providing chart review or care plan input to practice based care managers. The diabetes educator provided ongoing support by developing and facilitating training sessions on self-glucose monitoring, nutrition, medication, and exercise (Zupa et al., 2019). Each high-risk diabetic was assessed at baseline for BMI, HbA1c, and LDL levels every three month over a year. Findings of the study reported a significant improvement in HbA1c control over one-year; an improvement of LDL levels over nine months although not maintained; and no significant change in BMI over time (Zupa et al., 2019).

Synthesis Related to Type-2 Diabetes Mellitus Care Outcomes

The management of care for T2DM seeks to prevent and delay complications and improve quality of life. The importance of understanding the individual patient, variables affecting treatment and patient engagement are important. The studies presented the clinical variables commonly associated with T2DM and the impact that incentives and patient education had on those variables. Misra-Hebert et al. (2016) supported the use of employee incentives to improve clinical variables and level of motivation while Sepers et al. (2015) supported a multidisciplinary approach to care coordination and the use of DSME and DSMS to improve patient engagement, knowledge, and understanding of T2DM. Burton et al. (2015) supported a diabetes management program to improve T2DM outcomes and Zupa et al. (2019) supported

DSME to improve T2DM knowledge. Overall, the studies improved T2DM outcomes, patient engagement, and knowledge.

On-site Health Centers and Clinics

An on-site health center is a health care facility that offers primary care and wellness services delivered by licensed providers to employees; it is employer provided to employees who are eligible for benefits (NAWHC, 2019). The on-site health center, also referred to as a workplace clinic, is usually located on the grounds or campus of the employer for easy access by employees. The ease of access and the utilization of employer sponsored benefits are variables which support the growing interests in these health care facilities.

O'Keefe & Anderson (2017) reviewed the implementation of a university developed on-site clinic. The case study examined the history of how an on-site clinic developed with a focus on primary care, health promotion and wellness. This study focused on several key themes: reduction in costs of care; decreasing health expenditures; increasing prevention, screening, and early detection; developing wellness programs optimizing a positive return on investment (ROI); and improving employee trust relationships (O'Keefe & Anderson, 2017). The study found that there was an increase in preventative care and diagnostic screening as well as early detection; all of which were associate with a decrease costs associated with managing disease processes and negative sequalae (O'Keefe & Anderson, 2017). The authors concluded that the on-site health center had a positive financial impact on reduction of costs, expenditures and ROI. The reduction of costs was estimated to be $62,500 annually based on on-site clinic utilization compared to physician off-site or outpatient services; reduction in sick leave utilization from approximately 16,000 hours to 11,000 hours over 3 years; and reduction in health insurance claims (O'Keefe & Anderson, 2017). The most significant finding was the savings associated

with lost productivity (employer compensated time while off or away from work) calculated as number of visits off-site multiplied by the employee's hourly wage, which for the university, over an eight-year period, equated to over $2 million dollars in savings (O'Keefe & Anderson, 2017).

Tarride and colleagues (2017) examined the effectiveness of a T2DM screening and education program in the Canadian workplace health center in terms of diabetes risk reduction, changes in productivity, and well-being outcomes. This prospective pilot study consisted of 724 eligible participants with 577 completing the first on-site face-to-face meeting with a nurse for clinical screening at baseline and 293 completing the second face-to-face meeting again at six months. Of the 293 participants screened at baseline and six-months, 21% were diagnosed as either pre-diabetic or T2DM. The study included a health risk assessment, a diabetes risk questionnaire, and four telephonic educational sessions by a certified diabetes educator. The clinical screening included a HbA1c, BP, blood glucose, HDL, total cholesterol, waist circumference and 10-year Framingham Coronary Heart Disease risk score (Tarride et al., 2017). Findings of the study included a statistically significant decrease in HbA1c at six months for T2DM and pre-diabetics, however no statistically significant change in HbA1c for those at risk or with normal levels at baseline (Tarride et al., 2017). Additional findings included 30-40% of participants had hypertension and hyperlipidemia and an overall risk of 5% for developing coronary heart disease over a 10-year period (Tarride et al., 2017). Limitations of this Canadian study included the inability to compare to other on-site settings, a potential for selection bias related to participant motivation from baseline to six month assessment; and the follow-up period post-study was short which did not allow for analysis of results over time or evaluation of sustainability of results (Tarride et al., 2017).

An additional Canadian study by Padwal et al. (2017) examined the feasibility of cardiovascular risk factor screening and management by worksite providers. As Canadians spend an average of 30 hours per week at work, the study focused on the worksite as a viable place for screening of risk factors for cardiovascular disease, primarily diabetes, hypertension, dyslipidemia and smoking (Padwal et al., 2017). The primary aims of the study were to improve BP, LDL levels, and achieve smoking cessation; and secondary aims were improvement in weight, BMI, HbA1c levels, and Framingham risk estimate (Padwal et al., 2017) Variables assessed included baseline medical history and demographics, weight, height, BMI, BP, blood glucose, HbA1c, and lipids; and the Canadian Cardiovascular Society Framingham Risk Score was calculated. Pharmacists provided pharmacotherapy, case management, and behavior counseling over six months (Padwal et al., 2017). The results of the study were statistically significant improvements in systolic BP and triglycerides, though no significant changes in weight, BMI, HbA1c, LDL, HDL or Framingham risk estimate. (Padwal et al., 2017). Though this study lacked a specific focus on T2DM, the study supported the presence of a worksite provider to increase access and convenience to health care preventing the need to take time away from work for medical appointments; especially for those patients who were less likely to be aware of cardiovascular risks (Padwal et al., 2017).

Dalal et al., (2014) examined performance at an on-site health center by evaluating costs of medical and pharmacy services, clinical outcomes, and employee utilization. On-site health center performance was evaluated based upon cost, quality, and utilization to determine if there was a link between employee engagement and improved health outcomes (Dalal et al., 2014). The study period was from the opening of the on-site health center to the end of eighteen months. The study utilized three cohort groups of employee de-identified medical and pharmacy claims

data to estimate the variables of cost, quality, and engagement. Cohort groups consisted of employee users of the on-site health center, employees utilizing services outside the health center in the nearby geographical area, and other employees in satellite locations outside the on-site health center area. The ROI was calculated by utilization, but also included diagnosis, procedure code, and identified a cohort of high visit users during the study period. The data analysis was adjusted to allow for demographic and regional cost variances (Dalal et al., 2014). The on-site health center users consisted of employees, dependents, retirees, contractors, and community members.

The study findings of Dalal et al. (2014) reflected utilization of one in four employees for the first six months and increasing to thirty percent in the next six months. By the end of the first year, utilization was up to fifty-six percent of which two-thirds consisted of employees. With the increase in visits there was also an increase in preventative screenings and an increase of trust with patient-provider relations (Dalal et al., 2014). The study identified the profile of on-site health center users as having a higher prevalence of diabetes, asthma, and coronary artery disease than non-users of the health center, which reflected a need for both health care services and chronic disease management (Dalal et al., 2014).

The pharmacy program included ninety-day refills on generic medications, which ranged from a dispensing rate of fifty to eighty-five percent depending upon health center utilization and medical condition. Dispensing rates for diabetes medications were significantly higher for users of the on-site health center than for non-users of outside services (Dalal et al, 2014). Health outcomes identified lower outpatient hospital and emergency room visits and a decrease in severe or expensive episodic care and the final ROI for the on-site health center was below the breakeven point and remained stable during the study period (Dalal et al., 2014). Although key

factors of medical and pharmacy costs, identification of chronic disease, and employee utilization were addressed, there was no significant data presented regarding actual clinical outcomes and chronic disease management.

One retrospective study assessed the effect an on-site health center had on employee utilization of preventative services (Ostovari et al., 2017). The study objectives were to evaluate the impact on overall health before and after implementation of an on-site health center and to evaluate factors affecting the on-site health center's utilization (Ostovari et al., 2017). The on-site health center provided primary care and wellness, acute care, condition management and laboratory services. Health claims data of employees and their dependents of a public university were evaluated over three consecutive years. The study determined employees significantly increased their utilization of preventive services and the most common chronic conditions identified were diabetes, hypertension, and hyperlipidemia (Ostovari et al., 2017).

The findings of the study suggested individuals with diabetes, hypertension, and hyperlipidemia were less likely to utilize the preventive services offered at the on-site health center as the on-site health center was not considered a permanent provider of health care (Ostovari et al., 2017). The study presented the argument that patients with chronic diseases would rather utilize settings and providers such as "medical homes" or providers with which they have already established primary care (Ostovari et al., 2017). The study's focus on utilization of preventative services and not inclusion or implementation of care coordination or chronic disease management further support the need for further study.

Levy & Thorndike (2019) performed a retrospective study which examined health care expenditures and whether a workplace ten-week wellness program had any effect on improving weight, cholesterol, and BP at the end of the ten-week program and again after one year. Claims

data from 2010 and 2014 was utilized for 289 employees was examined and matched with a control group of 194 employees for comparison. The study reported no decrease in health care expenditures for the one-year period but did have a positive effect on reducing cardiovascular risk factors. The study suggested that the cost savings would likely have been illustrated by improving chronic disease management rather than by primary prevention efforts (Levy & Thorndike, 2019).

Synthesis Related to On-Site Health Centers and Clinics

The literature presented about on-site health centers support their utilization related to reduction of costs and health care expenditures, decreasing losses associated with employee absenteeism and lack of productivity, while increasing employer ROI. The on-site health center removes the barrier to access by increasing convenience to health care and strengthening patient and provider engagement and trust. The clinical implications for T2DM outcomes and utilization of on-site health centers is further supported by the studies exhibiting improvements in clinical variables of HbA1c, BMI, BP and lipids, but also identifying comorbidities and cardiovascular risks. The Tarride et al. (2017) and Padwal et al. (2017) Canadian studies provide a foundation for further study in the US regarding the utilization of on-site health centers to improve T2DM outcome. The importance of the patient perspective and the provider trust relationship (Dalal et al.,2014) as well as increasing the utilization of preventive services (Ostovari et al., 2017) were further supported by studies regarding on-site health centers. The studies presented support the role of the on-site health center as a viable option to become the "medical home" for employees to obtain primary care. The utilization of the on-site health center can have an integral role in bridging chronic disease management, care coordination, T2DM education, and outcomes.

Care Coordination

Care coordination is organizing the health care activities of patients and the sharing of patient information between all health care providers involved in that care to achieve and provide the optimal level of health care services (AHRQ, 2018). It is a process of health care delivery that focuses on safety, effectiveness, efficiency, and quality of care that is patient centered.

A retrospective study conducted by McLendon et al. (2019) evaluated a pilot diabetes care coordination program which targeted rural adults ages 21-76 years old with poorly controlled diabetes whose HbA1c was 8 or greater in primary care settings. The sample size included 59 adults for interventions consisting of nurse care management, telemedicine consults, and diabetes self-management education (DSME) to enhance disease management and prevent complications. The outcomes measures evaluated included pre/post laboratory test results, diabetes medical education (DME) test scores, hospital claims data, satisfaction surveys, and focus group responses. The intervention demonstrated statistically significant reductions in HbA1c levels, improvement in DSME test scores achieved, and a reduction in hospital utilization. Hospital utilization was reported as a reduction in emergency room visits by 52.4% and inpatient hospitalizations by 96%. Additionally, patients and providers indicated strong satisfaction with the components of the program and the focus group represented by a rural advisory network indicated satisfaction with delivery of program and outcome measures (McLendon et al., 2019). The implications of this study support the potential for improving diabetes control through care coordination, access to care, and education while also reducing the costs of health care utilization.

Berkowitz, Eisenstat, Barnard, & Wexler (2018) implemented a qualitative study that explored the patient perspective regarding T2DM care management from a multidisciplinary

coordinated care approach using not only providers, but also including team members experienced in physical fitness, exercise, and handling finances. The study included eight focus groups of 53 randomly selected primary care patients who were queried regarding their perceptions of diabetes team care. The feedback was recorded, transcribed, coded, and analyzed using content feedback. Results included positive patient perceptions for the coordinated multidisciplinary diabetes team care. General themes included patient perceptions of diabetes care as complex and requiring more than one provider; diabetes care requires coordination and a single point of contact to be effective (Berkowitz et al., 2018). The implications for this study support the concept of care coordination of T2DM in the primary care setting from a patient perspective.

Fitzgerald and colleagues (2017) performed a qualitative data analysis which highlighted care coordination and the strategies used to implement and sustain programs focused on T2DM disease management. The study utilized a community health center location for patient site visits. Site visits with recorded interviews were conducted three times during a 5-year period and transcribed for analysis. From this data overriding themes regarding care coordination were identified across sites (Fitzgerald et al., 2017). The results included collaboration between clinics and community; utilization of community health workers; and data sharing via electronic health record (EHR) all focused on promoting comprehensive care, improving communication, supporting diabetes education, and facilitating care coordination (Fitzgerald et al., 2017). This analysis supports care coordination in relation to T2DM disease management, however the community health center is the focus rather than an on-site health center.

There is limited literature regarding on-site health centers and their effects on T2DM and care coordination. One study by Solorio, Bansal, Comstock, Ulatowski, & Barker (2015)

evaluated the impact of clinic-based chronic care coordination on the quality of diabetes care and outcomes. The retrospective cohort study evaluated six community health centers serving predominantly low income non-Hispanic white and Hispanic patients over a two- year period with chronic care coordination. The study examined the frequency of testing of HbA1c, LDL cholesterol, and microalbumin screening; outcomes of HbA1c lipids, and blood pressure control; and health care service utilization (Solorio, et al., 2015). The sample population was 329 with all data compiled from an EHR. The results of chronic care coordination led to improvements in process measures which included increase checks of HbA1c, increased microalbumin screens, and increased primary care visits. However, one limitation of this study included no improvement in metabolic control (Solorio et al, 2015). There is some similarity between the care delivery offered at on-site health centers and community health centers, which would support care coordination in both settings; however further inquiry is needed specifically towards on-site health centers and their impact to affect T2DM outcomes.

Synthesis Related to Care Coordination

The studies suggest that diabetes care management can decrease costs of hospital utilization (McLendon et al., 2019) and a multidisciplinary approach can be achieved in a primary care setting to positively impact T2DM outcomes (Berkowitz et al., 2018). Further, utilizing EHR data across health care sites can guide T2DM management and care coordination (Fitzgerald et al., 2017) and has led to improvements in T2DM process measures (Solorio et al., 2015). The support for care coordination in an on-site health center providing primary care and wellness services, when supported with EHR data relative to T2DM outcomes promotes further study and this scholarly project.

Overall, the literature reviewed focused on three distinct areas: T2DM care management outcomes, the on-site health center, and care coordination. The utilization of all three concepts when fully integrated could provide the foundation to change health care delivery.

Rationale for the Project

Findings of these studies allow for further evaluation of the impact that on-site health centers and care coordination have upon T2DM outcomes. The growing burden of patients diagnosed with T2DM and the impact on resources for care delivery, associated health care costs, morbidity and mortality support further evaluation. Care coordination strives to ensure regular visits, appropriate laboratory work, timely referrals, and reconciled medication management; and increased efficiency of care delivery without duplication of services. The inclusion of the on-site health center is a logical approach to evaluate for improved care, as individuals may spend more than a third of a 24-hour day, typically five days a week in the work setting. The care received at on-site health center is covered by employer provided health benefits thereby eliminating the barriers of cost and access to care.

The rationale for this doctoral project is supported by gaps in the literature review relative to T2DM outcomes associated with on-site health centers and chronic disease management through care coordination. This doctoral project is timely and allows for further scholarly inquiry which will add to the body of existing evidence-based practice. This project aligns with the IHI's main goal regarding the "Triple Aim", focused on improving the patient experience of care by focusing on quality and satisfaction; improving the health of populations; and reducing the per capita cost of health care (IHI, 2020). The goal of this project was to evaluate the effects of an on-site health center and care coordination on T2DM outcomes.

Chapter III: Methods

This chapter provides the methods used to implement, collect, and analyze the data for this project. Information on the project design, project sponsors, human subjects review, sample population, privacy and confidentiality of data, data collection procedures, data collection tool, and data analysis plan will be provided. The primary outcome measures the evaluation of clinical and physiologic measures compared to organizational benchmarks and the secondary measure was comparison to national standards.

Project Design

The design of this study is a non-experimental, retrospective chart review utilizing secondary data from health risk assessments (HRAs) and an electronic health record (EHR). The purpose of this project is to assess changes in T2DM outcomes from initial entry compared to one year after receiving care coordination at an on-site health center. The study aimed to evaluate the effects of care coordination on T2DM outcomes as measured by weight, BMI, BP, blood glucose, HbA1c, microalbumin, LDL, HDL, and indications for ACE or ARB and statin medication therapy. The total number of health center visits, foot exams, and referrals for wellness, podiatry, and eye/optical exams was obtained. Utilizing these variables as units for analysis and measurement, a data set was created to allow for comparisons. The initial data point is the initial HRA survey which initiates care coordination at the on-site health center. The second data point was the post-HRA survey repeated at the end of one year at the next annual review. The outcomes of this project serve to identify internally whether organizational benchmarks are met and as a comparison to national standards of T2DM management identified by the ADA.

Project Sponsors

This study was implemented at an on-site health center with support of senior management who permitted the use of existing tools and resources designated for the care coordination program. A university provided statistician supported the statistical plan and data analysis.

Human Subjects Review

This project was approved by senior management and legal counsel of the parent on-site health center and agreed that Georgetown University would serve as the Institutional Review Board (IRB) of record. The principal investigator (PI) completed all required human subjects research training prior to initiating this study. The investigator obtained Georgetown University IRB approval. The study posed minimal risk to participants. All participant data was secured and deidentified to protect patient confidentiality and privacy and maintain the security of the study data.

Population

A review of the parent company's on-site health centers was completed by the Honest Broker who identified 50 on-site health centers with care coordination implemented for at least two years and a panel of at least 100 T2DM patients with three or more visits over 12 to 15 months. Of the on-site health centers meeting the criteria one was randomly selected. Data was compiled retrospectively based upon a diagnosis of T2DM as defined by ICD-10 coding or HbA1c greater than or equal to 7. Power analysis using G*Power indicated that a minimum sample size of 90 would result in a power of .80, given the use of two-tailed paired sample *t*-tests, with small to medium effect size (d = .3) and significance level of .05. The analysis will use an alpha level of <0.05 as the criteria for detection of statistical significance.

Data was not excluded from this project based upon gender, race, ethnicity, national origin, minority or economic status. Data from initial HRA and post-HRA surveys was compiled retrospectively from the on-site health center EHR by the Honest Broker reflecting the initial visit through the next 15 months. Data included only services and testing performed and reported by the on-site health center. This data provided measurable variables for comparison.

Inclusion criteria:

- Adults ages 18 years to 75 years
- T2DM diagnosis identified by ICD 10 coding and/or HbA1c of 7 or greater within the previous 2 years (2018, 2019)
- A minimum of 3 visits for one year

Exclusion criteria:

- None

Privacy and Confidentiality of Data

For this study, all data was collected by an Honest Broker employed by the project site with access to all pertinent data as a part of their designated role. All data was de-identified and collected retrospectively. IRB approval was granted with waiver of consent. In order to adhere to the IRB requirements, the Honest Broker was not a part of the study team. Privacy risks to individuals was mitigated through the process of de-identification in which personal identifiers were removed from all health information. The Safe Harbor method of de-identification under the US Health Insurance Portability and Accountability Act of 1996 (HIPAA) Privacy Rule eliminated 18 patient identifiers in healthcare data (U.S. Department of Health and Human Services, 2015). A reference number was used to characterize the data. All data results were de-identified and reported in aggregates. No identifiable organization information was used during

dissemination of results. The PI used all data responsibly and only for the purposes of this study and dissemination of results.

Data Collection Procedures

The PI had no interaction with subjects and no subjects were recruited for this non-experimental, retrospective chart review utilizing secondary data. Data collection began after approval from the university IRB of record. The PI utilized an Honest Broker for data collection and a statistician for assistance with data analysis. All potential data compiled by the Honest Broker was entered using a PI-created data extraction tool (Appendix 1), deidentified and transferred into a Microsoft® excel spreadsheet for use with a statistical package for social sciences (SPSS) software program version 26. The data was reviewed, cleaned, and assessed for inclusion/exclusion as necessary. Data extraction occurred retrospectively to include completion of the initial pre-HRA survey with clinical screening and first on-site health center visit and at the post-HRA survey with clinical screening at the end of one year.

Data Collection Tool

A PI created data collection tool was utilized for this study. The collection tool served as a guide for the Honest Broker when collecting individual patient information from the EHR. This tool consists of four sections and 37 items including, demographical data such as age, gender, race and ethnicity. The HRA survey consists of 11 questions regarding current medical conditions requiring medication management and general screening questions.

The tool captures initial pre- and post-HRA data for weight, BMI, BP, blood glucose, HbA1c, microalbumin, LDL, HDL, and indications for ACE or ARB and statin medication therapy. The total number of health center visits, foot exams, and referrals for wellness, podiatry, and optical exams were obtained. Internal benchmarks evaluated were improvement of

HbA1c level in a year, percentage of patients who received an ACE or ARB during the year, and percentage of patients who received a foot exam during the year. External benchmarks for comparison were the ADA national standards of diabetes care for the same variables.

Data Analysis Plan

Descriptive statistics describes the sample population and demographic data. Comparisons of pre- and post-entry into on-site primary care services was analyzed using a paired *t*-test. Clinical indicators of weight, BMI, BP, blood glucose, HbA1c, microalbumin, LDL, HDL, and indications for ACE or ARB and statin medication therapy were compiled. The total number of office visits, foot exams, and referrals for wellness, podiatry, and optical exams were obtained.

Chapter IV: Results

Data collection and analyses were performed to determine the effects of an on-site health center and care coordination on T2DM outcomes. The purpose of this chapter is to present the statistical analysis of the findings in relation to the aims of this project. The analysis of the data will be utilized to provide recommendations for further research and possible implications to practice.

Analysis of the Data

The sample consisted of 92 participant charts meeting inclusion criteria for data extraction. Data analyses were performed using SPSS software program version 26. Descriptive statistics were utilized for demographic data and clinical variable data for the sample. Descriptive statistics reported were frequency distribution for categorical variables and mean and standard deviation for continuous variables. In order to compare pre- and post-entry clinical data, inferential statistics were used. Specifically, paired *t*-tests were performed to determine any statistically significant differences between clinical variables at the initial HRA visit and the next HRA visit after twelve months in the care coordination at the on-site health center.

The demographic data of participant characteristics are outlined in Table 1. The participant sample included 59 males (64.1%) and 33 females (35.9%). Participants self-identified as: Caucasian (33.7%), Black or African American (48.9%), and Other/Hispanic ethnicity (17.4%). The mean age was 55.9 years old (SD = 5.9) with an age range between 44 and 67 years. All participants were reported as having a T2DM diagnosis identified by ICD 10 coding and/or HbA1c of 7 or greater and had completed a minimum of three or more visits in years 2018 and 2019.

Table 1

Participant Characteristics

	n	*%*
Gender		
Male	59	64.1
Female	33	35.9
Race		
Caucasian	31	33.7
Black or African American	45	48.9
Other	16	17.4
Hispanic	16	17.4
	M (Median)	*SD*
Age	55.9 (56.0)	5.9

M = mean *SD* = standard deviation

The participants were assessed for the existence of comorbidities that included hypertension, hyperlipidemia, cardiovascular disease and kidney disease as presented in Table 2. Of the 92 participants only one was noted as not having an existing comorbidity at time of T2DM diagnosis and end of study. Of the participants assessed, 94.5% had a diagnosis of hypertension, 98.9% had a diagnosis of hyperlipidemia, 14.3% had a diagnosis of cardiovascular disease, and 8.8% had a diagnosis of kidney disease. Patients with T2DM in the presence of multiple comorbidities have an increased cardiovascular risk which makes chronic disease management and care coordination even more important.

Table 2

Comorbidities (n = 91)

	n	*%*
Hypertension	86	94.5
Hyperlipidemia	90	98.9
Cardiovascular Disease	13	14.3
Kidney Disease	8	8.8

Medication therapy was evaluated for the 92 participants as presented in Table 3. The use of ACE, ARB, statin and other medications for T2DM care management was compiled at the

initial HRA visit. Of the 92 participants 70.7% were prescribed an ACE; 46.7% were prescribed an ARB; 75% were prescribed a statin; and 44.6% were prescribed other medications used in T2DM management.

Table 3

Medication Therapy (n = 92)

	n	*%*
ACE	65	70.7
ARB	43	46.7
Statins	69	75.0
Other	41	44.6

All 92 participants were assessed for foot examinations completed, the number of actual health center visits, and referrals pertinent to T2DM care management reported (Table 4). Referrals evaluated were for wellness, podiatry, and optic/eye examinations. Of the 92 participants 65.2% had at least three visits to the health center during the study period and 34.8% had four visits during the study period. Wellness referrals for health coaching including DSME and DSMS, were completed for 59.8% of participants. Referrals for optic/eye were completed for 62% of the participants. Of the 92 participants 80.4% received foot exams at each health center visit with none of the participants having a referral completed for a podiatry consult.

Table 4

Care Received (n = 92)

	n	*%*
Foot Exam	74	80.4
Wellness Referral	55	59.8
Podiatry Referral	0	0.0
Optic/Eye Referral	57	62.0
Number HC Visits		
Three	60	65.2
Four	32	34.8

The participants' clinical variables were assessed at two points: initial HRA visit and the post or follow-up HRA visit after a minimum of twelve months with three visits annually as presented in Table 5. All clinical variables had data on each participant except for LDL (missing data for one participant) and microalbumin (missing data for 16 participants). The participants had an initial HRA visit mean weight of 227.2 lbs and a follow-up HRA visit mean weight of 224.8 lbs. The initial HRA visit mean BMI was 34.4 and a follow-up HRA visit mean BMI of 34.4. The normal range for BMI is less than 25 and a BMI over 30 indicates obesity. The participants of this study showed improvement but remain at a level of obesity which increases the risk of poor health outcomes in T2DM. Participant initial HRA visit mean systolic blood pressure (SBP) and diastolic blood pressure (DBP) were 133.7 mm Hg and 82.2 mm Hg, respectively and follow-up HRA visit mean SBP and DBP were 131.5 mm Hg and 80.5 mm Hg, respectively.

Participants exhibited weight loss and decreases in BMI, SBP and DBP from initial HRA visit to follow-up HRA visit, however, these differences were not statistically significant. Similar findings were noted relative to FBS, LDL, and HDL. The initial HRA visit mean FBS was 159.8 mg/dL and at follow-up HRA visit was 140.9 mg/dL. The initial HRA mean LDL was 88.7 and 85 at follow-up HRA visit. The initial HRA mean HDL was 46.9 and 46.8 at follow-up HRA visit. The HbA1c and microalbumin showed statistically significant improvements from initial HRA measurement to the follow-up evaluation, however lacked clinical significance as the normal microalbumin level in less than 20mg/L. The initial HRA visit mean HbA1c was 7.9% and at follow-up HRA visit was 7.5% ($p = .045$) and the initial HRA visit mean microalbumin was 18.2 and at follow-up HRA visit was 17.8 ($p = .006$).

Table 5

T2DM Clinical Variables - Initial to Post-Care Coordination

	Pre	*Post*			
	M (SD)	*M (SD)*	*t*	*df*	*p*
Weight (lbs)	227.2 (48.3)	224.8 (48.1)	1.84	91	.070
BMI	34.4 (7.1)	34.2 (6.7)	0.82	91	.415
SBP	133.7 (10.6)	131.5 (10.0)	1.46	91	.149
DBP	82.2 (6.0)	80.5 (6.1)	1.96	91	.053
HbA1c	7.9 (1.7)	7.5 (1.4)	2.04	91	.045
FBS	159.8 (88.7)	140.9 (47.6)	1.96	91	.053
LDL	88.7 (31.0)	85.0 (30.4)	1.16	90	.248
HDL	46.9 (12.1)	46.8 (11.7)	0.08	91	.933
Microalbumin	18.2 (28.8)	17.8 (28.1)	2.83	75	.006

M = mean *SD* = standard deviation *p* = significance level

Summary of Findings

This chapter presented the results of the data. The participant sample was presented with demographical data that included median age of 55.9 years, predominantly male (64.1%), and Black or African American (48.9%), with multiple comorbidities in addition to T2DM. The clinical data evaluated was relevant to T2DM care management which included weight, BMI, SBP, DBP, HbA1c, FBS, LDL, HDL, and microalbumin test results. Additional clinical variables evaluated were comorbidities, medication therapy, and T2DM care received related to number of health center visits, foot exams, and referrals for wellness, eye/ophthalmology, and podiatry.

There was evidence of modest improvements in clinical variables evaluated, HbA1c and microalbumin improvements were statistically significant. The primary existing comorbidities were hypertension 98.5% and hyperlipidemia 98.9%. Medication therapy reflected management with ACE inhibitors 70.7%, ARB 46.7%, and statins 75%. Participant care received reflected

wellness referrals of 59.8%, eye/ophthalmology referrals of 62%, and podiatry referrals of 0% with 80.4% receiving foot exams during health center visits.

The ADA national standards of care for patients with T2DM focuses on glycemic control, BP control and lipid management. The target goal of glycemic control is a HbA1c less than 7% with the recommendation for testing at least 2-3 times per year depending upon glycemic goal or when the treatment regimen changes (ADA, 2019). Participants of this study failed to meet this standard, however there was a statistically significant decrease in HbA1c of 7.5%. The ADA target goal of BP for patients with T2DM is less than 130/80 to 140/90 mmHg depending upon level of cardiovascular risk (ADA, 2019). Participants of this study had a post or follow-up HRA mean SBP/DBP of 131.5/80.5 mmHg which met the standard, however, this study did not include calculations for level of cardiovascular risk. The goal of management for patients with T2DM and elevated BP includes medication therapy with an ACE or an ARB (ADA, 2019). Of the participants in this study 70.7% were on an ACE and 46.7% were on an ARB, which met the standard of care. The ADA target goal of lipid management for patients with T2DM is an LDL less than 100mg/dL and HDL greater than 40mg/dL for men and 50mg/dL for women (ADA, 2019). Participants in this study had a post or follow-up HRA mean LDL of 85.0 and HDL of 46.8. This study did not delineate the mean HDL and LDL by gender although most participants were male at 64.1%.

Overall, the findings of this study provide a modest support for on-site health centers and care coordination having a positive effect on T2DM outcomes. Further study over time and across several locations could potentially support implementation of this type of care delivery.

Chapter V: Discussion and Conclusion

The final chapter discusses the findings of this scholarly project and a corresponding interpretation of the results. The purpose of this project was to assess changes in T2DM outcomes at an on-site health center with enrollment into the care coordination program. This chapter addresses whether organizational outcomes are meeting internal benchmarks for care coordination of T2DM and provides a comparison to national standards. Lastly, the possible implications for practice and policy changes are discussed.

Discussion of Findings

The sample population consisted of a majority of African American males with T2DM and multiple comorbidities which included obesity, hypertension, hyperlipidemia, and cardiovascular disease. Some of the baseline findings were already in the normal range and this made it difficult to find statistically significant differences. There were statistically significant improvements in both HbA1c and microalbumin laboratory results and there near significant results for DBP and FBS during the evaluation period of the project. Overall, there were modest improvements of clinical variables associated with weight loss, BMI, BP, FBS, and LDL.

More than 70% of participants were prescribed ACE and statin medication therapy. In addition, 46.7% were prescribed an ARB, which is indicates some patients may have been managed with both an ACE and an ARB. Care management received included more than 80% of participants receiving foot exams, although none received a podiatry referral. Approximately 60% of participants received wellness referrals for health coaching with DSME/DSMS and 62% received eye/ophthalmology referrals.

Type-2 Diabetes Mellitus Care Management

The ADA national diabetes standards of care guidelines goal for HbA1c testing is 2-3 times per year depending on glycemic control (ADA, 2019). This study population had 3 or more visits in a year and a HbA1c measurement at each visit. The visits facilitated regular monitoring of BP and glycemic control. Regular HbA1c testing met the ADA national standard of care and the organizational internal benchmark. The study findings were a mean BP of less than 140/90 mmHg in the presence of unknown cardiovascular risk. The baseline BP was within normal range, but there was a very modest improvement from initial HRA visit to follow-up HRA visit. Most participants were prescribed ACE or ARB medication therapy, thus meeting ADA target goals for BP control in T2DM with elevated BP and organizational internal benchmarks. The study met the ADA standard of care for lipid management of LDL less than 100mg/dL and HDL greater than 40md/dL, which were also within normal at baseline, however the LDL showed a very modest improvement and HDL remained relatively unchanged. The ability to see the very modest improvements over a longer period support further study of these variables associated with T2DM care management.

A similar study by Burton et al. (2015) used a pre- and post-survey combined with clinical screenings that were repeated at six and twelve months. The results of this study show no statistical significance in the presence of self-efficacy support that included a health coach, dietician, pharmacist, and counselor. The study by Misra-Hebert et al. (2016) which utilized retrospective cohort data obtained from an EHR to evaluate similar clinical variables in the presence of employee incentives. The study findings reflected a larger decline in HbA1c and weight with BP and LDL remaining relatively unchanged. Sepers et al. (2015) examined clinical outcomes of T2DM care and showed improvements in HbA1c, BMI, and FBS when DSME and

DSMS was also implemented on-site. The study by Zupa et al. (2019) assessed the effectiveness of diabetes education on T2DM clinical variables and found significant improvement in HbA1c over a period of a year and LDL for nine months, but no significant change in BMI. Overall, the studies had similar outcomes to this project and were reinforced with diabetes patient education and support. Although this project allowed for assessing for the wellness referral which included health coaching, DSME and DSMS resources, further evaluation was needed to determine if participants utilized the wellness referral and to what degree of engagement.

Care Coordination

This study provided an assessment of variables that incorporated access to an on-site health center and its care coordination program. The care coordination program involved regular health center visits, laboratory testing of pertinent T2DM clinical variables, and referral for wellness services that included DSME and DSMS. Additionally, referrals were provided for specialty care focused on preventing T2DM complications, specifically for wellness and optic/eye examinations, but no podiatry referrals were documented. The importance of regular office visits and laboratory testing allow for monitoring of BP, blood glucose and screening for kidney disease. This study showed statistically significant decreases in microalbumin in a population that was predominantly male and African American. There were very modest improvements in weight loss, BMI, BP, and LDL findings. Regular foot exams and referrals for wellness and eye/optic examinations met organizational internal benchmarks. All these findings together can support the positive impact of T2DM outcomes associated with properly coordinated care.

The Berkowitz, Eisenstat, Barnard & Wexler (2018) study showed positive results regarding patient perceptions of T2DM care from a single point of contact with care coordination

from a multidisciplinary team. The study assessed a similar model with T2DM care being implemented using the on-site health center provider as the point of contact with care coordination monitoring visits, laboratory work, and referrals provided. Similarly, Solorio et al. (2015) evaluated care coordination and T2DM outcomes of Hispanic patients and found improvements in HbA1c relating increased primary care visit and microalbumin screenings. Similar to these studies this project was predominantly African American males and assessed numbers of health center visits and measured pre and post clinical variables showing near significant findings and modest improvements from baseline.

A similar retrospective study by McClendon et al. (2019) evaluating a pilot diabetes care coordination program that included pre/post laboratory results demonstrated statistically significant reductions in HbA1c levels and a reduction in hospital utilization. There are potential cost savings related to preventing T2DM associated complications of hypertension, vision loss, kidney failure, and lower limb amputation particularly in the population identified in this study. The idea of the broader implications of this study could support further inquiry of a cost-benefit analysis to better assess the dollars potentially spent on treating and managing T2DM complications and support T2DM care management with care coordination.

On-Site Health Center

An additional study performed by Padwal et al. (2017), in which the focus was a worksite showed statistically significant improvements in SBP and triglyceride levels and supported the presence of a worksite provider to increase access and convenience of care. The Padwal et al. (2017) study implemented screenings at a worksite clinic and showed statistically significant improvements in SBP though no significant changes in BMI. Tarride et al. (2017) also examined the effectiveness of T2DM screening and found a statistically significant decrease in HbA1c at

six months for pre-diabetics and those with T2DM, but no significant change for those at baseline or at risk for developing T2DM. This project further supports the utilization of the on-site health center with more than two-thirds of study participants having at least three visits with annual screenings thought improvements were modest with near statistically significant improvements in T2DM outcomes.

Lastly, the O-Keefe & Anderson (2017) study of the implementation of an on-site heath center and the associated effects of increasing prevention, screening and early detection, as well as decreasing health expenditures and costs of care support the importance of this study. Although this study lacked a costs analysis the coordination of routine testing, follow-up, management, and referrals resulted in modest improvement. Overall, the clinical implications for utilization of an on-site health center and care coordination are supported by this and other studies exhibiting improvements in T2DM clinical variables in addition to providing access to care and decreasing health care costs.

Organizational Benchmarks

Organizational internal benchmarks included participant improvement in HbA1c to less than 7% at post or follow-up HRA. This benchmark was not met although the median HbA1c decreasing from 7.9% to 7.5% at end of the evaluation year. An additional benchmark was more than 50% of participants would receive and ACE or ARB prescription during the evaluation year. This benchmark was met with 70.7% receiving an ACE and 46.7% receiving an ARB or both for medication therapy. An additional benchmark was more than 50% of participants would receive a foot exam during the measurement year. This benchmark was met with 80.4% receiving a foot exam. Overall, there were modest improvements in most clinical variables evaluated.

Limitations

This scholarly project included several limitations. First, the study period was short and more time was needed to evaluate clinical significance of the data over an extended time. Participants were evaluated at a minimum of twelve months to a maximum of fifteen months from initial HRA. The changes seen in HbA1c, BP, LDL, and HDL may require an extended period to allow for more apparent effects and trending of the data. Second, a small sample size limited to one on-site health center. Third, a control group in similar location would have provided an opportunity for further comparisons of the impact of the intervention. Fourth, though there was data regarding wellness referrals completed there was no evidence to support what impact, if any, there was on the actual clinical outcomes. Lastly, the project failed to include a component geared toward participant perceptions relative to on-site health centers as primary care providers for chronic disease management.

Implications for Practice

The on-site health center has the potential to provide a place for addressing key components of the "triple aim". The ability to provide primary care and chronic disease management without the limitations of access to care and time is key. This project could serve as a guide for potentially improving preventative screenings and identifying gaps in care. The ability to capture chronic diseases before they manifest could potentially improve health care expenditures. The opportunity to increase patient engagement, encourage self-care, and facilitate active patient participation in achieving their health care goals could further improve T2DM outcomes.

Recommendations for Further Study

The continuation or extension of the study would assess outcomes of the identified population of African American males for an extended period focusing on BP control, HbA1c glycemic control, microalbuminuria, and potential effects of kidney disease. Further study would assess the effectiveness of the wellness referral relative to content, patient engagement, and patient perception of effectiveness, which could be compared to clinical outcome related to weight loss, decreased BMI, and BP control. Further study of podiatry and eye/optic referrals in relation to loss of the lower extremity by amputation and the development of eye complications associated with T2DM would provide further data to guide referral policy and processes.

A cost benefit analysis was needed to assess any associated cost savings generated by an on-site health centers which could further support their implementation and viability for employers considering this type of health care service. The further examination of the potential cost savings that could be gained by effective, efficient, and coordinated care could be evaluated by comparing on-site health center costs to similar offerings in the general marketplace. The ability to reduce losses related to decreases productivity and employee absenteeism could be compared to utilization of paid time off and vacation time spent on obtaining health care services.

Conclusion

The on-site health center has the potential to alleviate the variables of lack of access to care, lack of affordability, and lack of time to visit the health care provider. This scholarly project supports that an on-site health center and care coordination can have a significant effect on T2DM outcomes.

Appendix: Data Extraction Tool

PATIENT DEMOGRAPHICS	
Variable	**Description**
Pt. Age	Patient age according to medical record
Pt. Gender	Patient's identified gender in the medical record
Pt. Race	Patient's identified race
Pt. Ethnicity	Patient's identified ethnicity
PATIENT CLINICAL DATA	
HRA1 Pre	First Health Risk Assessment completed at entry to care
HRA2 Post	Second Health Risk Assessment completed after 12 months of care
Height	Height recorded in the medical record
Wt1 PreHRA	Weight recorded at initial Health Risk Assessment
Wt2 PostHRA	Weight recorded at second Health Risk Assessment (12 months)
BMI1 PreHRA	Body mass index recorded at initial Health Risk Assessment
BMI2 PostHRA	Body mass index recorded at second Health Risk Assessment (12 months)
BPsyst1 PreHRA	Blood pressure: systolic recorded at initial Health Risk Assessment
BPsyst2 PostHRA	Blood pressure: systolic recorded at second Health Risk Assessment (12 months)
BPdias1 PreHRA	Blood pressure: diastolic recorded at initial Health Risk Assessment
BPdias2 PostHRA	Blood pressure: diastolic recorded at second Health Risk Assessment (12 months)
HbA1c1 PreHRA	Hemoglobin A1c lab results from initial Health Risk Assessment
HbA1c2 PostHRA	Hemoglobin A1c lab results from second Health Risk Assessment (12 months)
TotHbA1c/yr	Total number of HbA1c lab results from initial Health Risk Assessment to the second Health Risk Assessment
FBS1 PreHRA	Fasting blood glucose results from initial Health Risk Assessment
FBS2 PostHRA	Fasting blood glucose results from second Health Risk Assessment (12 months)
LDL1 PreHRA	Low density lipoprotein results from initial Health Risk Assessment
LDL2 PostHRA	Low density lipoprotein results from second Health Risk Assessment (12 months)
HDL PreHRA	High density lipoprotein results from initial Health Risk Assessment
HDL PostHRA	High density lipoprotein results from second Health Risk Assessment (12 months)
Microalbu1 PreHRA	Microalbumin results from initial Health Risk Assessment
Microalbu2 PostHRA	Microalbumin results from second Health Risk Assessment
Meds1 PreHRA	Medications in ACE/ARB classes prescribed pre-HRA (initial)
Meds2 PostHRA	Medications in ACE/ARB classes prescribed post-HRA (12 months)
Meds3 PreHRA	Medications in Statin/Other classes prescribed pre-HRA (initial)
Meds4 PostHRA	Medications in Statin/Other classes prescribed post-HRA (12 months)
Comorbs PreHRA	Co-morbidities existing at initial Health Risk Assessment
Comorbs PostHRA	Co-morbidities existing at second Health Risk Assessment (12 months)
Foot Exam	Total number of foot exams completed from initial Health Risk Assessment to the second Heath Risk Assessment
WellRef	Wellness referral completed from initial Health Risk Assessment to second Health Risk Assessment
Podiatry Referral	Podiatry referral completed from initial Health Risk Assessment to second Health Risk Assessment
Optical Referral	Optical referral completed from initial Health Risk Assessment to second Health Risk Assessment
#TotHCvis	Total number of health center visits completed from initial Health Risk Assessment to second Health Risk Assessment (12 months)

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