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Measuring Return-on-Investment (ROI) of a Worksite Wellness Program Using an Accountable Care Organization Software Program: What is the ROI at 12 Months?

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BY

Andrew J. Hartung

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MEASURNG RETURN-ON-INVESTMENT (ROI) OF A WORKSITE WELLNESS PROGRAM USING AN ACCOUNTABLE CARE ORGANIZATION SOFTWARE PROGRAM: WHAT IS THE ROI AT 12 MONTHS?

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DEDICATION

This dissertation is dedicated to my wife, Sarah,

my son Joe, and my daughter Libby.

Without their encouragement, support, and patience

I would have not been successful in earning my doctorate.

I love you all very much.

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When I first began my dissertation, I understood that it was going to take a great amount of work and time on my part. I had no idea the amount of work and time so many other people would put forth in assisting me to reach my goal.

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Over the past several decades, significant research has been completed in an effort to understand the impact Type 2 diabetes has on the expense associated with disease treatment and maintenance, health care industry resources, and prevention of the disease. At the same time many corporations have taken on the challenge of providing workplace wellness programs to reduce health care expense associated with chronic illness or unhealthy behaviors and improve the overall health of employees. Coupling these efforts with the accountable care organization model established via the Patient Protection and Affordable Care Act, this research determined that obtaining a positive return on investment for a diabetes workplace wellness accountable care organization is very difficult but the ability to improve participants management of diabetes is a worthy venture that should be continued to be evaluated to determine how program variables need to be modified to provide a positive return on investment.

INTRODUCTION

Fourteen years ago the Institute of Medicine published *Crossing the Quality Chasm* (Institute of Medicine, 2001) that called for extensive modifications to the health delivery system. One of the key modifications identified in the document was "creating and aligning incentives for quality and increasing the transparency of quality information for quality improvement, accountability and consumer choice (Damberg, Raube, Williams and Shortell, 2005). One of the resulting innovations in the organization and payment for medical care has been the development of Accountable Care Organizations. Most recently the final ruling for Accountable Care Organizations (ACO) has specified a model in which provider compensation, initially for Medicare, will utilize a pay-for-performance model. The ACO model "is meant to improve the value of health care services, controlling costs while improving quality as defined by outcomes, safety, and patient experience" (McLellan, *et al.*, 2012) The challenge with both the pay-for-performance and ACO model is the ability to demonstrate the reduction in cost of care by transitioning from episodic care models to preventive care treatment. However, recent innovations in computer software that aggregate medical care use and cost at the patient level hold promise for enabling us to identify cost reductions rapidly and with ease.

While payers have been working on models to reorganize the delivery of medical care to focus on and reward prevention, employers have been developing sophisticated worksite wellness programs to change the individual worker's behavior toward disease prevention, in an effort to minimize the expenses associated with lifestyle decisions that

directly impact the cost of health insurance and health care. Many employers have expended significant effort to improve health and reduce expense via workplace wellness programs. When implemented, the majority of workplace wellness programs demonstrate a cost savings and a focus on lifestyle changes to improve overall health and productivity of employees. Participation in the programs can be voluntary or established by providing incentives to employees. The services provided in a workplace wellness program are very similar to components of effective ACO programs; utilizing disease identification, coordinated care, and results tracking for the improvement of individual health while reducing the cost of providing health care.

Thus, worksite wellness programs have contributed to better employee health for a decade and have shown some financial benefits. However, they have been lacking in ability to identify the total financial benefits that they produce because they lack the ability to capture all medical expenditures. ACO's are innovative structures that encourage evidence-based medical practice with a focus on prevention. However, most ACOs lack the ability to provide powerful incentives for patients to change behavior and have only limited resources for providing individual patient support for change. They do, however, have sophisticated software tools to aggregate patient utilization and cost data to measure the financial benefits of an increased focus on prevention. The combination of a workplace wellness program with incentives and patients support structures, and the use of an ACO software program to capture expenditures, may enable us to measure the return-on-investment (ROI) for behavior change over a short (1 year) time horizon. This study will demonstrate how a workplace wellness program can be combined with ACO

software to asses ROI in the short term. We will focus this examination on a common, high cost condition that, when managed well, holds promise for even short-term cost saving. The best choice for demonstration purposes is diabetes.

Diabetes, specifically Type 2 diabetes, is a disease that impacts a large percentage of the United States population. Either as a confirmed diagnosed disease, as an undiagnosed disease, or as an increased potential to develop the disease (Statistics About Diabetes, 2014). Significant clinical information is available to evaluate individuals with diabetes or those that are considered pre-diabetic. This information also provides guidance for appropriate disease management to maintain a healthy lifestyle mitigating disease progression (Diabetes Care, 2014). Although the prevalence of diabetes is well documented and the various degrees of the disease can be clinically diagnosed, the number of individuals diagnosed with diabetes has increased significantly over several decades (National Health and Nutrition Examination Survey). As such, the health care costs associated with providing care for individuals with diabetes continues to burden the United State health care system (American Diabetes Association, 2013). However, targeted interventions to change patient behavior have shown some short term financial benefits for patients with diabetes, which makes it an excellent disease for demonstrating short term financial impacts.

Research Question(s)

The main research question for this study is: Can using an ACO commercially available software tool and a diabetes workplace wellness management program be combined to identify 1 year ROI in a sample of patients within an average size institution?

If a ROI cannot be measured at 1 year, a follow-up question will be posed as follows: If a trend is identified, then 1) how large an increase in sample size; or 2) how large an increase in exposure time is recommended to have at least 80 percent power to identify a statistically significant improvement?

Research Hypothesis

The hypothesis for this study is, “Utilizing the tools provided with both commercially available ACO software and workplace wellness program structure, the cost associated with managing the health care of individuals diagnosed with diabetes will be reduced.”

REVIEW OF THE LITERATURE

Diabetes the Disease

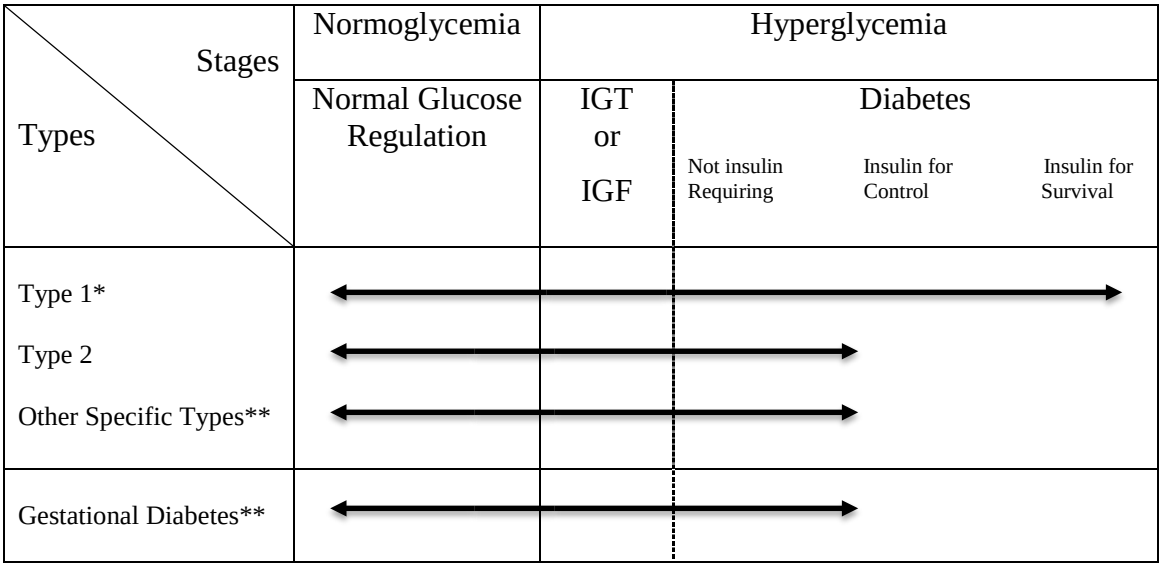
Diabetes is defined as, “a group of metabolic diseases characterized by hyperglycemia resulting from defects in insulin secretion, insulin action, or both.” (Diabetes Care, 2014) To better understand the disease, the following provides information on the background of diabetes, diagnosing diabetes, health conditions that increase the likelihood of diabetes, and historic trend of diabetes in the United States.

Background of Diabetes

The development of diabetes is based on two possible pathogenic processes, the dysfunction of the pancreas resulting in inadequate production of insulin or the abnormal insulin action by target tissues impacting one or more points in complex hormone action pathways. While both paths frequently coexist in the same patient, it is difficult to determine if the lack of insulin secretion or the inadequate insulin action is the direct cause of the disease. These two predominant pathogenic processes are categorized as Type 1 and Type 2 diabetes. Type 1 diabetes is specific to the dysfunction of the pancreas preventing appropriate secretion of insulin. Type 2 diabetes is related to the abnormal insulin action by target tissues. There are other specific types of diabetes but the majority of diabetes is classified as either Type 1 or 2.

Symptoms of diabetes are polyuria, polydipsia, weight loss, polyphagia, and blurred vision. Diabetes can cause impaired growth, increased types of infections, and the potentially fatal conditions of ketoacidosis or nonketotic hyperosmolar syndrome. While both Type 1 and Type 2 diabetes present with similar symptoms, it is important to understand that Type 1 diabetes can be diagnosed via serological evidence that detects the inflammatory autoimmune condition of the pancreas or by utilizing genetic marker analysis but the abnormal insulin reaction of tissues associated with Type 2 diabetes may exist for a long period of time before presenting with clinical symptoms. Type 2 diabetes can be diagnosed by measuring plasma glucose after a fasting period or by A1C (Diabetes Care, 2014). The pathologic response of both Type 1 and Type 2 diabetes is hyperglycemia, high blood sugar, which can exist in two different categories. The first category, prediabetes, consists of impaired glucose tolerance (IGT) or impaired fasting glucose (IFG). Prediabetes is the result of having elevated blood glucose levels but not to the level of being diagnosed with diabetes (Mayo Clinic, 2014). Prediabetes can lead to diabetes but can also be corrected if detected early and proper lifestyle changes of managing weight and participating in regular exercise are implemented. The second category of hyperglycemia is diabetes. Obtaining the appropriate management of blood glucose levels in conjunction with diabetes ranged from non-insulin therapy to insulin dependency to sustain life (Figure 1).

Figure 1: Disorders of Glycemia: Etiologic Types and Stages



*Patients presenting with ketoacidosis may return to Normoglycemia. **In rare cases patient may require insulin for survival (Diabetes Care, 2014).

As stated previously, there are multiple types of diabetes with Type 1 and 2 being predominant. Type 1 diabetes accounts for 5-10% of individuals with diabetes and is historically known as insulin dependent diabetes or juvenile-onset diabetes. The specific cause of Type 1 diabetes is the result of cellular-mediated destruction of the β-cells of the pancreas reducing the secretion of insulin by the pancreas (Diabetes Care, 2014). Type 2 diabetes accounts for 90-95% of individuals with diabetes and is previously described as the non-insulin dependent diabetes. Type 2 diabetes is directly related to an individual developing insulin resistance or insulin deficiency (Diabetes Care, 2014). The other types of diabetes (Table 1) consist of genetic abnormalities, diseases of the exocrine pancreas, endocrinopathies, drug or chemical induced, infections, and gestational diabetes (Diabetes Care, 2014).

Table 1: Etiologic Classification of Diabetes (Diabetes Care, 2014)

I. Type 1 diabetes (β-cell destruction)
- A. Immune mediated
- B. Idiopathic

II. Type 2 diabetes (insulin resistance)

III. Other specific types
- a. Genetic defects of β-cell function
  - i. MODY 3 (Chromosome 12, HNF-1α)
  - ii. MODY 1 (Chromosome 20, HNF-4α)
  - iii. MODY 2 (Chromosome 7, glucokinase)
  - iv. Other very rare forms of MODY (e.g., MODY 4: Chromosome 13, insulin promoter factor-1; MODY 6: Chromosome 2 *NeuroD1*; MODY 7: Chromosome 9, carboxyl ester lipase)
  - v. Transient neonatal diabetes (most commonly ZAC/HYAMI imprinting defect on 6q24)
  - vi. Permanent neonatal diabetes (most commonly KCNJ11 gene encoding Kir6.2 subunit of β-cell K_{ATP} channel)
  - vii. Mitochondrial DNA
  - viii. Others
- b. Genetic defects in insulin action
  - i. Type A insulin resistance
  - ii. Leprechaunism
  - iii. Rabson-Mendenhall syndrome
  - iv. Lipoatrophic diabetes
  - v. Others
- c. Diseases of the exocrine pancreas
  - i. Pancreatitis
  - ii. Trauma/pancreatectomy
  - iii. Neoplasia
  - iv. Cystic fibrosis
  - v. Hemochromatosis
  - vi. Fibrocalculous pancreatopathy
  - vii. Others
- d. Endocrinopathies
  - i. Acromegaly
  - ii. Cushing's syndrome
  - iii. Glucagonoma
  - iv. Pheochromocytoma
  - v. Hyperthyroidism
  - vi. Somatostatinoma
  - vii. Aldosteronoma
  - viii. Others
- e. Drug or chemical induced
  - i. Vacor
  - ii. Pentamidine
  - iii. Nicotinic acid
  - iv. Glucocorticoids
  - v. Thyroid hormone
  - vi. Diazoxide
  - vii. B-Adrenergic agonists
  - viii. Thiazides
  - ix. Dilantin
  - x. γ-Interferon
  - xi. Others
- f. Infections
  - i. Congenital rubella
  - ii. Cytomegalovirus
  - iii. Others
- g. Uncommon forms of immune-mediated diabetes
  - i. Stiff-man syndrome
  - ii. Anti-insulin receptor antibodies

	iii. Others h. Other genetic syndromes sometimes associated with diabetes i. Down syndrome ii. Klinefelter syndrome iii. Turner syndrome iv. Wolfram syndrome v. Friedreich ataxia vi. Hunington chorea vii. Laurence-Moon-Biedl syndrome viii. Myotonic dystrophy ix. Porphyria x. Prader-Willi syndrome xi. Others
IV.	Gestational diabetes

Diagnosing Diabetes

Diabetes has a long term impact on the eyes, kidneys, nerves, heart, and blood vessels with the specific long term complications including: retinopathy that could lead to the loss of vision; renal failure as a result of nephropathy; peripheral neuropathy with the additional complications of foot ulcers, amputations, and Charcot joints; and autonomic neuropathy resulting in gastrointestinal, genitourinary, cardiovascular symptoms, and sexual dysfunction (Diabetes Care, 2014). Individuals diagnosed with diabetes could also experience increased rates of atherosclerotic cardiovascular disease, cerebrovascular disease, and peripheral arterial disease with specific comorbidities of hypertension and abnormal lipoprotein metabolism (Diabetes Care, 2014).

Prior to 1997, a diagnosis of diabetes was based on either, fasting plasma glucose (FPG) greater than 140 mg/dL (7.8 mmol/L) or an oral glucose tolerance test (OGTT) that demonstrates an increase in blood glucose greater than 200 mg/dL. The Expert Committee on Diagnosis and Classification of Diabetes Mellitus issued two reports, one

in 1997 and a follow up report in 2003 that identified a gap in the diagnosis values that excluded individuals having glucose levels that are considered above normal ranges but not high enough to meet the diagnosis criteria for diabetes (Expert Committee on the Diagnosis and Classification of Diabetes Mellitus, 1997 and Genuth, Alberti, Bennett, et al., 2003). Based on the work of the expert committee, the individuals with glucose levels above the normal range but below established diabetes diagnosis ranges were classified as having impaired fasting glucose (IFG), which is defined by FPG levels of 100 mg/dL (5.6 mmol/L) to 139 mg/dL (6.9 mmol/L), or impaired glucose tolerance (IGT) with 2-h values in the OGTT ranging from 140 mg/dL (7.8 mmol/L) to 199 mg/dL (11.0 mmol/L).

In 2009, the Expert Committee on the Diagnosis and Classification of Diabetes Mellitus recommended the use of A1C to diagnose diabetes (International Expert Committee, 2009). A1C is a minor component of hemoglobin to which glucose is bound. A1C levels depend on the blood glucose concentration: The higher the glucose concentration in blood, the higher the level of A1C. (MedicineNet, 2014) To further support the use of A1C to diagnose diabetes, observational studies have provided evidence of a strong correlation between retinopathy and A1C (van Leiden H.A., Dekker J.M., Moll A.C., 2003 and Tapp R.J., Tikellis G., Wong T.Y., Harper C., Zimmet P.Z., Shaw J.E., 2008). In addition to observational studies, the correlation between A1C levels and associated complications related to diabetes has been demonstrated in controlled clinical trials for both type 1 (DCCT Research Group, 1995) and type 2 (Stratton, et al., 2000) diabetes. As part of the Expert Committee's work, an A1C level great than 6.5 was identified as the appropriate diagnosis level when comparing the correlation between

patients with retinopathy and an elevated A1C. At the time of the initial A1C recommendation, the Expert Committee noted that the individuals above the normal range but below the diagnostic indicator for diabetes (6.0 - 6.5) were at significant risk of developing diabetes but the range failed to identify a substantial number of patients with IFG and/or IGT (Diabetes Care, 2014). Subsequent research did determine that a FPG of 110 mg/dL (6.1 mmol/L) corresponds to an A1C of 5.6 and a FPG of 100 mg/dL corresponds to an A1C of 5.4 (Diabetes Care, 2014) providing evidence of the A1C ranges that supports the diagnosis of IFG utilizing A1C.

Individuals that are identified to have IFG or IGT are considered to have pre-diabetes. The relevance of this diagnosis is anyone with IFG or IGT have a relatively high risk of developing diabetes in the future but implementing lifestyle changes such as increasing physical activity, reducing body weight by 5 – 10%, and utilizing certain pharmacological agents has demonstrated the delay or prevention of developing diabetes in people with IGT (Diabetes Care, 2014). Research by the Diabetes Prevention Program provides evidence that preventive interventions are effective for individuals with a mean A1C of above and below 5.9 (Knowler, W.C., Barrett-Connor, E., Fowler, S.E., et al., 2002). In addition, a systematic review of 44,203 individuals showed those with an A1C of 5.5 - 6.0 had a 9% to 25% risk of developing diabetes over a 5-year period and those with an A1C of 6.0 - 6.5 had a 20% to 25% over a 5-year period (Zhang, X., Gregg, E. W., Williamson, D. F., et al., 2010).

Prevalence of Diabetes

In 2012, 29.1 million Americans had diabetes (Centers for Disease Control and Prevention, 2014). This is an increase of 3.3 million since the 2010 reporting period. Of the approximately 29 million Americans diagnosed with diabetes, 21 million were clinically diagnosed and the remaining individuals were identified as undiagnosed. In addition to the 29.1 million Americans that had diabetes, there were an additional 86 million Americans over the age of twenty that had prediabetes in 2012 compared to 79 million in 2010 (Statistics About Diabetes, 2014). The youth statistic, those individuals under twenty years old, identified roughly 280,000 Americans compared to 23,525 youth in 2008-2009 (Statistics About Diabetes, 2014). Of the over 23,000 individuals under twenty years old with diabetes in the 2008-2009 report, 5,089 were diagnosed with type 2 diabetes.

Further dissection of the 29.1 million adult Americans living with diabetes in 2012, specifically percentage by age, shows that individuals sixty-five years or older account for 25.9% of the 29.1 million while individuals forty-five to sixty-six years old and twenty to forty-four years old are 16.2% and 4.1%, respectively. Evaluation by sex indicates that more men (13.6%) than women (11.2%) are living with diabetes (Centers for Disease Control and Prevention, 2014). Examination based on race and ethnicity yields the following composition among individuals diagnosed with diabetes: 7.6% of non-Hispanic whites, 9.0% of Asian Americans 9.0%, 12.8% of Hispanics, 13.2% of non-Hispanic blacks, and 15.9% of American Indians/Alaskan Natives (Statistics About

Diabetes, 2014). Asian American adult diabetes rates are further segmented into 4.4% for Chinese, 11.3% for Filipinos, 13.0% for Asian Indians, and 8.8% for other Asian Americans. Similarly, Hispanic adults are broken down by 8.5% for Central and South Americans, 9.3% for Cubans, 13.9% for Mexican Americans, and 14.8% for Puerto Ricans (Statistics About Diabetes, 2014).

Comorbidities Associated with Diabetes

Based on data from 2010, diabetes is the seventh leading cause of death in the United States as it was listed as the underlying cause of death on 69,071 death certificates (Heron, 2013). It is thought that diabetes as a cause of death could be unreported as studies have shown that only 35% to 40% of people with diabetes had diabetes listed on their death certificate and only 10% to 15% had diabetes listed as the underlying cause of death (Statistics About Diabetes, 2014).

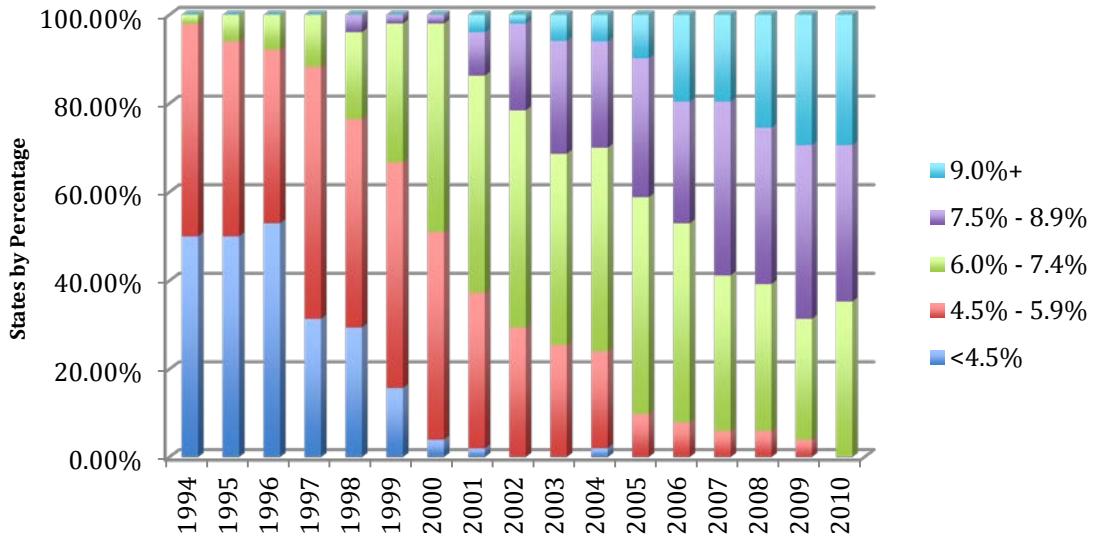
As mentioned previously, diabetes can increase the risk of serious complications such as heart disease and stroke, blindness, kidney failure, and lower-limb amputation. Individuals with diabetes can also experience microvascular disease such as retinopathy that could lead to the loss of vision; renal failure as a result of nephropathy; peripheral neuropathy and autonomic neuropathy (Diabetes Care, 2014). Early diagnosis of diabetes with proper glucose management and preventative health exams can reduce the risk or further development of these complications. Failure to properly manage diabetes resulted in 282,000 emergency room visits in 2011 that had hypoglycemia as the first diagnosis

and diabetes listed as an additional diagnosis. In addition, 175,000 emergency room visits in 2011 were associated with a hyperglycemic crisis such as, diabetic ketoacidosis and hyperglycemic hyperosmolar state, as the first diagnosis. Data from 2009 to 2012 indicated that 71% of individuals diagnosed with diabetes had a blood pressure equal to or above 140/90 millimeters of mercury or managed their blood pressure with prescription medications. Data from the same timeframe also showed that 65% of adults diagnosed with diabetes had increased LDL cholesterol levels or were using cholesterol-lowering medications (Centers for Disease Control and Prevention, 2014). Adults with diabetes were 1.7 times more likely to die from cardiovascular disease from 2003 to 2006. During 2010, diabetics were 1.8 and 1.5 times more likely to be hospitalized for a heart attack and stroke, respectively. From 2005 to 2008, 4.2 million diabetics, forty years or older, were diagnosed with retinopathy or damage to small blood vessels in the retina that could result in vision loss. During this same time period, 665,000 adults with diabetes from the same age demographic suffered from advanced diabetic retinopathy that could lead to severe vision loss (Centers for Disease Control and Prevention, 2014). In 2011, 44% of new nephropathy or renal failure diagnoses listed diabetes as the primary cause. Data from 2011 also showed that 49,677 diabetics of all ages began treatment for renal failure and 228,924 individuals with renal failure, as a result of diabetes, were living on chronic dialysis or with a kidney transplant. Diabetics twenty years or older were about 60% of the non-traumatic lower-limb amputations in 2010. This percentage was equal to roughly 73,000 non-traumatic amputations (Centers for Disease Control and Prevention, 2014).

Historic Trend of Diabetes in the United States

Over the last several decades, there has been a significant increase in diabetes diagnosis. The Centers for Disease Control reports a 2.8% increase in diagnosed diabetes among U.S. Adults (Figure 2). Further research based on NHANES (National Health and Nutrition Examination Survey) data demonstrates a 3.8% increase in the prevalence of diabetes from 1988 to 2010. Specifically, the prevalence of diabetes was reported as follows; 5.5% with 4.6% diagnosed and 0.9% undiagnosed from 1988 - 1994, 7.7% with 6.4% diagnosed and 1.3% undiagnosed from 1999 - 2004, and 9.3% with 8.3% diagnosed and 1.0% undiagnosed. The rate of prediabetes based on A1C levels of NHANES was 5.8% in 1988 – 1994, 11.9% in 1999 – 2004, and 12.4% in 2005 – 2010 (Selvin, Parrinello, Sacks, and Coresh, 2014).

Figure 2: Age-Adjusted Prevalance of Diagnosed Diabetes Among U.S. Adults



Although a 3.8% increase in diabetes was reported over the period of 1988 – 2004, the rate of undiagnosed diabetes remained relatively consistent. This demonstrates that while diabetes as a disease is becoming more prevalent in the United States, the diagnosis of diabetics is staying relatively consistent. When evaluating the prevalence of diagnosed diabetes among minorities compared with the previously reported data with whites, non-Hispanic blacks was 15.4%, Mexican Americans was 11.6%, and whites was 8.6%. As expected the ethnic minority groups also had a higher prevalence of undiagnosed diabetes. While diabetes is not directly related to obesity, it is important to note that the mean BMI of the United States undiagnosed diabetes population increased from 21.2% in 1988 – 1994 to 32.4% in 2005 – 2010 (Selvin, Parrinello, Sacks, and Coresh, 2014).

Health Care Costs Associated with Diabetes

As stated previously, diabetes is a very complex disease that can be caused by many factors and a wide range of comorbidities. The following section will provide an overview of proper disease management, the financial impact on personal health care expense and quality of life, and financial impact to the health care industry.

Proper Disease Management

Disease management has evolved over many decades. In 1997, Ellrodt, et al. defined disease management as, "programs that used a systematic approach to care and included more than one intervention component." Expansion of the idea of disease management has further developed the definition as the following, "Disease management is a system of coordinated health care interventions and communications for populations with conditions in which patient self-care efforts are significant. Disease management supports the physician or practitioner/patient relationship and plan of care, emphasizes prevention of exacerbations and complications utilizing evidence-based practice guidelines and patient empowerment strategies, and evaluates clinical, humanistic, and economic outcomes on an ongoing basis with the goal of improving overall health." (Congressional Budget Office, 2004)

As stated in the definition of disease management, patient self-care effort is a significant component of disease management. Specifically, proper disease management requires a patient to engage in activities and life style changes that prevent further exacerbation and complications of diabetes. Recommended diabetic patient self-care behaviors include proper nutrition therapy, exercise, glycemic control, and management of dyslipidemia.

Proper nutrition therapy is focused on maintaining blood-glucose levels within normal range, proper lipid and lipoprotein profile management, normal blood pressure levels, and proper nutrition intake to prevent and treat obesity, dyslipidemia, cardiovascular disease, hypertension, and nephropathy (Brantle, et al., 2006). The specific goals and recommending body for each of the nutritional therapies are listed in Table 2. A key component of maintaining normal glucose levels is the monitoring of total carbohydrate intake in reference to postprandial glucose levels. The ability for a diabetic to process glucose is related to the amount of insulin available in the body. The variation of low and high glycemic index foods as well as the amount and type of carbohydrates consumed during a meal, determines the amount of insulin needed to return to a normal postprandial glucose level.

Exact exercise guidelines for a diabetic, specifically aerobic and resistance exercise, tend to follow the general guidelines of 150 minutes of moderate-intensity or 90 minutes of vigorous exercise per week to achieve glycemic control as well as reduce the risk of coronary heart disease (Zimmerman, 2013). Due to the complications associated with diabetes, as it relates to loss of sensation in the feet, the types of exercise should be

evaluated appropriately. The risk of coronary heart disease associated with diabetes is also an area of concern. Individuals should be screened and cleared by their health care provider prior to beginning any exercise programs.

Table 2: Goals for Risk Factor Management in Patients with Diabetes (Zimmerman, 2013)

Risk Factor	Goal of Therapy	Recommending Body
Cigarette smoking	Complete cessation	ADA
Blood pressure	<130/85 mm Hg <130/80 mm Hg	JNC VI (NHLBI) ADA
LDL cholesterol level	<100 mg/dL	ATP III (NHLBI), ADA
Triglyceride level 200-499 mg/dL	Non-HDL cholesterol level <130 mg/dL	ATP III (NHLBI)
HDL cholesterol level <40 mg/dL	Raise HDL (no set goal)	ATP III (NHLBI)
Prothrombotic state	Low-dose aspirin therapy (patients with CHD and other risk factors)	ADA
Glucose	HbA1c <7%	ADA
Overweight and obesity (BMI ≥ 25 kg/m^2)	Decrease BMI	OEI (NHLBI)
Physical inactivity	Exercise prescription depending on patient's status	ADA
Adverse nutrition		ADA, AHA, and NHLBI's ATP III, OEI, and JNC VI

ADA, American Diabetes Association; AHA, American Heart Association; ATP III, National Cholesterol Education Program Adult Treatment Panel III; BMI, body mass index; CHD, coronary heart disease; HDL, high-density lipoprotein; JNC VI, Sixth Report of the Joint National Committee on Prevention, Evaluation, and Treatment of High Blood Pressure; LDL, low-density lipoprotein; NHLBI, National Heart, Lung, and Blood Institute; OEI, Obesity Education Initiative Expert Panel on Identification, Evaluation, and Treatment of Overweight and Obesity in Adults. (Zimmerman, 2013)

Glycemic control, when administered properly, has the ability to reduce a diabetic's A1C level. Successful glycemic management is based on an intensive management of insulin, blood glucose monitoring, and regular evaluations by a health

care provider. The Diabetes Control and Complication Trial (DCCT Research Group, 1993) is a well-known study that demonstrated a difference between intensive and conventional glycemic treatment. The intensive glycemic treatment consisted of randomly selected study participants receiving insulin via an insulin pump or insulin injection three or more times per day as determined by self-monitoring of blood glucose three or four times per day. A health care provider saw the participants at least once a month. The conventional glycemic treatment consisted of randomly selected study participants receiving only two injections of insulin per day based on the monitoring of blood glucose no more than twice a day and were seen by a health provider every two or three months. The study resulted in an average A1C of 7.2% for the intensive treatment group and 9.1% for the conventional treatment group over a 6.5-year period (DCCT Research Group, 1993).

Management of dyslipidemia also contributes to proper disease management of diabetes. Specific guidelines were developed as a result of lipid-lowering trials that included diabetic patients and were confirmed in additional trials (Zimmerman, 2013). The guidelines are as follows: (1) Diabetic's should have an LDL cholesterol level of <100 mg/dL, (2) If LDL cholesterol level is <100 mg/dL and triglycerides levels are elevated then HDL cholesterol should be <130 mg/dL, (3) Diabetic patients that have suffered a myocardial infarction should have an LDL cholesterol level of <70 mg/dL, and (4) Patients with an LDL cholesterol level, without medication of <100 mg/dL, should have a treatment plan of 30% reduction in LDL cholesterol level.

In addition to the self-patient care requirements, individuals with diabetes need to establish and maintain a relationship with health care professionals that can provide screenings and evaluations specific to the progression of diabetes. Diabetic's should be evaluated for: diabetic retinopathy to monitor eye health and establish a plan of treatment to avoid vision loss, diabetic nephropathy to maintain kidney health, peripheral neuropathy in the feet as a predecessor to the potential development of foot ulcers, and ischemic coronary disease as many patients with diabetes do not experience the associated chest pain with exertion (Zimmerman, 2013).

The Financial Impact on Personal Health Care Expense and Quality of Life

In 2007, the estimated economic burden from elevated glucose levels (diagnosed and undiagnosed diabetes, prediabetes, and gestational diabetes (GDM)) was reported to be $218 billion. This amount consisted of $153 billion in increased medical costs and $65 billion representing reduced productivity (Dall, Zhang, Chen, Quick, Yang, and Fogli, 2010). More recent research from the American Diabetes Association estimated the total estimated cost of diagnosed diabetes in 2012 as $245 billion, which included $176 billion in direct medical costs and $69 billion in reduced productivity (American Diabetes Association, 2013). The 2013 study by the American Diabetes Association further segregated the estimated $176 billion in direct medical costs by listing the contributing percentages as follows: hospital inpatient care (43%), prescription medications to treat the complications of diabetes (18%), anti-diabetic agents and diabetes supplies (12%), physician office visits (9%), and nursing/residential facility stays (8%). Additional

research reports an increase of 48% from the burden identified in 2007. Dall et al, (2014) estimates the economic burden of elevated glucose levels for 2012 to be in excess of $322 billion consisting of $244 billion in excess medical costs and $78 billion in reduced productivity.

To evaluate the financial impact for individuals with diabetes, it is important to assess the number of people with diabetes for 2012. The CDC reports during the 2012 time period that approximately 29.1 million people with diagnosed diabetes, 8.1 million with undiagnosed diabetes and 86 million prediabetic adults in the United States (Centers for Disease Control and Prevention, 2014). The American Diabetes Association identifies a 6% increase in diagnosed diabetics compared to the CDC with an estimated 22.3 million individuals in 2012 (American Diabetes Association, 2013). The difference between the CDC and the American Diabetes Association is based on the prevalence calculations utilized and the adjustment for the prevalence of diabetes among residence in nursing homes.

Utilizing the population statistics provided the CDC and the American Diabetes Association, the national cost of diabetes by specific category is reported as $244 billion for diagnosed diabetes, $33 billion for undiagnosed diabetes, $44 billion for prediabetes, and $1.3 billion for GDM. This information, as well as a detailed individual cost by age is presented in Table 3. From the period of 2007 and 2012 the financial burden of diabetes grew by 40% for diagnosed diabetes, 82% for undiagnosed diabetes, 74% for prediabetes, and 103% for GDM (Dall, et al., 2014).

Table 3: U.S. Economic Costs Associated with Diabetes and Prediabetes, by Age Group, 2012 (Dall, et al., 2014)

Cost	Diagnosed	Undiagnosed	Prediabetes	GDM	Total
Total national cost (millions of dollars)	244,465	32,762	43,910	1,290	322,427
Medical costs	175,819	23,433	43,910	1,290	244,452
Nonmedical costs	68,646				77,975
Average cost per case (dollars)					
Total	10,970	4,030	510	5,800	
By age group	7,890	2,880	510	5,800	
<35 years (<26 years for GDM)	4,120	3,570	300	6,340	
35-44 years (26-35 years for GDM)	4,540	1,380	250	6,370	
45-54 years (≥36 years for GDM)	5,170	2,060	420	4,330	
55-59 years	5,540	1,850	470		
60-64 years	6,250	1,560	520		
≥ 65 years	11,820	4,190	870		
Nonmedical cost by age group (dollars)	3,080	1,150			
18-34 years	3,620	980			
35-44 years	5,520	700			
45-54 years	5,600	2,800			
55-59 years	4,300	1,980			
60-64 years	3,130	1,150			
≥65 years	900	380			

Assessing the quality of life impact attributed to diabetes is based on several factors. As mentioned earlier, loss of productivity is a key impact area attributed to diabetes. Productivity can be measured based on absenteeism or presenteeism from work, inability to work, productivity reductions for those outside of the workforce, and early mortality. Absenteeism is defined as the number of workdays missed due to poor health. It has been reported that workers with diabetes average three more missed days at work than individuals without. Presenteeism is defined as reduced work productivity while at work and is reported at a greater rate than those without diabetes, ranging from 1.8% to 38% (American Diabetes Association, 2013). Inability to work is related to the impact of

long-term disability as a direct result of diabetes. The CDC estimates that approximately 65,700 lower-limb amputations are performed each year on diabetics (CDC, 2011). As stated previously, diabetes has the potential to impact vision and renal functionality in addition to lower limb amputations. All of which would have a significant impact on quality of life. Productivity reductions for those outside of the workforce is a measure of reduced time spent providing childcare, household activities, and being active in the community. Premature death as, it relates to diabetes, is measured by determining the number of premature deaths that are attributed to diabetes and calculate the expected future earnings (American Diabetes Association, 2013). Table 4 lists the specific data collected for diabetics in the United States, 2012.

Table 4: Quality of Life Impact of Diabetes in the United States, 2012 (American Diabetes Association, 2013).

Quality of Life Component	**Productivity Loss**
Absenteeism	25 million days
Presenteeism	113 million days
Inability to Work Due to Disability	130 million days
Reduced Productivity Outside of Workforce	20 million days
Mortality	246,000 deaths

What is not included in the data of Table 4 is the more subjective impact to quality of life. Individuals with diabetes have an increased risk of diabetic retinopathy, renal failure and lower limb medical issues that could consist of peripheral neuropathy, ulcers, and possibly amputations. Diabetes is also considered the leading cause of blindness among individuals in the twenty to seventy-four year old age range (CDC, 2013). These health concerns will cause lifestyle modifications for the diabetic as well as

impact the quality of life for friends or family members serving as primary care providers.

Financial Impact to the Health Care Industry

When considering the financial impact of diabetes, it is also important to assess the impact the disease has on the health care industry. Specifically, the American Diabetes Association (2013) has provided 2012 data (Table 5) that demonstrates how diabetes is attributed to health resource utilization. In the U.S. in 2012, roughly 25.7% of hospital inpatient days are incurred by people with diabetes. That accounts for 43.1 million of the 168.0 total inpatient days of which 26.4 million are attributed to diabetes. Of the 3.6 billion outpatients care visits reported for 2012, 942.3 million are incurred by people with diabetes and 487.9 million are directly attributed to diabetes care. Further evaluation of the 2012 data shows that 8.3% of all outpatient visits, 5.7% of all emergency department visits, and 11.8% of medication prescriptions are associated with some type of diabetes care. In comparison with 2007 data, it is reported that use of medication attributed to diabetes has more than doubled (American Diabetes Association, 2013).

Analyzing health resource data utilization attributed to diabetes by medical condition and type of service, specifically diabetes, chronic complications, and general medical conditions demonstrates that of the 85.7 million diagnosis codes recorded for physician office visits in 2012 33% were specific to diabetes, 34% were from chronic

complications of diabetes (neurological, peripheral vascular, cardiovascular, renal, metabolic, ophthalmic, and others related to diabetes), and 33% were for general medical conditions. Similarly, of the 7.8 million outpatient diagnosis codes reports for 2012, 39% were diabetes, 33% were for chronic complications of diabetes, and 28% were general medical (American Association of Diabetes, 2013).

Table 5: Health Resource Use in the United States by Diabetes Status and Cost Component, 2012 (in millions of units) (American Diabetes Association, 2013)

	Population with diabetes					
	Attributed to diabetes		Incurred by people with diabetes		Incurred by population without diabetes	U.S. total*
Health Resource	Units	% of U.S. total	Units	% of U.S. total		
Institutional care						
Hospital inpatient days	26.4	15.7%	43.1	25.7%	124.9	168.0
Nursing/residential facility days	101.3	16.4%	198.4	32.2%	418.0	616.4
Hospice days	0.2	0.3%	9.3	12.8%	63.1	---
Outpatient care						1026.7
Physician office visits	85.7	8.3%	174.0	16.9%	852.8	128.7
Emergency department visits	7.3	5.7%	15.3	11.9%	113.5	100.7
Hospital outpatient visits	7.8	7.8%	15.0	14.9%	85.6	279.7
Home health visits	25.7	9.2%	64.9	23.2%	214.7	72.4
Medication prescriptions	361.4	11.8%	673.1	22.1%	2377.9	3051.1

Health care costs for 2012, based on the total health care expenditures for people with diabetes minus the projected level of expenditures that would have occurred for those people in the absence of diabetes, were projected to be over $1.3 trillion, of which, $306 billion were incurred by individuals with diabetes and $176 billion is attributed to the cost of diabetes. That equates to more than one in every ten health care dollars being attributed to diabetes (American Diabetes Association, 2013). The greatest contributor to the overall health care expenditures attributed to diabetes is from higher rates of hospitalization admission and longer lengths of stay. It is estimated that $124 billion of

the projected $475 billion in hospital inpatient care is incurred by people with diabetes and $76 billion in national medical cost is directly related to diabetes. Similar analysis of medication expense shows that $77 billion of the projected $286 billion national medication expense is incurred by individuals with diabetes and $50 billion is attributed to their diabetes.

While diabetes impacts finances and quality of life for individuals and the resources of the health care system, it ultimately impacts all of society increasing insurance premiums and taxes, reduces earnings, and reduces the standard of living. Specifically, for the 314 million Americans in 2012, the financial burden of diabetes represents a hidden tax averaging over $1,000 per person in the form of higher medical insurance cost and reduced productivity (Dall, et al., 2014).

Wellness Programs

In recent years, many organizations have identified the need to introduce workplace wellness programs to improve the overall health of employees, positively impacting employee satisfaction, and reducing the cost to provide health care insurance as a workplace benefit.

The following section explains the difference between disease management and workplace wellness programs, characteristics of a successful workplace wellness program, and the financial and quality improvements of workplace wellness programs.

Disease Management and Workplace Wellness Programs

As mentioned previously, “Disease management is a system of coordinated health care interventions and communications for populations with conditions in which patient self-care efforts are significant. Disease management supports the physician or practitioner/patient relationship and plan of care, emphasizes prevention of exacerbations and complications utilizing evidence-based practice guidelines and patient empowerment strategies, and evaluates clinical, humanistic, and economic outcomes on an ongoing basis with the goal of improving overall health.” (Congressional Budget Office, 2004) “Disease management programs are comprised of the following six components: (1) population identification processes, (2) evidence-based practice guidelines, (3) collaborative practice models to include physician and support-service providers, (4) patient self-management education (may include primary prevention, behavior modification programs, and compliances/surveillance), (5) process and outcomes measurement, evaluation, and management, and (6) routine reporting/feedback loop (may include communication with patient, physician, health plan and ancillary providers, and practice profiling). Full-service disease management programs must include all six components. Programs consisting of fewer components are disease management support services.” (Congressional Budget Office, 2004).

Wellness programs, specifically workplace wellness programs, differ from disease management programs based on the fact that workplace programs are, “a coordinated and comprehensive set of health promotion and protection strategies implemented at the

worksite that includes programs, policies, benefits, environmental supports, and links to the surrounding community designed to encourage that health and safety of all employees." (CDC, 2015) Workplace wellness programs address multiple risk factors and health conditions simultaneously facilitating individual employee behavior change, organizational culture, and worksite environment. Per the CDC (2015), workplace wellness programs can be divided into the following four major categories: (1) Health-related programs defined as opportunities available to employees at the workplace or through outside organizations to begin, change, or maintain health behaviors, (2) Health-related policies defined as formal or informal written statements that are designed to protect or promote employee health, affecting large group of employees at the same time, (3) Health benefits or a part of an overall compensation package including health insurance coverage and other services or discounts regarding health, and (4) Environmental supports referring to the physical factors at and nearby the workplace that help protect and enhance employee health. By utilizing these categories individually or in combination will provide the framework to further assist employees to improve current health or identify specific health risks that may require more specific disease management.

Characteristics of Successful Workplace Wellness Program

In reviewing the literature related to workplace wellness programs, most authors reference the Live for Life (Henke, Goetzel, McHugh, Isaac, 2011) program that was

initiated in 1979 and has been used as the basis for most workplace wellness programs that followed. As reported by Phillips (2009), Johnson & Johnson's Live for Life program has been associated with decreased medical spending and employee health risk factors and an increased return of investment for the organization since 1980. Based on the Live for Life program and additional workplace wellness programs modeled after the program, six specific characteristics are associated with successful workplace wellness programs. First, corporate culture must introduce and maintain the wellness program as a benefit to the health of the individual participant and not primarily a cost savings measure. Second, employees and corporate leadership are dedicated to the wellness program and overall health improvement. Third, the program support is attributed to having participation-friendly corporate policies and physical environment. Fourth, the wellness program is not static but adaptive to the changing needs of the participants. Fifth, community health organizations are engaged in the wellness program and provide support, education, and treatment. Sixth, technology is utilized to complete health assessment and wellness education (Kaspin, Gorman, and Miller, 2013). In addition to the six characteristics associated with successful workplace wellness programs, key wellness interventions included are health risk assessments, lifestyle management activities, and behavioral programs (Kaspin, Gorman, and Miller, 2013).

Health risk assessments are used to determine if individual employees may be at risk for conditions such as cardiovascular disease or diabetes. Generally, health assessments consist of biometric screenings to score specific risk factors such as cholesterol, A1C, body mass index, blood pressure, and tobacco use. Questionnaires may

be included in health risk assessments to evaluate behaviors that contribute to overall health condition such as diet, exercise, sleep patterns, alcohol use. Through the health assessment, it is possible to identify risk factors that can be addressed via lifestyle management (Kaspin, Gorman, and Miller, 2013).

Lifestyle management consists of activities such as fitness programs and competitions that engage employees in becoming more active. Lifestyle management can also include educational programs that inform employees on health behaviors and provide guidance on how to integrate the behaviors into daily routines. In addition to fitness programs education sessions, some wellness programs may also offer health coaches to assist with obtaining more directed success in becoming healthier (Kaspin, Gorman, and Miller, 2013). Lifestyle management is a primary area of wellness programs that incentives are utilized to promote involvement.

Behavioral health programs consist of behavior modification programs that assist individuals with smoking cessation, drug and alcohol addictions, and psychological council to address mental issues that are impacting a healthy lifestyle (Kaspin, Gorman, and Miller, 2013).

In addition to offering the above-mentioned interventions, workplace wellness programs can provide incentives to encourage participation in completing health risk assessments, participation in lifestyle management programs, receiving preventative care

and for continued improvement in risk factors. Examples of the incentives are financial rewards, gift cards, vacations, prepaid gas cards, and electronics. Workplace wellness programs may also include financial assistance to minimize the impact to employees that are willing to improve health. This may include discounts on health insurance preventive premiums, preventive care coverage, and medicines (Kaspin, Gorman, and Miller, 2013).

Financial and Quality Improvements of Workplace Wellness Programs

Most workplace wellness programs can demonstrate a return on investment and overall quality improvements to support the value of initiating a program. Johnson & Johnson's Live for Life provided an annual savings of $225 per employee savings, which equates to an $8.55 million annual savings (Henke, Goetzel, McHugh, and Isaac, 2011). From 2002 to 2008, the Live for Life program was able to have a 3.7% lower than average annual growth in medical costs compared to a comparison group made of companies of similar size and in a similar industry (Kaspin, Gorman, and Miller, 2013). The program, in 2009, had an annual average savings of $565 per employee savings resulting in a return on investment ranging from 1.88 to 3.92 based on a conservative program cost estimate of $300 per employee. A similar review of a wellness program offered by Fairview Health Services reported that in 1999 the overall annual medical cost per employee was $4640 in 1999. For the time period the 1999 cost per employee was almost $1000 higher than the national healthcare averages. Each year of the program had a cost savings per employee culminating in 2003 with a savings of $282 per employee. In

2004 the average cost for health care per employee for Fairview Health Services was $6511, which was $200 per employee below the national average for the industry (Fairview, 2006). Naydeck reported in 2008 that the Highmark Health Tracks and Extra Mile workplace wellness program participants had a $176.47 per employee lower health care costs when compared to the nonparticipant group (Naydeck, Pearson, Ozminkowski, Day, and Goetzel, 2008). Providence General Medical Center's was able to reduce their monthly medical claims by 24% and saved over $2 million over a six year period (Providence, 2000).

In addition to evaluating overall health care cost savings, several studies reported decreases in health insurance premiums (Kaspin, Gorman, and Miller, 2013). In 2007, Cable reported that the Highsmith wellness program impacted health insurance premiums by incurring a 4.6% premium increase over a five year period while health care costs for United States employers increased 60% during the same period. A study completed by the Oswald Company, reported that companies with workplace wellness programs had insurance premiums $1030 per employees less than similar companies without wellness initiatives (Sammer, 2006). Redstone's workplace wellness program saw an 8% decrease in health care premiums in the first year of the program (Hodge, 2006).

Indirect health care costs were also reported as a positive impact workplace wellness programs (Kaspin, Gorman, and Miller, 2013). One study reported a decrease of 20% in workers compensation costs that had a wellness coach located at the facility for a

year or longer. The same study also reported 75% fewer lost workdays annually for locations that participated in wellness program activities (Abt, 2009). Both the Providence and Highsmith workplace wellness programs resulted in a reduction of lost work time by reporting a 37% annual reduction in sick time and a one third to one half reduction in the annual absenteeism rate, respectively (Providence, 2000 and Cable, 2007).

The top four categories of health quality improvements reported across twenty separate workplace wellness programs were, increased exercise level, health risk reduction, smoking cessation, and decreased blood pressure (Kaspin, Gorman, and Miller, 2013). Participants in Live for Life program offered by Johnson & Johnson experienced decreased health related risks for high blood pressure (4.1% lower), high cholesterol (0.3% lower), poor nutrition (6.7% lower), obesity (6.6%), physical inactivity (0.7% lower), and tobacco use (10.6% lower) (Henke, Goetzel, McHugh, and Isaac, 2011). Highsmith employees in the high-risk category for cholesterol improved by 66% and overall health measurements and blood pressure improved (Cable, 2007). Con-way Freight's workplace wellness program resulted in 831 employees losing a combine total of 6,269 pounds, 170 employees quitting smoking, 669 employees reduced hypertensive blood pressure levels, almost 1,470 employees successfully lowered blood pressure through exercise and proper diet, and over 5,300 employees benefited from a total of 74,360 one-on-one coaching sessions (Con-way Inc., 2008).

The Patient Protection and Affordable Care Act

The Patient Protection and Affordable Care Act was signed by President Barack Obama, March 23, 2010 with the goal of improving access to affordable health care. Initial analysis of the 906-page act estimated that 95% of all Americans would be insured, providing insurance coverage to an additional 32 million citizens (Healthcare Reform, 2011). The following analysis of the Patient Protection and Affordable Care Act, outlines the: (1) policy options that lead to the final law, (2) identification of proponents and opponents, and (3) the outcome for health care finance, delivery and quality.

Policy Options

Health care reform is a significant public policy debate that many presidents have attempted to address during their time in office (Hartung, 2012). During the 2008 United States presidential election, Senator Barak Obama, campaigned on the platform that the cost of health care was a threat to the United States economy and that health care should be a right for every American (Healthcare Reform, 2011). After winning the 2008 United States presidential election, President Barak Obama challenged Congress to create a health care reform bill based on eight principles (President's Plan for Health Care, 2009):

1. Reduce long-term growth of health care costs for businesses and government
2. Protect families from bankruptcy or debt because of health care costs

3. Guarantee choice of doctors and health plans
4. Invest in prevention and wellness
5. Improve patient safety and quality of care
6. Assure affordable, quality health coverage for all Americans
7. Maintain coverage when you change or lose your job
8. End barriers to coverage for people with pre-existing medical conditions.

In response to President Obama's challenge the U.S. House of Representatives approved the Affordable Health Care for America Act (HR 3962) with a vote of 220-215. While House Democrats predominantly supported the bill, 39 Democrats voted against the bill and only 1 Republican voted in favor of the bill (Clerk of the U.S. House of Representatives, 2009). The estimated impact of the proposed bill was; (1) a cost of over $1.1 trillion dollars, (2) provide coverage for 36 million uninsured Americans, (3) create a government health insurance program, and (4) reduce the federal deficit by $118 billion dollars over a nine-year period (Healthcare Reform, 2011).

The Senate approved Patient Protection and Affordable Care Act (HR 3590), in a 60-39 party-line vote in response to health care reform challenge from President Obama (U.S. Senate Roll Call Votes, 2009). Interestingly, bill HR 3590 was originally passed in the U.S. House of Representative as the Service Members House Ownership Tax Act of 2009, which modified the home buyer's credit for members of the Armed Forces and certain Federal Employees (Healthcare Reform, 2011). The original bill had nothing in common with health care reform but was co-opted by the Senate, changing the existing

language, to become the Patient Protection and Affordable Care Act. The Senate took this approach because the Constitution requires all revenue-based bills to start in the House of Representatives and the proposed Senate bill on healthcare reform involved revenue (GovTrack, 2013). Senate Republicans argued that the bill was unconstitutional, socialistic, and too costly and would increase the cost of health insurance for those already insured. The estimated impact of the Patient Protection and Affordable Care Act was; (1) a cost of $871 billion dollars, (2) provide coverage for 31 million uninsured Americans, (3) would require the majority of Americans to have health insurance, and (4) reduce the federal deficit by $138 billion dollars over a nine-year period (Healthcare Reform, 2011). Figure 3, provides a detailed comparison of the House and Senate bills.

Figure 3: Comparison of the Patient Protection and Affordable Care Act (HR 3590) to the Affordable Health Care for America Act (HR 3962) – December 24, 2009
SOURCE: Side-By-Side Comparison of Major Health Reform Proposals, Henry J. Kaiser Family Foundation (2009).

	Similarities	Difference
Public Option	Both create Health Insurance/Benefit Exchanges, which governments may administer, where individuals and employers can purchase coverage. Both have restrictions on coverage for abortion beyond what is permitted by federal law (to save the life of the woman and in cases of rape and incest).	HR 3962: Creates the Health Insurance Exchange, where a public insurance option is offered. States may operate their own Exchanges. Access to the exchange is limited to all individuals who do not already have coverage through individual, employer, or government insurance. HR 3590: Requires at least two multi-state plans in each Exchange, one of which must be a non-profit. Access to the health insurance exchanges is limited to U.S. Citizens and legal immigrants who are not incarcerated.
Individual Mandate	Both require individuals to have qualifying health coverage, and both penalize those without coverage, with exemptions for religious objections and financial hardship.	HR 3962: Penalty is equal to 2.5% of adjusted income up to the cost of the average national premium for coverage under a basic plan in the Exchange, effective 2013.

		HR 3590: Penalty is equal to $750/year for individuals and up to $2,250 for families. Penalty is phased-in starting in 2014.
Employer Mandate	Both assess penalties on employers who do not offer health care coverage to their employees.	HR 3962: Penalty for not offering to contribute at least 72.5% of premium cost of coverage (65% for families) is equal to 8% of payroll for employers with payroll of $750k or more; penalties are phased in for employers with $500 - $750k, exempt for employers with payroll of less than $500k. Automatic enrollment into lowest-cost plan for all employees. Report on impact of employer responsibility requirements to consider whether an employee hardship exemption is appropriate due by 1/1/12. HR 3590: No penalty is assessed for employers with less than 50 employees/employers whose employees do not receive insurance exchange tax credit. Lesser of $3,000 per employee receiving coverage subsidy or $750 penalty per full-time employee if at least one employee receives coverage subsidy in a business with 50+ employees. Fee of $400 for any full-time employee on which a 30-60 day waiting period for coverage is imposed and $600 for a 60-90 day waiting period. Employers with 200+ employees automatically enroll employees into health plans (employees may opt out).
Individual Subsidies	Both offer subsidies to low- and middle-income individuals and families on a sliding scale up to 400% of the Federal Poverty Level. Both allow individuals to seek subsidies if their employer offers health premiums above a threshold percentage of income. Both limit subsidies to U.S. citizens and legal immigrants. Both restrict use of subsidies for coverage of abortion that goes beyond what is federally permitted.	HR 3962: Employer premium threshold is 12% of income. Subsidies are effective January 1, 2013. Establishes sliding scale limits on out-of-pocket spending. HR 3590: Employer premium threshold of 9.8% of income. Subsidies are effective January 1, 2014.
Employer Subsidies	Both offer subsidies to employers with less than 25 employees and average annual wages of less than a specific threshold. Both offer a temporary reinsurance program for employers providing health insurance coverage to retirees over the age of 55 that are not eligible of Medicare. Both reinsurance programs reimburse employers for 80% of retiree claims between $15K-$90K, which will be used to	HR 3962: Average annual wage threshold is below $40K. Subsidy is provided for no more than two years. Offer 50% credit of premium costs paid by employers who have less than 10 employees or average annual wages of less than $20K. Effective 2013. Appropriates $10 billion for the reinsurance program. HR 3590: Average annual wage threshold is below $50K. Starts of offering up to 35% credit for

	lower the costs for enrollees in the employer plan.	employer's premium costs paid if employer contributes at least half of the premium cost, phases in up to 50%. Full credit available to employers with less than 10 employees and average annual wages of less than $25K and phases out as firm size and average wage increases. Appropriates $5 billion for the reinsurance program.
Financing Reform	Both make cuts to Medicare and Medicaid payments. Impose fees on medical device makers, collect fines from individuals and employers that do not obtain/offer health care coverage, prohibit reimbursement of non-prescribed drugs through health savings accounts, and increase tax on health savings distributions that are not used for qualified medical expenses.	HR 3962: Income tax of 5.4% of gross income on individuals making $500K/couples making $1M annually. HR 3590: Excise tax on health plans with value of $8,500 for individuals and $23,000 for families. $2.3B annual tax on pharmaceuticals, $2B tax on medical device makers, $2B on health insurance sector (increases to $10B by 2017). 10% tax on amount paid for indoor tanning services.
Private Insurance Regulation	Both establish a temporary high-risk pool to provide coverage to individual with pre-existing conditions that have not been insured for at least six months prior. Both prohibit private insurance companies from denying coverage or charging higher premiums because of a person's medical history. Both prohibit lifetime limits on coverage. Both would strip private insurance from antitrust exemptions.	HR 3962: Requires medical loss ratio of no less than 85%. Children up to 27 years old have access to dependent coverage. Removes anti-trust exemption for health insurers and medical malpractice insurers. HR 3590: Requires medical loss ratio of no less than 80% for individual and small group markets and 85% for all others. Children up to 26 years old have access to dependent coverage. Prohibits waiting periods of coverage of more than 90 days. Limit deductibles for individuals to $2k, $4k for families.
Prevention/Wellness	Both create task forces to develop, update and disseminate evidence-based recommendations on the use of clinical and community prevention services and offer grants to fund these efforts. Both cover proven preventive services and eliminates cost sharing for preventive services in Medicare and Medicaid. Both require chain restaurants and food sold from vending machines to disclose nutritional content. Both offer grants to employers for offering wellness programs to its employees.	HR 3962: Grants available to community health workers to promote positive, healthy lifestyles in underserved communities and grants to plan and implement programs to prevent obesity. HR 3590: Requires qualified health plans to provide coverage of effective preventive services.
Improvements to Health System Performance	Both support comparative effectiveness research with establishment of institutes; seek to explore alternatives to medical liability laws; create Independence at Home demo program to provide	HR 3962: Strengthens financial support to primary care providers; enact studies on geographic variation adjustments for Medicare payments; conduct study on Medicare payments for English

	high-need Medicare patients with primary care services in their home and allow providers to share in cost-savings associated with reduced hospital admissions; improve care coordination for dually eligible; expand Medicaid and CHIP Payment and Access Commission to include adults; establish best practices for health care delivery; require disclosure of financial relationships between health entities, enhance collection and reporting of data on race, sex, primary language, and disability status.	language assistance. Increases Medicaid payments for primary care (cont.) providers to 100% of Medicare rates. HR 3590: Pays hospitals based on performance on quality measures; establishes pilot program for bundled payments.
Expansion of Public Programs	Both would expand Medicaid eligibility and federal government would pick up the cost of expansion for at least two years, eventually moving to a federal-state shared funding plan.	HR 3962: Medicaid expanded to all individuals under the age of 65 with incomes up to 150% of the Federal Poverty Level. Federal government would pick up full cost of expansion from 2013 - 2014. Afterwards, federal government would pay 91% and states pick up the remaining 9%. Repeals Children's Health Insurance Program (CHIP) and requires enrollees to instead enroll in the Exchange. If children have below 150% of the Federal Poverty Level, they may remain enrolled in Medicaid. HR 3590: Medicaid expanded to all individuals under the age of 65 with incomes up to 133% of the Federal Poverty Level. Federal government would fully finance expansion for three years. Maintains CHIP, with a planned match-rate increase for states in 2015.
Cost Containment	Both simplify health insurance administration by setting standards for financial and administrative transactions; reduce payments to Medicare Advantage plans and offer bonus payments for higher-quality plans; reduce payments to Disproportionate Share Hospitals; create innovation centers to test more efficient service delivery models; reduce Medicare payments to hospitals for preventable readmissions, prohibit federal payments to state for services related to health care acquired conditions; increase Medicaid drug rebate percentage to 23.1% (from 15.1%); authorize FDA to approve generic versions of drugs.	HR 3962: Require drug manufacturers to provide rebates for dually eligible; Secretary to negotiate drug prices directly with manufacturers; halt agreements between brand name and generic manufacturers that obstruct competition from generic drugs. HR 3590: Penalty of $1 per covered life for those health plans that do not document compliance with finance/admin standards; eliminate the Medicare Improvement Fund; develop database capture/share data across federal/state programs, increase penalties for submitting false claims, increase funding for anti-fraud activities.

Overall Cost	Both are estimated by the Congressional Budget Office to reduce the federal budget deficit by over $100B over ten years.	HR 3692: Congressional Budget Office estimates that the net cost of the proposal to be $894B over ten years. Net savings from Medicare and Medicaid are estimated at $426B over ten years. The largest source of revenue ($461B over ten years) would come from a 5.4% tax on families with incomes over $1M and individuals with incomes over $500k. HR 3590: Congressional Budget Office estimates that the cost of coverage components of the proposal to be $871B over ten years. Net savings from Medicare and Medicaid are estimated at $438B over ten years. Largest source of revenue from excise tax on high-cost insurance, amounting to about $149B over ten years.

There are several similarities between HR 3962 and HR 3590 but some of the key differences are: (1) HR 3590 was proposed to be phased in starting in 2014 instead of 2013; (2) HR 3590 established compliance thresholds for employers that have less than 50 employees; (3) HR 3962 proposed financing health care reform by applying a 5.4% gross income tax on individuals making more than $500,000 or families making more than $1,000,000 annually. HR 3590 proposed financing health care reform by applying an excise tax on “Cadillac” health care plans, pharmaceutical companies, medical device makers, and the insurance sector; (4) HR 3590 proposed paying hospitals based on performance and quality measures; (5) the cost of HR 3692 would be fully funded by the federal government the first year and then shift to 91% federal / 9% state matching model. HR 3590 would be covered 100% by the federal government for the first three years; and (6) HR 3590 proposed a net savings for Medicare and Medicaid of $438

billion dollars over ten years. HR 3962 proposed a net savings for Medicare and Medicaid of $426 billion dollars over ten years (Figure 11).

In February of 2010, President Obama proposed his own bill bridging both the House and Senate's bill. This increased the pressure on the U.S. House of Representatives to pass health care reform legislation, which they did by amending the Patient Protection and Affordable Care Act with Health Care and Education Reconciliation Act of 2010 (Healthcare Reform, 2011). President Obama signed the final version of the Patient Protection and Affordable Care Act (PPACA) on March 23, 2010 (GovTrack, 2013).

Proponents and Opponents of the Legislation

The simplest way to describe the political division created by PPACA, is Democrats are for healthcare reform and the Republicans are against it. Reviewing the U.S. Senate and U.S. House of Representatives vote record for both the Patient Protection and Affordable Care Act and the Health Care and Education Reconciliation Act of 2010, where no Republican Representatives or Senators voted in favor of either bill, it is clear that the Republican Party opposes health care reform and the Democratic Party supports it (GovTrack, 2013). Health care reform strikes at the core ideologies of both parties. For the Republicans, health care reform represents the expansion of government, increased taxation, and negative financial impact to businesses. For the Democrats, health care reform provides the expansion of health insurance to millions of uninsured citizens

creating greater access to medical treatment, increases the cost sharing for medical treatment with the industries that are directly benefiting from the high cost of health care in the United States, and introduces the model of fee for value versus fee for services by associating reimbursements with the quality of care received. Opposition to PPACA resulted in the U.S. House of Representatives approving The Repealing the Job-Killing Health Care Law Act in January of 2011 after the Republican Party regained the majority. The Repealing the Job-Killing Health Care Law Act was subsequently rejected by the U.S. Senate in a 51-47 party-line vote (Healthcare Reform, 2011).

In addition to the attempted repeal of PPACA, opponents also argued that Congress did not have the authority to enact the individual mandate that all citizens are required to participate in health coverage or be subject to a fine. Opponents point to the lack of provision(s) within the U.S. Constitution guaranteeing a right to health care services provided by the government to those who cannot afford it. Proponents argue that based on the Commerce Clause and the Necessary and Proper Clause, Congress does have the authority to enact such laws (Burgess, 2013). The Commerce Clause gives Congress the authority "to regulate commerce with foreign nations, and among the several states, and with the Indian tribes" (Commerce Clause, 2013) and the Necessary and Proper Clause states that Congress has the power "to make all laws which shall be necessary and proper for carrying into Execution the foregoing Powers, and all other Powers vested by this Constitution in the Government of the United States, or any Department or Officer thereof." (Necessary and Proper Clause, 2013) Six challenges to PPACA were submitted to the U.S. District Courts, of which the Sixth Circuit Court of

Appeals in Cincinnati, OH upheld the entirety of PPACA but the Eleventh Circuit Court of Appeals in Atlanta, GA found the individual mandate to be unconstitutional (Burgess, 2013). In response to the Eleventh Circuit Court's ruling, the Supreme Court was petitioned by the Justice Department to decide the constitutionality of the individual mandate within PPACA. The Supreme Court heard arguments, for and against, the constitutionality of the individual mandate and on June 28, 2012 Justice John Roberts summarized the ruling in his concluding opinion as follows:

> "The Affordable Care Act is constitutional in part and unconstitutional in part. The individual mandate cannot be upheld as an exercise of Congress's power under the Commerce Clause. The Clause authorizes Congress to regulate interstate commerce, not to order individuals to engage in it. In this case, however, it is reasonable to construe what Congress has done as increasing taxes on those who have a certain amount of income, but choose to go without health insurance. Such legislation is within Congress's power to tax." (Roberts, 2012)

Due to the lack severability in PPACA, if any component of the act is found unconstitutional the act in its entirety is at risk. The Supreme Court ruling addressed the constitutionality of the individual mandate based on the Commerce Clause but the ruling did not eliminate the potential for further litigation. As part of this ruling, the Supreme Court also ruled that state participation in Medicaid expansion is optional and that states choosing to not participate cannot be penalized (Roberts, 2012).

At the state level, many Governors refused to accept the Medicaid expansion funds offered under PPACA. The Medicaid expansion program was effective January 2014 providing increased medical access to the poorest Americans by broadening Medicaid eligibility to individuals less than sixty-five years of age with income below

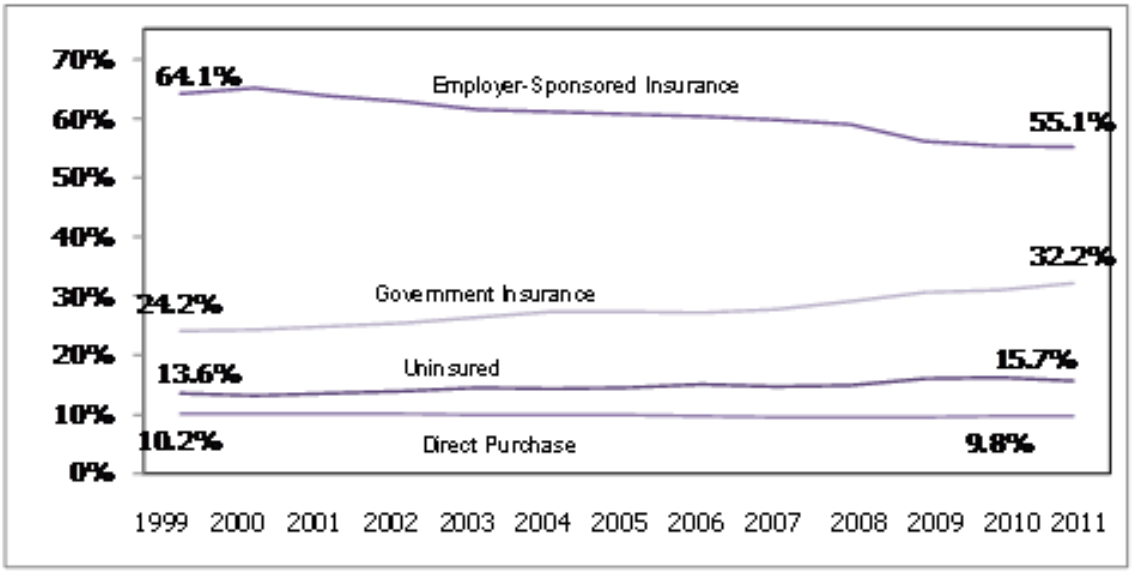
133% of the federal poverty level. The financial impact to individual states will begin in year four of the program when the 100% federal funding shifts to a shared funding model ultimately resulting in PPACA receiving 90% federal and 10% state funding in the year 2020. The expansion of Medicaid creates greater access for the uninsured but increases the federal and state financial burden to provide funding for treatment reimbursements. South Carolina would add an estimated 500,000 individuals to Medicaid by opting into the expansion, but the cost of covering 10% of the program is estimated to reach $1.7 billion dollars by the year 2020 (The State Paper, 2013). Proponents of expanding Medicaid in South Carolina estimate that the total economic output of opting in would be $3.3 million dollars and support nearly 44,000 jobs (SCHA, 2012). The expansion of Medicaid is a critical debate among health care providers who are concerned about the increasing demand to provide quality health care for uninsured/underinsured individuals while maintaining financial viability. Hospitals across the state are addressing the pending reduction in reimbursements as the industry shifts from fee for service to fee for value by initiating cost saving programs.

Finance

It is estimated that without the implementation of health care reform legislation, the combined expense of Medicare, Medicaid and Social Security would exceed the projected tax revenue of 18.2% in approximately 2050 (Hartung, 2012). As noted in Figure 4, the payer mix from the period of 1999-2011 has seen a 9% decrease in employer sponsored insurance and a 10.10% increase in government insurance and the

uninsured, combined. This trend demonstrates that employer sponsored health insurance is declining and individuals are either receiving health care through government insurance programs or are foregoing health insurance. The impact of an increasing uninsured population translates to individuals being limited in their health care spending. This limitation results in a percentage of the population that only obtains episodic care when it is absolutely necessary, avoiding the expense of preventive care.

Figure 4: Insurance Trends, 1999-2011



Notes: Data is for the entire US population. Percentages do not add up to 100% because some people have more than one type of coverage. In 2010, the Census Bureau updated its coverage data for current and prior years to reflect changes in the methods used to impute health insurance for non-respondents. Government insurance includes military coverage. (U.S. Census Bureau, 2011)

PPACA addresses the trends described above by establishing the requirement that U.S. citizens and legal residents must have health insurance. This is accomplished by requiring states to establish state-based health insurance exchanges that provide cost effective purchasing options for individuals and small businesses to reduce the financial

burden associated with paying health insurance premiums. For those individuals and employers that choose not to participate in the insurance exchanges, individual and employer mandates to maintain health insurance will be instituted as part of PPACA. The individual mandate will require U.S. citizens and legal residents to have qualifying health coverage or pay a maximum annual tax penalty of $2,085 or 2.5% of household income. The tax penalty will be phased in over a three-year period starting in 2014. After 2016, the penalty will increase based on the cost-of-living adjustment (Kaiser Family Foundation, 2011). Employers with fifty or more full-time employees that do not offer health insurance will be assessed a fee of $2,000 per employee and employers with more than two hundred employees will be required to automatically enroll employees into company provided health plans (Kaiser Family Foundation, 2011). Small businesses with less than twenty-five employees and average annual wages less than $50,000 will receive a tax credit for purchasing employee health insurance. Individuals with incomes up to 133% of federal poverty level will be eligible for Medicaid coverage under PPACA Medicaid expansion provision. This will insure that individuals that are not able to purchase insurance through the state health insurance exchanges will be eligible to receive essential health benefits. As stated previously, Medicaid expansion will be federally funded for the first three years, transitioning to a 90% federal / 10% state supported program by the year 2020.

PPACA improves affordability of medication for seniors by reducing the gap known as the “donut hole” in Medicare Part D. As a result of the changes to Medicare part D people in the “donut hole” received a 50% discount on covered brand name drugs

and 14% discount on generic drugs in 2012. The financial gain of this improvement translates to a $5.7 million dollar savings on prescription drugs over the past two years (Healthcare.Gov, 2013). In addition to improving the affordability of medications, PPACA requires insurance plans to eliminate cost sharing (deductibles and co-pays) for a variety of preventive health services. In 2011 and 2012, 71 million Americans that were enrolled in private health insurance obtained preventive health services without cost sharing (Healthcare.Gov, 2013).

Delivery

To accommodate the increase in patient volumes due to greater access to medical care, PPACA addresses the workforce impact by providing the following provisions: (1) through the establishment of a multi-stakeholder Workforce Advisory Committee, develop a national workforce strategy; (2) redistribute unused General Medical Education (GME) slots to states with the lowest resident physician-to-population ratios, with primary care and general surgery being prioritized; (3) increase the number of Teaching Health Centers, defined as community-based, ambulatory patient care centers that are reimbursed under the same guidelines as primary care residency programs; (4) expand health professional workforce supply and support training via scholarships and loans providing specific focus to preventive medicine, public health, and interdisciplinary mental and behavioral health training; (5) prepare for the projected shortage of nurses by increasing the availability of nursing education programs, providing loan repayment assistance, and establishing a career ladder to nursing. Increase grant opportunities to

train family nurse practitioners that are willing provide care in federally qualified health centers and nurse-managed clinics; and (6) increase the support for the development of primary care training models that focus on medical homes, coordinated management of chronic disease, and programs that address both physical and mental health (Kaiser Family Foundation, 2011).

The National Health Services Corps is a great example of how workforce provisions of PPACA are making a difference. The National Health Service Corps is a federal government program that is part of the Department of Health and Human Services. Due to the investments from PPACA, nearly 10,000 Corps clinicians are providing care to more than 10.4 million people located in rural, urban and frontier communities (Healthcare.Gov, 2013). The expansion of the National Health Service Corps is in direct response to increased federal funding to repay educational loans and provide scholarships to clinicians that practice in areas of the country that do not have enough medical professionals to serve the people who live there. Specifically, The National Health Service Corps will receive $1.5 billion dollars over a five-year period, starting in 2011, in support of continued expansion into medically underserved areas (Kaiser Family Foundation, 2011).

Information Technology is a focal point of delivery under PPACA through the establishment of ACO's. Elliot S. Fisher first described the term ACO in 2007 as "the United States Health Care System suffers from serious gaps in quality and widespread waste stimulating a broad array of public - and private - sector initiatives to improve

performance. These include not only public reporting, pay-for-performance (P4P), and quality improvement programs but also major initiatives by the organizations responsible for institutional accreditation and professional certification" (Fisher, 2007). Under the guidance of The Centers for Medicare and Medicaid Services (CMS), health organizations can utilize electronic medical record solutions that are meaningful in use to exchange patient data and coordinate care. The coordination in care is meant to establish specific cost saving benefits through the reduction of duplication in services and establish a preventive health care model to replace the current reactionary model (Hartung, 2012). The specifics of the CMS proposal for ACO's is: (1) have a minimum of 5000 patients, all participants must have a medical home; (2) meet a minimum standard with respect to 65 quality measures before being eligible to receive bonus payments; (3) produce minimum savings targets based on the quantity of patients participating; (4) establish and maintain a governing body that consists of 75% ACO participants with at least one patient participating on the governing board; (5) cannot exclude at risk patients from participating; and (6) must retain at least 25% of bonus payments as escrow for future losses (Medicare Program, 2011).

Quality

The need for a national quality improvement strategy is identified as part of PPACA and prioritizes the improvement of delivering health care services, patient health outcomes, and population health (Kaiser Family Foundation, 2011). PPACA prioritizes the improvement of overall health in an effort to reduce the expense of providing care. By

addressing the quality of care and gradually transforming the health care industry to a more preventive care model, patient outcomes will improve. The focus on quality is apparent by the increased value placed on reimbursement based on core measures of quality and the objectives of the stages of "Meaningful Use" identified as part of the HITECH Act.

The establishment of preventive care under PPACA is supported by the following: (1) eliminate preventive service cost-sharing under Medicare to promote access to essential preventive health screenings; (2) states that provide Medicaid coverage for preventive services can eliminate cost-sharing; (3) establish an annual comprehensive health risk assessment for Medicare participants; (4) provide behavior modification incentives for both Medicare and Medicaid enrollees; and (5) require qualified health plans to eliminate cost sharing for preventive services such as recommended immunizations, preventive care for infants and adolescents, and preventive care for women (Kaiser Family Foundation, 2011). In addition to offering preventive care measures, PPACA penalizes hospitals by reducing Medicare reimbursements for preventable hospital readmissions and hospital-acquired conditions. Both preventive care and the reduction of preventable hospital admissions require improved management of chronic diseases. Without chronic disease management a very small percentage of individuals within any health plan incur the majority of the expense. Through chronic disease management, the need of emergent care or prolonged episodic care can be reduced.

Accountable Care Organizations

Centers for Medicare and Medicaid Services define ACOs as "groups of doctors, hospitals, and other health care providers, who come together voluntarily to give coordinated care to their Medicare patients. The goal of coordinated care is to ensure that patients, especially the chronically ill, get the right care at the right time, while avoiding unnecessary duplication of services and preventing medical errors." (CMS, 2015). The incentive for health care providers and organizations to participate is the potential of increased reimbursement by sharing any savings associated with the reduction in patient care expense.

ACOs take the pay-for-performance model beyond the health care provider and introduce the idea of significantly reducing the overall expense of health care by integrating into the workplace, home and communities (McLellan, 2012). "It envisions the medical home as a central locus in a spectrum of health care services applying evidence-based approaches in joint ventures among organizations that decrease the fragmentation of the current system" (McLellan, 2012). Elements of an ACO are: (1) Care teams composed of primary care physicians, physician assistants, nurse practitioners, specialists, and others who coordinate patient care, (2) added focus on evidence based medicine, quality outcomes and safety, (3) increased use of information technology and (4) reduction of high-volume and high-profit margin services with a new emphasis on value and outcomes (McLellan, 2012).

While the origination of ACOs is linked to Medicare patients, it is not specifically a Medicare only initiative. The following section will describe the tools utilized in ACOs to evaluate overall health of participants and the coordination of care, how the ACO model is related to this project, and how the utilization of the ACO model differentiates this project from other wellness programs described previously.

Accountable Care Organization Tools

The premise of an ACO is that if the right patient care is delivered at the right time, expense will decrease and outcome quality will improve. To accomplish this, ACO's utilize patient risk modeling tools to identify high-risk patients, both current and potential, and provider coordination tools to assist in coordinating and tracking the care received to manage chronic illnesses.

Risk modeling is accomplished by using a variety of commercially available software tools. These tools utilize proprietary algorithms that assess health services claims data to determine the risk associated with a given patient and identify health care trends that may indicate specific disease maintenance. The claims data is collected using a specific submission file type, Health Claim Transaction Set (837) that was established as part of the HIPAA Act of 1996. The 837 transaction set includes the following items for a single care encounter between patient and provider: (1) a description of the patient, (2) the patient's condition for which treatment was provided, (3) the services provided, and (4) the cost of the treatment (1EDISCOURCE, 2015). The detailed specification for

the content and the uses of an 837 file is, “The X12 Transaction contains the format and establishes the data contents of the Health Care Claim Transaction Set (837) for use within the context of an Electronic Data Interchange (EDI) environment. This transaction set can be used to submit health care claim billing information, encounter information, or both, from providers of health care services to payers, either directly or via intermediary billers and claims clearinghouses. It can also be used to transmit health care claims and billing payment information between payers with different payment responsibilities where coordination of benefits is required or between payers and regulatory agencies to monitor the rendering, billing, and/or payment of health care services within a specific health care/insurance industry segment. For purposes of this standard, providers of health care products or services may include entities such as physicians, hospitals and other medical facilities or suppliers, dentists, and pharmacies, and entities providing medical information to meet regulatory requirements. The payer refers to a third party entity that pays claims or administers the insurance product or benefit or both. For example, a payer may be an insurance company, health maintenance organization (HMO), preferred provider organization (PPO), government agency (Medicare, Medicaid, Civilian Health and Medical Program of the Uniformed Services (CHAMPUS), etc.) or an entity such as a third party administrator (TPA) or third party organization (TPO) that may be contracted by one of those groups. A regulatory agency is an entity responsible, by law or rule, for administering and monitoring a statutory benefits program or a specific health care/insurance industry segment.” (ASCX12, 2015) In addition to utilizing EDI 837 files, adjudicated claims from individual payers also provide an indication of the types and cost of care being received. Adjudicated claims are the finalized reconciliation of service and

payments that are agreed upon by the provider and the payer. This information is specific to items that occurred in the past so it is not appropriate for assessing current health issues but provides a significant retrospective view by payer. By collecting this information, it is possible to evaluate both the care and the cost associated with medical treatment and assign a risk score for the individual patient, accordingly. Those individuals scoring higher in a risk scale can then be evaluated to determine if the score is related to specific episodic care, chronic disease management, or excessive use of health care services.

Utilizing the risk modeling tools identifies individuals that may benefit from additional care planning or care management. Physicians and care managers utilize information system care coordination tools that require additional clinical information to be available to provide a complete picture of the care each patient is receiving. The challenge with these systems is the ability to collect all care information and provide a complete clinical picture. To overcome this challenge, most care coordination tools are in the form of an electronic dashboard that consolidates multiple sources of clinical information into a single view. This allows physicians and care managers to evaluate care received over a period of time as well as dive deeper into the details of any given episode. Collecting all clinical information is achieved through a health information exchange solution that receives clinical data via information system interfaces from electronic health record systems. Conceptually, collecting clinical data and consolidating the information into a single view is simplistic, but when considering the number of physicians, clinics, and hospitals that may be utilized by an individual increases the

complexity exponentially. The benefit of collecting the clinical information into an electronic dashboard allows providers to evaluate prior clinical information collected by other providers to potentially reduce duplication in services as well as create a source for care coordination and patient compliance tracking. This can be demonstrated when a primary care provider has the ability to review current medications, laboratory results, and possibly condition monitoring by the patient.

Accountable Care Organizations and This Project

The focus of this project is to evaluate the return on investment for individuals that are participating in a workplace wellness program to improve both the cost and quality of life associated with diabetes disease management. The accountable care tools described previously are utilized in this process by first assigning a risk score for individuals of a specific population within an organization via a commercially available ACO risk management tool. Once the individuals with high-risk scores are identified, care coordination in the form of case managers can be established to assist with specific disease management. The ACO model provides broader visibility to individual's health care utilization, which allows for a more holistic approach to care management. Establishing the risk score using ACO tools prior to implementing care coordination also provides the ability to track individual participant's progress over a period of time versus tracking disease specific diagnostic scores. Specifically, utilizing ongoing risk score evaluations based on adjudicated claims or 837 files will provide insight into health care visits, medication expenses, and laboratory results versus traditional diabetes disease

management that consists of regular monitoring of glucose or A1C levels.

Difference from Other Diabetes Wellness Programs

Previous research utilizing PepsiCo's HealthRoads workplace wellness program, assesses the financial impact of workplace wellness programs, specifically diabetes, by evaluating claims data and providing a self-administered health risk assessment (Liu, et al., 2013). Based on the results of the evaluation and health risk assessment, individuals were eligible for case management, disease management, lifestyle management, and a nurse advice line. The program did not utilize commercially available ACO tools to assess the claims data or evaluate overall success of the program. The research completed by Liu et al. (2013) only evaluated the benefit side of a cost-benefit equation and was unable to estimate the return on investment due to not having access to the related program costs.

Additional workplace wellness programs discussed previously, identify the top four categories of health quality improvements as, increased exercise level, health risk reduction, smoking cessation, and decreased blood pressure (Kaspin, Gorman, and Miller, 2013). Diabetes disease management is a relatively new focus area of workplace wellness programs that requires a higher level of participant support systems to improve the management of the disease. The coordinated care team, provided to participants as a support system, is focused on improving the access to care as well as reducing the cost of care to manage a healthy lifestyle which is a commonality between ACO's and

workplace wellness programs. Utilizing an ACO model within a specified workplace with access to the program costs information and clinical data will provide better insight into the return on investment associated with a workplace wellness program focused on diabetes disease management.

METHODOLOGY

Population

The population of this study to answer the research question, “Can using an ACO commercially available software tool and a diabetes wellness workplace management program be combined to identify 1 year ROI in a sample of patients within an average size institution?” is a subset of individuals that receive health benefits from a self-insured employer at a reduced insurance premium. To participate in the reduced insurance premium plan, individuals that have at least one or any combination of the following physiological indicators: a BMI greater than or equal to 50, a glucose of greater than or equal 200 mg/dL, an A1C equal to or greater than 7.0, and a risk score as calculated by the CCMS commercial ACO software must comply with a workplace wellness program. The workplace wellness program is provided by the employer in an effort to improve the management of workforce health and assist employees that need focused care management for diabetes. Focused care management is accomplished by assigning health coaches to employees that qualify for the program.

Study Design

In an attempt to answer the proposed research question, de-identified data obtained will be evaluated using the outcome evaluation model. The outcome evaluation model, which is also known as an impact assessment, “focuses on the accomplishments

and impact of the service program, or policy and its effectiveness in attaining the intended results that were set prior to program or policy implementation" (Shi, 2008). It allows for an evaluation of an enhanced or modified program compared to standard program methods. The outcome evaluation model allows the program to be evaluated based on the benefits of the intervention to determine if the program changes are an improvement of the program. Specifically, outcome evaluations are interested in answering the following questions: (1) What are the goals and objectives of the program?, (2) How are they measured and assessed?, (3) What alternative programs are available to this program?, (4) How are the essential components of the program related to achieving goals and objectives?, (5) How successful is the program in accomplishing intended results?, (6) How effective is the program?, (7) How costly is the program?, (8) Which program components best accomplish goals?, (9) What gaps exist in meeting the goals?, (10) What changes should be made to improve the efficiency of meeting program goals?, (11) What are the positive and negative unanticipated outcomes of the program?, and (12) What decisions can be made regarding the program continuation or expansion? (Shi, 2008). Outcomes research performed at the patient level is generally focused on the most prevalent, costly, medical conditions that have alternative clinical strategies. This type of research involves linking the care received by a variety of patients with a particular condition to positive and negative outcomes in order to determine what interventions work best for patients (Guadagnoli and McNeil, 1994).

The purpose of the evaluation described in more detail later in this Methods section, is to compare retrospective cost data of providing health care for diabetics in the

study, prior to and after twelve months of participating in the program, in an effort to calculate the return on investment utilizing a diabetic ACO model. In addition to determining the return on investment, using the outcome evaluation model will also provide insight into the strengths and weaknesses of the program as well whether to continue the program as originally implemented.

It has also been noted that outcome research is concerned with the "movement to managed care and the organization of previously independent health care providers into integrated networks" (Shi, 2008) which can range from the older model of managed care solutions into the most recently proposed ACO model. As mentioned previously, a key goal of the ACO model is to change the health care reimbursement model from a fee for service model to a pay for performance reimbursement model focused on the reduction of overall individual health care expenses via proactive health and/or disease management. To elicit the adoption of this new reimbursement model by providers requires this assessment to determine if the additional expenses associated with providing care management results in a positive return of investment.

The actual evaluation of the data will be performed as a repeated measures longitudinal study (Shi, 2008), which will allow for a review of program participants A1C values over a twelve-month period during the time frame of October 2013 to September 2014. The data collected from the individual participant will be used to trend the impact of care management on each individual participant's A1C for those identified with a BMI greater than or equal to 50, a glucose of greater than or equal 200 mg/dL, and

an A1C equal to or greater than 7.0, during an annual work place wellness health assessment. The longitudinal trend analysis will be based on the prior year health care cost compared to the health care and program cost for the twelve-month program period for each participant. The data will be an A1C score recorded, at least quarterly, for each participant and trended for a twelve-month period. This information will be matched to the specific care management interventions that were provided during the same period. Based on both sets of data, an additional ACO risk score will be calculated at the end of the evaluation period to determine if the program expenses incurred per participant results in an improvement in the overall, prior to program participation, medical care costs associated with the treatment of diabetes. The ACO risk score is calculated using a commercially provided software tool with proprietary algorithms that assess health services claims data to determine the risk associated with a given patient and identify health care trends that may indicate specific disease maintenance. The claims data is collected using a specific submission file type, Health Claim Transaction Set (837) that includes the following items for a single care encounter between patient and provider: (1) a description of the patient, (2) the patient's condition for which treatment was provided, (3) the services provided, and (4) the cost of the treatment (1EDISCOURCE, 2015). Due to the proprietary nature of the algorithm used to calculate the risk score, it is difficult to know all the factors, other than the 837 file, used to calculate the participant risk score. It is assumed that participant age and corresponding diagnoses have an impact as well. This design is best suited to answer the research question as it allows for the evaluation of the pre and post program health care costs for diabetic patients that participate in a workplace diabetes wellness program based on the utilization of ACO risk scoring software.

Measures

Self Regional Healthcare, in partnership with McKesson, is an ACO demonstration site. As a demonstration site, Self Regional Healthcare has decided to validate the ACO model by enrolling all current team members in McKesson's Coordinated Care Management System (CCMS), which is a workflow tool that enables payers to focus resources, better coordinate care through automation and effective communication, integrate data at key points in the workflow, and base interventions on evidence-based standards of care (McKesson, 2012). The CCMS solution collects insurance claim data from insurance companies via technical interfaces, matching patient claims and assessing the current patient diagnosis. It does this in an effort to provide patient populations that are in need of specific health interventions to obtain improved health through appropriate care management. Through the CCMS tool, individuals receive a risk score based on their specific insurance claims information reported in an industry standard 837 insurance claims file. Individuals that receive a high-risk score are assigned a health coach that facilitates a specific care plan based on the specified categorizations of obesity, hypertension, and diabetes. The health coach is responsible for providing education to each participant that explains the program benefits. During the initial meeting, each participant is interviewed by the health coach. The health coach assesses current limitations of access to appropriate health care or lifestyle challenges for each participant and offers solutions or guidance to obtain better health. The interventions provided by the health coach range from providing access to a primary care provider and medication assistance to gym membership and appropriate footwear to facilitate a more

active lifestyle. The health coach maintains regular contact with each participant, monthly if possible but quarterly at a minimum, to assess each individual participant's progress and compliance with improving diabetes management and overall health.

In addition to analyzing Self Regional Healthcare team member's 837 insurance claims file using McKesson's CCMS tool, each team member covered under the corporate health insurance plan is required to complete a health risk assessment that includes the collection of key health indicators such as: weight, blood pressure, body mass index (BMI), lipid panel, and A1C. Individuals that have a BMI greater than or equal to 50, a glucose of greater than or equal 200 mg/dL, or an A1C equal to or greater than 7.0 are also provided a health coach to assist in disease management specific to diabetes. Having values greater than those required to participate in the program does not always correlate with a high-risk score. For this reason participants of the study may not have both a high-risk score and correlating physiological values.

To be included as a participant in the research, the Self Regional team member needs to be enrolled in the program for at least twelve months and have any of the four following indicators; a BMI greater than or equal to 50, a glucose of greater than or equal 200 mg/dL, an A1C equal to or greater than 7.0, and a risk score as calculated by the CCMS commercial ACO software. The program was initiated in 2013 and enrolled team members in the first year it was established as well as during the second year in 2014. Table 6 lists the specific research measures that will be collected for each participant during the research period.

Table 6: Research Measures for Each Participant

Measures	Scales
Participant characteristics	Age, sex, and race
Length of time in the program for each participant	Reported in months
Initial results of health risk assessment for each participant	Reported as a numeric value
Initial risk score as determined by commercial ACO software	Reported as a numeric value
Risk score as determined by commercial ACO software after 12 month participation in the workplace wellness program	Reported as a numeric value
Weight loss while participating in the program	Reported in pounds
Physical activity while participating in the program	Number a daily steps or physical activity as reported by the Walkingspree program
Annual health care cost for each participant while participating in the program	Dollar amount for health care provided as reported in the participant's 837 file
Total cost of ownership for the ACO software	Dollar amount of McKesson CCMS product. Initial capital cost plus the maintenance cost for the program period
Full time equivalents associated with the care management staff of the program	Compensation, including benefits, for each full time equivalent health coach and program manager
Health insurance premium reduction for each participant (incentive)	Dollar amount of reduced monthly health insurance premium as a result for participating in the program
Program expense for each participant	Dollar amount of the combined costs for the following items if provided to each participant: gym membership, exercise shoes, reduced meal plan, and reduced prescription co-pays

Data Collection

The data for this research is based on information collected from participant records and health claims information, pre- and post-research time frame, as well clinical information collected by the care managers during the research period. The data collected is: health specific information (A1C and weight), intervention data (physical activity), and health care costs (emergent, inpatient, and ambulatory care) as reported for payment via 837 insurance files. In addition to the participant specific health, intervention, and claims data, the associated risk score as determined by the CCMS product, is collected for each participant at the beginning and the end of the twelve month research period. As submitted and approved by the IRB committees at Self Regional Healthcare and the Medical University of South Carolina, the data is de-identified by the program administrator prior to being analyzed.

During the study period, the health coach meets with each participant on a regular basis, but no more than monthly, to collect program specific health data and assess if any additional program interventions are needed. The care managers use a basic spreadsheet tool to collect data during each of the interviews with the program participants. The data collected is abstracted manually as needed to perform data analysis.

Data Analysis

Due to the lack of a control group associated with the specific research, data will

be evaluated using a before-and-after time-series comparison. Specifically, “pre-program and post-program outcome measurements are compared to see if the differences are significant.” (Shi, 2008). The main focus of the data analysis for this research will be determining if the health care cost for each participant during the twelve months, October 2013 to September 2014, leading up to initiating the program is reduced as a result of the program interventions and if the post-program health care expense in addition to the program expense provides a positive return on investment. In addition to evaluating the return on investment, descriptive data, specifically minimum, median or mean, and maximum of each measure, will be determined to provide a detailed understand of the study data. To determine if there is a significant difference in individual participant medical cost pre- and post- intervention, a two-tailed T-test will be completed (Shi, 2008).

The tool utilized to evaluate the return on investment of the diabetes wellness management program is a cost benefit analysis (CBA) which allows for the benefits and the costs of the program to be quantified and translated into a common monetary unit. Using the cost benefit analysis as the evaluation tool assists in the decision making process for the planning, implementation, continuation, and expansion of health service programs (Shi, 2008).

The cost benefit analysis will be assessed by determining: the total health care cost for the program participants prior to program initiation (Y_0); the health care cost for the program participants during the program period (Y_1); and the total cost of the

program including software expense (P_s), program personnel (P_p), and program incentives (P_i). Using these factors, the following formula will be used to calculate the program cost benefit analysis which will be used to answer the research question proposed previously:

$$CBA = Y_0 - (Y_1 + P_s + P_p + P_i)$$

Using this formula, it will be possible to determine if the cost of implementing the diabetes workplace wellness program combined with the reduced health care costs of all the participants is less expensive than the health care cost of the participants prior to initiating the program. If the CBA is a positive number than the program reduced the expense of managing the participant population.

While the CBA formula evaluates the cost of implementing the diabetes workplace wellness program, it does not account for calculating the actual return on investment of the program for the study period. To determine the ROI of the diabetes wellness program the ROI formula below was used.

$$\text{Return on Investment} = \frac{\text{(Investment Gain – Investment Cost)}}{\text{Investment Cost}}$$

RESULTS

Participant Descriptive Data

The participants included in this project are part of a diabetes workplace wellness program at Self Regional Healthcare, Self Cares. Self Cares is an incentive based workplace wellness program to maintain healthy habits in return for reduced health insurance premium. As part of the program, any individual identified having at least one of the following physiological measures as reported during Self Regional Healthcare's annual health assessment: a BMI greater than or equal to 50, a glucose of greater than or equal 200 mg/dL, an A1C equal to or greater than 7.0, and a risk score as calculated by the CCMS commercial ACO software, were required to participate in a focused diabetes workplace wellness program that included health coaches to assist with eliminating barriers to improved health behaviors.

From the original group of Self Cares participants, fifty individuals qualified for the focused diabetes workplace wellness program. Of the fifty individuals identified, twenty-eight participated in the program for at least the first twelve months from October 2013 to September 2014 and had pre-program data and post-program data. The data points required for the analysis where: weight, A1C, health care and medication expense, CCMS risk score, diabetes workplace wellness program expense. The demographics for the twenty-eight participants were: 54% (n=15) Caucasian, non-Hispanic, 46% (n=13) African American, 29% (n=8) male, and 71% (n=20) female. The age of the twenty-eight

participants ranged from the youngest being twenty-five years old and the oldest being sixty-four years old at the beginning of the program. The median age of the participant group was forty-nine years old. The largest grouping of the participants was from forty to fifty-nine years old as shown in Table 7.

Table 7: Summary of Program Participant Data

Age Group (years of age)	Program Participants by Age Group	Percentage by Age Group
25 – 29	3	10.71%
30 – 34	3	7.14%
35 – 39	3	7.14%
40 – 44	4	14.29%
45 – 49	4	14.29%
50 – 54	5	17.86%
55 - 59	6	21.43%
60 - 64	2	7.14%
N =	28	100%
Minimum	25 years of age	
Median	49 years of age	
Maximum	64 years of age	

The annual health assessment that all Self Regional Healthcare employees are required to complete collects: weight, blood pressure, BMI, glucose, cholesterol, LDL/HDL, triglycerides, and A1C. Table 8 provides a summary of the initial health assessment data for the twenty-eight participants in the diabetes workplace wellness program. The minimum, median, and maximum values are calculated based on the individual value by category not as a collective set of values for an individual participant.

Table 8: Summary of Initial Health Assessment Data

	Weight (lbs.)	Syst/ Diast	BMI	Gluc mg/dL	Chol	LDL/HDL	Trig	A1C
Minimum	174	115/55	25	80	99	29/17	53	5.9
Median	253	143/76	41	191	166	96/39	107	8.15
Maximum	388	176/100	58	328	419	145/77	3456	14.5

When reviewing the raw data, it is interesting that the participant with the lowest weight (174 lbs.) also has the lowest BMI (25) but has an A1C of 8.0 which is very close to the median (8.1) for the group. This participant's glucose is reported as 142 mg/dL which is below the recommend diabetic threshold of 200mg/dL. This participant's data validates the need to evaluate multiple physiological indicators versus a single indicator when assessing an individual's ability to process glucose. The reported data for this individual is also an example of how A1C and fasting glucose screenings can contra indicate each other as previously discussed. A fasting glucose of 200mg/dL or greater and an A1C of 7.0 or greater results in a diagnosis of diabetes. This participant has a glucose of 142mg/dL, well below the established diabetic threshold, and an A1C of 8.0 which is above the diabetic threshold of 7.0.

Program Specific Data

The program specific data collected for the diabetes workplace wellness program was pre- and post- program values for weight comparison, recorded step counts as a measure of physical activity, A1C scores, risk score as calculated by the CCMS software, health care costs as reported by the participants individual 837 file submissions, and

pharmaceutical costs as recorded by Self Regional Healthcare's health insurance provider. The purpose of collecting the pre and post program data is to evaluate the impact of the diabetes workplace wellness program on the participant's specific collected physiological values.

Overall, as a group, the twenty-eight participants of the study had a mean weight of 269 pounds pre-program and a mean weight of 271 pounds after the first twelve months. The difference between pre- and post- program mean weight was an increase of a 1.6 pounds, see Table 9. Although there was a mean increase from the beginning of the program several participants succeeded in losing weight over the twelve month program. Eleven participants lost weight during the program. The weight loss by participant ranged from 1.0 pound to the maximum loss of 19 pounds. In contrast, seventeen of the participants gained weight during the program. Those participants that gained weight saw an increase ranging from 1.0 pound to 25 pounds. One participant was recorded as maintaining weight with a weight of 202 pounds during the initial health assessment and after twelve program months.

Table 9: Participant Weight Comparison

Participant Identifier	Pre-Program Weight (lbs.)	Post-Program Weight (lbs.)	Weight Difference (lbs.)
Minimum	174	175	-19
Mean	269	271	1.6
Maximum	388	413	25

As part of the diabetes workplace wellness program, participants were provided pedometers that facilitated physical activity reporting on a quarterly basis over the twelve months of the program. Table 10 provides a summary of the results of the quarterly tracking of participant step counts as recorded on personal pedometers. The mean step count for each quarter was reported as 624,993 steps in the first quarter decreasing to 491,371 steps in the fourth quarter of the program. Similarly to the decrease in total steps per quarter, the mean for the daily step average of the twenty-eight participants was 6,844 in the first quarter declining to 4,791 in the last three months of the twelve month program. Only one participant did not record any steps for the twelve months of the program. Three quarters of the program participants (75%) recorded steps for the duration of the program. A point of interest from the data was three of the four quarters of maximum steps was completed by the same program participant with the first quarter step count for this participant being 15,290 steps less than the maximum reported.

Table 10: Participant Step Count Summary

Participant Identifier	Total Steps Q1	Daily Aver Q1	Total Steps Q2	Daily Aver Q2	Total Steps Q3	Daily Aver Q3	Total Steps Q4	Daily Aver Q4
Minimum	0	0	0	0	0	0	0	0
Mean	624993	6844	532883	5941	516278	5298	491371	4791
Maximum	1222178	13285	1369752	15219	1369752	15219	1178633	12952

To evaluate the improvement of diabetes disease management as part of the diabetes workplace wellness program, A1C scores were recorded during the initial health assessment and used to identify program candidates that had a value equal to or greater than 7.0. To evaluate the impact of the program on the blood glucose management for

each participant, A1C values were also collected after twelve months of the program. It is important to note that not all participants had an A1C equal to or greater than 7.0 but the lowest A1C reported at the initiation of the program was 5.9 which close to the A1C range (6.0 to 6.5) that is used to qualify an individual as pre-diabetic and at risk for developing Type 2 diabetes.

The pre-program A1C mean for the twenty-eight participants was 8.5 with a 0.7 mean improvement over the twelve month program (Table 11). The greatest reduction by a single participant in A1C over the program period was 5.6, from 14.5 to 8.9. With one participant recording an increase in A1C from 6.3 to 8.5. Overall 64% of participants experienced a reduction in A1C during the program period with two participants seeing no change. Both of these participants recorded a pre- and post-program A1C of 6.0. Six of the participants that recorded an initial A1C equal to or greater than 10.0 had a reduction in A1C greater than or equal to 1.0, see Table 16. It is also important to note that the pre-program maximum A1C value was 14.5 and the maximum post-program value was 11.1.

Table 11: Participant A1C Comparison

Participant Identifier	Pre-Program A1C	Post-Program A1C	A1C Difference
CHP15746290901	6.6	6.3	-0.3
CHP25178081501	10.2	8.6	-1.6
CHP21482500701	8.5	7.1	-1.4
CHP25008433601	6	6	0
CHP25053503301	9.3	9.5	0.2
CHP24723330601	6.4	6.8	0.4
CHP25021709601	11.1	10.1	-1
CHP25041451701	9	8.7	-0.3
CHP41664936301	11.1	10.2	-0.9
CHP24745113901	6	6	0
CHP24841728501	7.9	8.6	0.7
CHP24813901301	8.4	8.5	0.1
CHP25080979301	8.2	7.2	-1
CHP43169645401	9.7	9	-0.7
CHP24785613901	6.3	8.5	2.2
CHP26023799601	6.8	6.6	-0.2
CHP24943148401	12.1	8.7	-3.4
CHP24841256101	11.7	10.6	-1.1
CHP24704060101	6.3	5.7	-0.6
CHP24911060701	6.2	6.3	0.1
CHP06460042601	8.1	7.5	-0.6
CHP25092857801	11.9	11.1	-0.8
CHP30904538401	7	6.3	-0.7
CHP13070296401	8	7.6	-0.4
CHP24781670701	5.9	6	0.1
CHP25117954601	14.5	8.9	-5.6
CHP24711478601	10	6.3	-3.7
CHP24955270901	6.1	6.4	0.3
Minimum	5.9	5.7	-5.6
Mean	8.5	7.8	-0.7
Maximum	14.5	11.1	2.2

The risk score data reported as part of the program was determined by using the commercially available risk ACO software, CCMS, provided by McKesson. The risk score software uses the individual participant's 837 insurance file and pharmaceutical

claims data provided by the organizational health care insurance provider to calculate a risk score that is used to rank the individual financial risk associated with an individual's health. While the risk score was not used as an identifier for program participants, it was a key data point that needed to be analyzed to determine if the risk score is similar to changes in the other program indicators, such as change in weight and A1C values for each participant.

The pre-program risk scores for the twenty-eight participants ranged from 0.13 to 10.91 with a mean of 2.09 (Table 12). The higher the score, the greater the financial risk of the individual participant. The post-program risks for the same group were from 0.65 to 12.25 with a mean of 2.35. As represented by the pre- and post-program mean values, risks score for the twenty-eight participants increased over the twelve month program period. In fact, only 29% of the program participants were successful in reducing their individual risk score. The greatest decrease and increase in the risk score for the twenty-eight program participants was -3.87 and 3.92, respectively.

Table 12: Participant Risk Score Summary

Participant Identifier	Pre-Program Risk Score	Post-Program Risk Score	Risk Score Difference
Minimum	0.13	0.65	-3.87
Mean	2.09	2.35	0.26
Maximum	10.91	12.25	3.92

Participant health care cost, including emergent, inpatient, and ambulatory care, is analyzed by calculating the pre-program and post-program difference for all twenty-eight

program participants. Total health care cost pre-program is $152,677. Total health care cost after the twelve months of the program is $107,915 which resulted in a savings of $44,763. It is important to note that the health care cost does not include the pharmaceutical cost during the program. Since the health care cost and pharmaceutical data was available separately, it was not combined to allow for an independent evaluation of the associated cost. The mean health care cost pre-program was $5,453 compared to a post-program mean of $3,854 which yields a mean pre- to post-program difference of $1,599 (Table 13). The greatest cost savings recorded was $49,739 and the greatest increase in health cost was $17,423. Without a detailed medical record chart abstraction, it would be difficult to determine the exact cause of the cost savings or increase. Based on the research question and the approved use of de-identified data by the IRB committee, medical record chart abstraction is outside the scope of this project. Sixteen of the twenty-eight participants (57%) did record a cost savings over the twelve months of the program.

Table 13: Participant Health Care Cost Summary

Participant Identifier	Pre-Program Health Care Cost	Post-Program Health Care Cost	Health Care Cost Difference
Minimum	$41	$228	-$49,739
Mean	$5,453	$3,854	-$1,599
Maximum	$64,300	$28,477	$17,423

Similar to the health care cost analysis, pharmaceutical cost was calculated by determining the difference between the pre-program pharmaceutical cost and post-

program pharmaceutical cost. The data used for this analysis was provided by Self Regional Healthcare's insurance provider as a de-identified annual pharmaceutical cost summary by program participant from October of 2012 to September of 2013 (pre-program) and October 2013 to September of 2014 (post-program), Table 14. Total pharmaceutical cost pre-program is $114,753. Total pharmaceutical cost after the twelve months of the program is $152,636 which is an increase year over year of $37,883. The mean pharmaceutical cost for pre-program and post-program is $4,098 and $5,451, respectively. The mean difference between pre- and post-program is an increase $1,353 which supports the recorded increase for all twenty-eight participants. Evaluating the difference in pharmaceutical cost for the twenty-eight participants, 71% recorded an increase. Of those that increased, thirteen of the twenty-eight participants had an increase of $1,000 or greater in pharmaceutical cost with the greatest increase being $10,369.

Table 14: Participant Pharmaceutical Cost Summary

Participant Identifier	Pre-Program Pharmaceutical Cost	Post-Program Pharmaceutical Cost	Pharmaceutical Cost Difference
Minimum	$22	$247	-$4,838
Mean	$4,098	$5,451	$1,353
Maximum	$36,381	$31,543	$10,369

Statistical Analysis

To determine if there is a significant difference in individual A1C, risk score, and participant's weight as a result of the program, a two-tailed T-test was completed by comparing the pre- and post-program data. The results of the two-tailed T-test are reported in Table 15. Evaluation of the reported results for the A1C data suggests a statistical difference based on the P-Value being less than 0.05 and the T-Calculated Two Tail Value of 2.58 being greater than the T-Critical Two Tail Value (2.05). The difference for the risk score and weight was not determined to be statistically significant. The mean difference for A1C, risk score, and weight is -0.7, 0.26, and 1.6 respectively with the A1C data being the only data set to demonstrate a reduction in the A1C values for the twenty-eight program participants.

Table 15: Two-Tailed T-Test Results of Program Specific Data

Data Set	T-Critical Two Tail Value	T-Calculated Two Tail Value	P - Value	Lower Confidence Level	Upper Confidence Level
A1C	2.051830516	2.583585604	0.007756048	-1.294372296	-0.148484847
Risk Score	2.051830516	1.09132171	0.284774636	-0.228206046	0.746777474
Weight	2.051830516	0.817661404	0.420707917	-2.42580372	5.640089434

To evaluate the health care and pharmaceutical cost difference between pre- and post-program participant data, the Wilcoxson Signed Rank Test was used. The Wilcoxson Signed Rank Test is used to analyze the cost difference since it is a non-

parametric version of the T-Test. The Wilcoxson Signed Rank Test compares a critical value based on sample size and a calculated test value. If the calculated test value is less than the critical value, sufficient evidence exists to suggest there is statistical difference between the pre- and post-program cost data. The Wilcoxson Signed Rank Test critical value for a sample size of twenty-eight is 116. The calculated test value for health care cost and pharmaceutical cost is 171 and 78, respectively. This suggest that there is statistical difference in the pharmaceutical cost data (78<116) but not the health care cost data (171>116).

In addition to determining statistical differences in the A1C, risk score, weight, health care cost, and pharmaceutical cost for the diabetes workplace wellness program, correlation between the A1C and health care costs was evaluated. Using the Spearman Rank Correlation Test to evaluate the correlation between the A1C values and health care cost without assuming a linear relationship. Spearman's Rank Correlation Test compares a calculated value based on a 1 to -1 scale, where 1 and -1 implies a correlation of the data and 0 implies no correlation. The calculated Spearman Correlation value for the pre- and post-program difference for A1C and health care cost is 0.073618 which is closer to 0 than 1 indicating little to no correlation between: (1) the difference between the A1C values pre-program and post-program and (2) the difference in health care cost pre-program and post-program.

Program Cost Data

The cost benefit analysis (Table 16) assesses: the total health care cost for the program participants prior to program initiation (Y_0); the health care cost for the program participants during the program period (Y_1); and the total cost of the program including software expense (P_s), program personnel (P_p), and program incentives (P_i). Using these factors, the following formula was used to calculate the program cost benefit analysis.

$$CBA = Y_0 - (Y_1 + P_s + P_p + P_i)$$

P_i is the program incentive for the twenty-eight participants. It includes: the annual cost of gym memberships for those participants that enrolled as part of the program, the total cost of sneaker vouchers provided to those participants that lacked appropriate exercise footwear, and the $200 per month per participant reduced health insurance premium. P_i for the twenty-eight program participants equals $94,920.00 for the twelve months of the program. P_p is the labor expense for the employees that administered the program which included the health coach and a .25 portion of a team leader. The total program expense for P_p was $117,944.00. P_s is the cost to implement the CCMS ACO software that was used to calculate each participants risk score. The total cost of P_s was $573,640.64. Y_1 is the total health care and pharmaceutical cost recorded for each program participant of the twelve month program, equaling $260,550.90. Y_0 is the same calculation as Y_1 accept it is using the pre-program health care and pharmaceutical data. Y_0 equals $267,429.99. The calculated Cost Benefit of the diabetes

workplace wellness program is a - $779,625.55. The resulting negative CBA value indicates the diabetes workplace wellness program cost more in the first twelve months than the savings associated with health care and pharmaceutical cost. It is important to note that the cost difference of health care and pharmaceutical cost pre- and post-program was a savings of $6,879.09.

Table 16: Program Cost Benefit Analysis

	Y_0	Y_1	P_s	P_p	P_i
Gym Membership					$27,520
Sneakers					$200
Reduced Insur. Premium					$67,200
1.25 FTE's				$117,944	
Risk Software			$573,640.64		
Health Care Expense	$152,677.47	$107,914.60			
Pharmaceutical Expense	$114,752.52	$152,635.30			
CBA Total	($779,625.55)				

In addition to calculating the CBA of the diabetes workplace wellness program, a return on investment calculation was needed to answer the research question, "Can using an ACO commercially available software tool and a diabetes wellness workplace management program be combined to identify 1 year ROI in a sample of patients within an average size institution?" To determine the ROI of the diabetes wellness program the ROI formula below was used.

$$\text{Return on Investment} = \frac{\text{(Investment Gain – Investment Cost)}}{\text{Investment Cost}}$$

The investment gain for the program was the health care and pharmaceutical cost savings of $6,879.09, previously discussed. The investment cost is the total cost of P_s, P_p, and P_i (Table 21) which equals $786,504.64. Using the calculated investment gain and investment cost, the ROI for the diabetes workplace wellness program is –99% as shown below.

$$ROI = \frac{(\$6{,}879.09 - \$786{,}504.64)}{\$786{,}504.64}$$

$$ROI = -0.99$$

Although the program cost data does not indicate a significant cost savings or return on investment for the diabetes workplace wellness program, it is important to evaluate all data results of the program before assuming a lack of positive outcome.

In addition to calculating the ROI based on the savings and expenses associated with the twelve month program, a sensitivity analysis was completed on the data collected in an effort to understand the impact to ROI. The first sensitivity analysis was focused on extrapolating the ROI over a five year period using the data collected as the basis of the calculation. Table 16 provides the results of the analysis which is based on: an annual growth in participants; expensing the commercial software (P_s) equally over a five year period instead of in the first year as above and assuming the software cost is static regardless of the number of program participants; increasing the program incentive expense (P_i) according to the participant number; and increasing the labor cost (P_p) to provide appropriate staffing as the program participants increase. The program savings is determined by assuming the expense for each participant will be reduced by $248.68

annually. This was calculated by using the total health care and pharmaceutical cost savings and dividing it by the number of program participants, twenty-eight, yielding a cost savings per participant.

Table 17: ROI Sensitivity Analysis

	Year 1	**Year 2**	**Year 3**	**Year 4**	**Year 5**
Number of Program Participants	100	250	500	750	1000
P_s	$114,728	$114,728	$114,728	$114,728	$114,728
P_i	$339,000	$847,500	$1,695,000	$2,542,500	$3,542,112
P_p	$117,944	$117,944	$235,888	$235,888	$283,066
Program Savings	$24,568	$61,420	$122,841	$184,261	$245,682

Using the extrapolated data in Table 22 to calculate the ROI over a five year period results in the following:

$$ROI = \frac{(\$638{,}773 - \$10{,}378{,}370)}{\$10{,}378{,}370}$$

$$ROI = -0.94$$

Performing a similar analysis but assuming P_s is the only program expense and the number of participants increase over a five year period as described in Table 16, results in a ROI of 0.11. Using the data collected to create a five year forecast, highlights the significant amount of expense associated with P_i even in comparison to P_s.

DISCUSSION

The findings of the evaluation are: (1) The statistically significant difference in participant's A1C values pre- and post-program; (2) The medical and pharmaceutical cost difference pre- and post-program; (3) The lack of change in the pre- and post-program for both the participant's weight and ACO risk score; and (4) The negative results of the financial evaluation, specifically for the cost based analysis (CBA) and the return on investment (ROI).

The improvement in the A1C scores of the study population is the most significant finding of the research. As a result of providing a workplace wellness program at Self Regional Healthcare, the individuals that participated saw an improvement in the management of diabetes as it relates to A1C scores. Through the focused efforts of health coaches, the participants not only received assistance with how best to manage their diabetes, they understood their current health and how behavior changes could provide better overall health. Empowered with this information, the program population began this improvement by positively changing their A1C values over the twelve month program. Significant evidence exist that demonstrates the more engaged patients are in their own care, the better the results are from health interventions or recommended behavior changes. The fact that the population of this study saw improvement in their A1C scores as a result of the diabetes workplace wellness program is a similar result to previous research. The diabetes workplace wellness program provided can be built upon by further expanding the program to Self Regional employees that are within the current

program range but more importantly individuals that have an A1C 5.5 to 6.0 range, considered pre-diabetic, since minimal weight loss and behavior change could prevent these individuals from becoming diabetics. Ultimately, that is a policy goal of ACOs which is to improve patient's health and reduce the expense of the health care system by having engaged patients that take responsibility for being healthier versus being dependent on the health care industry to correct preventable health conditions.

Prior research demonstrates the ability to provide a positive return on investment in workplace wellness programs by reducing the overall health care expense per employee year over year and/or maintaining or reduce the expense related to provide health insurance as an employee benefit. The medical and pharmaceutical cost difference from pre- to post-program was the second most significant finding of the research. The medical and pharmaceutical costs for the twenty-eight participants was $152,677 and $114,753, respectively. The medical and pharmaceutical costs post-program was $107,915 and $152,636, respectively. When comparing the combined costs for medical and pharmaceutical costs pre- and post-program it was determined that the total cost savings was $6,879.09 over the twelve month period. Evaluating the cost data for medical and pharmaceutical expenses separately demonstrated that an almost equal cost shift occurred. That is, while the medical costs associated with caring for the twenty-eight participants decreased, the pharmaceutical costs over the evaluation period increased. This is an indication of using medication to better manage diabetes for the twenty-eight participants. As discussed previously, patient engagement in their care is a key factor in managing a disease like diabetes. Another key component is making sure appropriate

health care is accessible. By providing health coaches as part of the program, participants were able to receive assistance in obtaining appropriate care in the form of improved medication access while reducing episodic treatment by medical professionals. The increase in pharmaceutical cost over the twelve month period while medical cost was reduced points to engaged participants having access to appropriate disease management. Again, tying the diabetes workplace wellness program to the policies of ACOs, accessibility to appropriate medical care is included by requiring ACO patients to have a medical home and reduce the expense of medical care by focusing more on preventive care in place of expensive episodic care. While the diabetes workplace wellness program did not eliminate diabetes for the participants, the focused care management did provide a more stable management of the disease by reducing the amount of medical treatment needed.

There is minimal if any correlation between the difference in program medical cost and the reduction of A1C participant values. Based on the statistical analysis, the efforts of the diabetes workplace wellness program did not result in a statistical difference or correlation between the cost difference and change in participant A1C values. This indicates that the change in cost, whether as an increase or decrease, from pre- to post-program did not provide influence on the improvement of the A1C values for the study group. Based on the program evaluation being a twelve month period, the A1C value appears to be more related to the impact of the health coaches than the change in cost associated with the medical care. Based on the improved health behaviors of the participants, the medical cost savings is more an indication of patient engagement.

The third most significant finding of this project is the evaluation of the pre- and post-program weight and ACO risk score. The twenty-eight participants had a mean pre-program weight of 269 pounds. Over the twelve month period the program group increased the mean weight to 271 pounds, though not statistically significant. This was not an expected outcome based on the utilization of health coaches to assist each participant with adjusting behaviors to better manage their diabetes. In addition to the health coaches, each participant received program incentives that eliminated barriers to a healthier lifestyle. These incentives included appropriate exercise footwear, gym membership, and pedometers. While these incentives appeared to be of benefit during the first quarter of the program, there utilization appeared to decline over the twelve month program. By evaluating the quarterly step data tracked on the participant's pedometers, the mean daily average number of steps decreased by over 2,000 steps from the beginning of the program to final quarter of the twelve month period. The recommended daily average step count goal is 10,000 steps a day and the program participants cumulative daily average step count was under 7,000 steps in quarter one and declined to less than 5,000 steps in quarter four of the twelve month program. This result assists in explaining why the program participant's weight remained relatively unchanged as part of the part of the workplace wellness program.

The ACO risk scores calculated using the CCMS tool, pre- and post-program, were compared to determine if the reduction in medical cost and increase in pharmaceutical cost had an impact on the participant risk scores. As reported in the results section, the mean risk scores of program participants only changed by 0.26 over

the twelve month program. Since the risk scores are directly related to the overall health care cost for each participant, minimal change in the mean risk score aligns with the marginal change in the total medical and pharmaceutical cost recorded for the program participants. As with the weight evaluation, the results of a two-tailed T-Test comparing risk scores did not determine a statistical difference. What is interesting, is the risk score saw little change as a result of the program even though the A1C values for the program are statistically different. This is an indication why evaluating a patient's health solely based on cost may not be the most accurate method and that even though the cost for the twenty-eight program participants to receive medical and pharmaceutical care did not have a significant savings the overall value used to assess diabetes, A1C, did improve. As reimbursement within the health care industry continues to be more restrictive, the industry is become much more cost conscious. Eliminating wasteful spending in health care is the correct direction and is part of accountable care policy. That being said, health care is not an industry of "widget making" and should be evaluated from multiple disciplines such as finance, clinical efficiency, and quality of care received. By evaluating one of these, such as finance, without consideration of the other two could result in the improvement of the specific discipline at the expense of inefficient clinical practice or poor quality outcomes for the patient. The other challenge of evaluating the true impact of this study is the unknown cost avoidance for the twenty-eight participants. Determining if the diabetes workplace wellness program prevented more costly care, such as hospitalization due to acute ketoacidosis, would require data collection over a longer period of time to apply national diabetes trending data in comparison to the care required to the twenty-eight participants.

Diabetes is reported as consuming one in every ten health care dollars in the United States. That translates to the cost of care associated with diabetes accounts for over a trillion dollars a year. For this reason, many health care providers understand the value of reducing the cost associated with caring for patients with diabetes and finding ways to reduce the number of new diabetes diagnoses on an annual basis. As discussed previously, the ACO model attempts to achieve better engagement by individuals in maintaining good health and reducing the expense of services needed when health care is necessary.

The fourth significant finding of this research is the negative results of the financial evaluation, specifically for the CBA and ROI of the diabetes workplace wellness program. The CBA is a basic calculation used to determine if the total costs for the diabetes workplace wellness program were lesser or greater than the total cost of providing medical and pharmaceutical care to the twenty-eight program participants. As reported in the Results section, the CBA Total was a loss at -$779,625.55 for the program. The pre-program cost, which was the total medical and pharmaceutical expense, for the participants was $267,429.99. The total cost for the diabetes workplace wellness program, which included program personnel, software expense, incentive expense, and total health care costs, was $1,047,055.54. For a positive CBA to occur the total program expense would have needed to be less than $267,000.00 within the first year. Adding the commercial ACO software and health coach staff made it very difficult to achieve a positive CBA. Both of these program components cost, ACO software and staff, cost the program $573,640.64 and $117,944.00, respectively. Removing those two program

expenses would have resulted in a negative CBA of -$88,040.91 for the first year of the program. While the cost of the health coach staff and commercial software had a significant impact on the overall CBA, it would be difficult to eliminate both of these components of the program. The health coach employees worked directly with the patients to eliminate barriers to receiving appropriate care and drive higher engagement and responsibility by the participants. Without the health coach involvement, the A1C values may not have improved as they did over the twelve month program. The commercial software expense is an unfortunate reality of health care information technology. The health care industry is very expensive and the non-direct patient care tools used are no exception. The software utilized in health care is very expensive and should be an area of focus for information technology professionals. As new software is being considered for purchase, information technology professionals should first evaluate what the return on investment will be by adding new tools. In many cases, software is purchased solely on new functionality with little consideration of how net revenues will be improved. If software is purchased without the financial analysis, the additional functionality could easily have a negative impact on the net revenue for the organization which could lead to increased fees for services to maintain operating margins. Once it is determined that the new functionality will be beneficial to clinical efficiency, quality outcomes, and organizational finances, information technology leaders should find ways to reduce duplication of products and identify the best pricing to avoid utilizing capital that is best spent on direct patient care tools. These types of expenses all relate back to the overwhelming expense patients incur when receiving care in the current health care model.

The ROI for the diabetes workplace wellness program has similar results to the CBA calculation. The ROI calculation is a formula that compares the investment gain and investment cost to determine if the program provided a positive or negative return on the funds invested to initiate the program. With the investment cost being so much greater than the investment gain in the twelve months of the program, it is not a surprise that the program had a – 99% ROI. As it was explained with the CBA results, the capital expense of adding the commercial ACO software and the staffing expense significantly reduced the ability of the program to generate a positive ROI. That coupled with the cost savings for medical and pharmaceutical expense only totaling $6,879.09, a negative ROI is to be expected. As mentioned previously, estimating the ROI of new information technology solutions should be completed prior to purchase and implementation of the product. In the new health care reimbursement model, all payers in the industry are reducing the reimbursement for care provided and hold health care organizations accountable for finding cost savings. At the same time health care legislation is challenging organizations to be more transparent with price and quality which requires new systems and services to be put in place, such as diabetes workplace wellness programs. The challenge of this model is the funding for service expansion is being reduced while capital investments are being increased. The diabetes workplace wellness program reviewed in this research has demonstrated an improvement in participant A1C values within the first twelve months of the program which is a success. The negative ROI indicates more money was spent than saved but typically ROI's are determined over a much longer period of time allowing for increased savings to offset the initial expense of establishing the program. Even after expanding the program via the sensitivity analysis, which allowed for greater program

time and more participants, only improved the ROI to -94%. Only by eliminating the program incentive expense over a five year period with program participant growth resulted in a positive ROI of 11%. Using the ROI calculation listed above could be considered too harsh of an evaluation for the purposes of this research, but using a financial ROI evaluation is a reality of the current health care industry. Not all processes in health care are driven by financial evaluations but ignoring these types of evaluations has a potential for greater impact than anticipated.

Limitations of the research associated with the diabetes workplace wellness program range from a small participant population to assuming the cost of a commercial ACO risk tool in the first year. The population used for the program originally was slated for fifty participants from a single organization but was reduced to twenty-eight participants due to a lack of data or failure of the participant to enroll. The fact that a small population from a single organization was used makes it difficult to generalize the findings. Most of the research reviewed in preparation for this project used populations that numbered in the tens to hundreds of thousands and were mostly focused on workplace wellness programs without ACO software. When considering the sample size of the research, it is almost important to note the impact of the law of large numbers and how a greater participant population would have an impact on the results of similar research. A second limitation was the program was developed as a pilot to assess the benefit of the ACO software in combination with a workplace wellness program. While pilots are beneficial to perform initial evaluations, that are also usually the first effort to develop processes and procedures. Developing the functionality of the program at the

same time of evaluating the program resulted in unexpected issues that would impact the outcome of the program such as adding or removing participants of the program to maintain the original program population. A third limitation, was the length of the study. Twelve months for a financial evaluation of a small population is challenging. Especially when the majority of program expenses are incurred in the first twelve months. Not accounting for the deflation or inflation of costs over the twelve month period is the fourth limitation and it should be noted that the costs of the medical and pharmaceutical care were realized and not observed. The fifth and possibly greatest limitation to the program was the cost of the commercially ACO software. Utilizing a fully functional, large population tool to assess the risk of a small population created excessive financial burden on both the CBA and ROI analysis.

Future research that should be attempted based on the findings of this project would be to evaluate the financial outcome of an identical project with a much larger population over a five year time frame. The five year time frame is the standard length of time to fully expense capital software purchases versus assessing the total software cost in the first year. Additionally, it would be interesting to understanding if a program based on increased pharmaceutical care for diabetics would provide the same benefit as this diabetes workplace wellness program. Based on the results of the program, it appears that the increase in pharmaceutical expense reduced the medical expense for the participants of the program and the overall A1C. This may be an artifact of the limited population size but is worth investigating further.

In conclusion, the answer to the research question, "Can using an ACO commercially available software tool and a diabetes workplace wellness management program be combined to identify 1 year ROI in a sample of patients within an average size institution?" is yes, it was possible to calculate an ROI but resulted in a negative return on investment. The research hypothesis, "Utilizing the tools provided with both commercially available ACO software and workplace wellness program structure, the cost associated with managing the health care of individuals diagnosed with diabetes will be reduced" must be rejected based on both the negative CBA and ROI results. That being said, understanding the dramatic impact diabetes has on individuals diagnosed with the disease, health care resources, and overall expense to the health care system, this research provides evidence that the ACO model combined with a workplace wellness program does address the impact on the individual by improving the management of the disease, as seen by the reduction in A1C values, and reduces the burden on health care resources by reducing the need for medical care by properly utilizing pharmaceutical care to manage the individual's diabetes. The program results also demonstrate that to positively impact the financial burden on the health care system, the ACO model is a long term proposition that requires substantial and continuous effort to modify the behaviors of individuals and increase their engagement in preventative care versus episodic care. Being able to move the A1C value in the right direction is the greatest success of this research. It is important that even though the financial evaluations of the program indicate a less than positive result, I believe this is more a reflection of the length of time and size of population of the program than determinant of program value.

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