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The effectiveness of St. Joseph Mercy Center for Diabetes Education Program at one and two years post education

Clisty Kinlin

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The Effectiveness of St. Joseph Mercy Center for Diabetes Education Program 

at One and Two Years Post Education 

by 

Clisty S. Kinlin, RD, CDE 

Thesis 

Submitted to the School of Health Sciences 

Eastern Michigan University 

in partial fulfillment of the requirements 

for the degree of 

MASTER OF SCIENCE 

in 

Human Nutrition 

Thesis Committee:

Chair: Rubina S. Haque, PhD, RD 

Anahita Mistry, PhD, RD 

Karen Karolle-Caton, MS, RD 

March 14, 2014 

Ypsilanti, Michigan
Dedication

I dedicate this thesis to those that have been affected by diabetes. Until there is a cure, may you find a way to not only live but also thrive with this disease.

I also dedicate this to my son Maxwell. May you always be courageous enough to think for yourself. May you always look at life and the world with wonder and amazement.
Acknowledgements

I would like to acknowledge my thesis advisor, Dr. Rubina Haque, I am deeply grateful for your guidance and unending patience.

Dr. Anahita Mistry, I would like to thank you for your guidance and support throughout this academic journey.

Karen Karolle, thank you for the ideas, knowledge, support, and friendship that you have given me throughout the years.

To my friends and family, thank you for your unwavering encouragement and support, especially when I needed it most. Without all of you, this would not have been possible for me.
Abstract

**Background:** Diabetes is a disease of the endocrine system characterized by hyperglycemia, which can lead to multiple microvascular and macrovascular complications. Successful control of blood glucose levels can decrease associated complications.

**Objective:** This study evaluated the effectiveness of nutrition and lifestyle interventions in people diagnosed with type 2 diabetes.

**Methods:** A retrospective study reviewed laboratory data of individuals that attended the St. Joseph Mercy Center for Diabetes education program. HbA1c and lipid value were evaluated to determine the effectiveness of the program.

**Results:** Baseline HbA1c for all groups was 8.33%. Post-Program HbA1c was 6.70%, showing a 1.63% (p<0.0001) reduction from Baseline to Post-Program. There was a significant reduction in HbA1c of 1.4% (p<0.0001) for all groups from Baseline to 2-years Post-Program. Lipid levels did not show a significant change from Baseline to Post-Program, however, lipid levels reached target levels and continued to improve through 2-years Post-Program.

**Conclusion:** This study supports the effectiveness of the St. Joseph Mercy Center for Diabetes education program for lowering HbA1c levels and maintaining HbA1c and lipid levels within the recommended ranges.
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LIST OF ABBREVIATIONS

The following table describes the various abbreviations and acronyms used throughout this thesis, as well as the page on which each one is defined or first used.

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<th>Abbreviation</th>
<th>Meaning</th>
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<td>ADVANCE</td>
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<td>ANOVA</td>
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<td>CVD</td>
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<td>DCCT</td>
<td>Diabetes Control and Complications Trial</td>
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<td>DM</td>
<td>diabetes mellitus</td>
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<tr>
<td>DPP</td>
<td>Diabetes Prevention Program</td>
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<td>DPPOS</td>
<td>Diabetes Prevention Program Outcomes Study</td>
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<td>DSME</td>
<td>Diabetes Self-Management Education</td>
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<td>DSMEP</td>
<td>Diabetes Self-Management Education Program</td>
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<tr>
<td>EDIC</td>
<td>Epidemiology of Diabetes Interventions and Complications</td>
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<td>FPG</td>
<td>fasting plasma glucose</td>
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<td>GDM</td>
<td>gestational diabetes</td>
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<td>HbA1c</td>
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<td>HDL</td>
<td>high-density lipoprotein</td>
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<td>MNT</td>
<td>medical nutrition therapy</td>
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<td>NP</td>
<td>Nurse Practitioner</td>
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<td>OGTT</td>
<td>oral glucose tolerance test</td>
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<td>PCMH</td>
<td>patient centered medical home</td>
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<td>RBC</td>
<td>red blood cell</td>
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<tr>
<td>RD</td>
<td>Registered Dietitian</td>
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<tr>
<td>SJM</td>
<td>St. Joseph Mercy</td>
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<td>SJMHS</td>
<td>St. Joseph Mercy Health System</td>
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<td>Type 1 diabetes mellitus</td>
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<td>T2DM</td>
<td>Type 2 diabetes mellitus</td>
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<tr>
<td>TC</td>
<td>total cholesterol</td>
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<td>UKPDS</td>
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<td>VADT</td>
<td>Veterans Affairs Diabetes Trial</td>
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<tr>
<td>VLDL</td>
<td>very low-density lipoprotein</td>
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Chapter 1: Introduction

Background

It is well known that diabetes mellitus (DM) is a growing epidemic. As of 2010, approximately 25.8 million people living in the United States were affected by diabetes, which is roughly 8.3% of the total US population. Nearly 19 million people are diagnosed with diabetes; this includes gestational diabetes (GDM), type 1 diabetes (T1DM), and type 2 diabetes (T2DM) (Center for Disease Control and Prevention [CDC], 2011). Type 2 diabetes mellitus accounts for approximately 90-95% of the diagnosed cases of diabetes (CDC, 2011). Along with this data, it is estimated that approximately seven million people are living with undiagnosed diabetes, while another estimated 79 million people have pre-diabetes (CDC, 2011). The current cost of medical expense is approximately 2.3 times higher in individuals with diabetes when compared to individuals without diabetes because of the associated complications (CDC, 2011). The greater burden of medical costs occurs with individuals diagnosed with pre-diabetes and T2DM (CDC, 2011). The cost of diabetes is likely to grow as more people are diagnosed with both pre-diabetes and T2DM. An effective Diabetes Self-Management Education program (DSMEP) can help lower the burden of cost that diabetes has on the health care system by helping to provide essential skills and education necessary to maintain optimal glycemic control and minimize related complications (American Diabetes Association [ADA], 2011).

What Is Diabetes?

Diabetes mellitus is a disease of the endocrine system, characterized by hyperglycemia (McCance, 2009). During digestion, consumed food is broken down into smaller units, which facilitates the absorption of nutrients and their utilization by the body (McCance, 2009). Carbohydrates are digested into the simplest form of sugar, known as glucose. Glucose circulates through the bloodstream and is distributed to cells throughout the body, including but not limited
to the hepatic, skeletal, and the adipose tissue, where it is used as energy (McCance, 2009).

Insulin, an anabolic peptide hormone produced by the beta cells of the pancreas and secreted into the blood stream, allows glucose to move from blood into the body cells. Normally, insulin attaches to its specific cell surface receptors and facilitates the transport of glucose into cells. This action makes insulin a requirement for the uptake of glucose from the blood stream into body cells, where it is metabolized and hence provides energy for cellular processes (McCance, 2009).

Diabetes results from aberrations in the production or use of insulin. Excessive amounts of glucose in the blood stream, hyperglycemia, occurs when insulin is not sufficiently produced or is inefficiently utilized, preventing glucose from entering the cells and forcing it to remain in the blood stream. (McCance, 2009). A consequence of hyperglycemia is the irreversible bonding of glucose to hemoglobin in the red blood cells (RBC’s). This process known as glycation, results in damage to many organs and systems of the body (McCance, 2009).

When blood glucose levels remain elevated, in addition to glycation of hemoglobin, other proteins and lipids in cellular structures also become glycated and interfere with normal cellular functions (McCance, 2009). In an individual with sustained elevated blood glucose levels, every organ and system of the body can be damaged because of the glycation process (McCance, 2009). Long-term chronic hyperglycemia increases the risk of development of microvascular and macrovascular complications. Microvascular complications include, retinopathy, neuropathy, nephropathy, and macrovascular complications involve the cardiovascular system (American Diabetes Association [ADA], 2012). Successful control of blood glucose levels can prevent and or delay the long-term complications associated with DM (ADA, 2011).
Lipids and Cardiovascular Disease

There are several types of lipoproteins—chylomicrons, very low-density lipoprotein (VLDL), low-density lipoprotein (LDL), and high-density lipoprotein (HDL)—in the human body that affect cardiovascular function and are measured to assess cardiovascular health. Lipoproteins are comprised of protein bound cholesterol, triglycerides, and phospholipids (McCance, 2009). Lipids have many important roles in the body. They function as components of plasma membranes, as hormones, and bile acids. However, abnormal levels in plasma can increase risk for CVD (McCance, 2009). The lipid metabolism cycle is complex, and involves several types of lipoproteins that are not routinely measured. For the purpose of this study, only the lipoproteins measured for analysis will be discussed. The low-density lipoprotein (LDL) is composed of mainly cholesterol and protein (McCance, 2009). While LDLs are necessary, higher levels promote atherogenesis thus leading to cardiovascular disease (CVD). This occurs with increased endothelial dysfunction and oxidation of the LDL, leading to formation of foam cells that get embedded in the coronary vessel wall, resulting in thickening and hardening of vessel walls and form plaques (McCance, 2009). The high-density lipoprotein (HDL) is composed of mainly phospholipids and protein (McCance, 2009). The main role of the HDL component is to clear excess cholesterol from the blood stream, cell membranes, and other lipoproteins and return them to the liver where they form other necessary components. Low HDL levels have been associated with increased risk for CVD (McCance, 2009).

A measure of the laboratory values for LDL, HDL, and total cholesterol (TC), the sum of the types of cholesterol measured in blood, is used to monitor CVD in patients with diabetes (Buse, 2007). Normal laboratory values used as standards are; TC <200 mg/dL, LDL <100 mg/dL, and HDL >40 mg/dL for men and >50 mg/dL for women (Buse, 2007).
Measures of Control and Interventions

Interventions provided by a qualified health care team can help delay progression and prevent long-term complications related to diabetes (ADA, 2011). These interventions may include pharmacotherapy agents, nutrition education and counseling. The health care provider may help manage diabetes by providing appropriate pharmacotherapy agents to help control glucose levels, as well as by monitoring glycemic control and treating complications that occur (ADA, 2011). Monitoring how well a person is controlling his/her blood glucose is often done with the use of laboratory values such as the Hemoglobin A1c (HbA1c), which is a measure of glycated hemoglobin in the blood stream (ADA, 2012). Since the life span of RBCs is two to three months, glycated hemoglobin or HbA1c is an important indicator of blood glucose levels during an eight to twelve week period. Normal levels of HbA1c are between 4-6% (ADA, 2012). Since HbA1c levels are not altered by daily variations it is currently used for diagnostic purposes as well as a marker for overall blood glucose control (ADA, 2012). People diagnosed with diabetes are also evaluated regularly for serum lipid values like total cholesterol (TC), low-density lipoprotein (LDL), and high-density lipoprotein (HDL) since they are at a higher risk for developing macrovascular complications (Buse, 2007).

Many available standards of medical care suggest that a Diabetes Self-Management Education program (DSMEP) is an effective intervention for helping individuals with diabetes to understand the disease, delay its progression and reduce associated complications (Funnell, 2007). A qualified DSMEP uses evidence-based guidelines and is formulated to provide education and necessary tools to patients managing diabetes, which can ultimately reduce the risk of related complications (ADA, 2011). A qualified DSMEP utilizes a team of health care professionals such as a Registered Dietitian (RD), a Registered Nurse (RN), and often times a Social Worker (MSW), who are trained to provide education, skills, and support to patients with
diabetes. The DSMEP may be delivered on an individual or a group basis, using an evidence-based diabetes education curriculum. Current and past research concludes that DSMEPs continue to remain a necessary and effective method of helping individuals control blood glucose levels while the patient is in contact with the DSMEP (ADA, 2011). Many programs currently exist, including the St. Joseph Mercy (SJM) Center for Diabetes DSMEP in Michigan.

**Saint Joseph Mercy Health System**

The St. Joseph Mercy Health System (SJMHS) has been providing Diabetes Self-Management Education (DSME) to patients for the past 20 years. Patients diagnosed with diabetes are referred to the SJM Center for Diabetes from their endocrinologist or their primary care physician using the SJM Center for Diabetes Service Request Form (Appendix 3). The SJM Center for Diabetes DSMEP is an accredited program by Michigan Department of Community Health and American Association of Diabetes Educators, and consists of an initial 30-minute evaluation by either a Registered Dietitian (RD) or a Registered Nurse (RN). If the patient has T1DM or T2DM and is on an exogenous insulin regimen, the initial individual visit is scheduled for 30 minutes with an RN and an additional 30 minutes with an RD or RN. Following the initial visit, the patient is scheduled for nine hours of group education in a classroom format, in the form of three 3-hour classes one week apart. Information is provided via live lecture and through supplemental books written by the SJM Center for Diabetes staff. Various topics are included during the course of nine hours including: diabetes overview, meal planning, medications, hypoglycemia, monitoring, exercise, hyperglycemia, sick day management, complications, foot care, community resources, dining out, label reading, chronic disease prevention, and goal setting.

Upon completion of the nine hours of classroom instruction, an hour-long individual follow-up visit is planned, three to six weeks subsequent to the classroom instruction. The
follow-up visit consists of 30 minutes with an RD and 30 minutes with an RN (Appendix 4). If the follow-up visit is not attended, the program is considered not completed, even if the group education classes were attended. The duration of the full program is approximately two to three months and typically no further follow-up visits are scheduled.

Statistics are collected on each patient at the beginning and conclusion of the program. Data collected for this program have continually supported favorable outcomes on HbA1c levels and have led to the conclusion that the SJM Center for Diabetes DSMEP is effective at lowering HbA1c levels in patients during attendance in the program (Karolle, 2011). To date, data have been lacking to support any inference that the DSMEP continues to remain effective after the patient is discharged from the program.

**Purpose of the Study**

The purpose of this study is to investigate the long-term effectiveness of the SJM Center for Diabetes DSMEP. Current data provided by SJM Center for Diabetes states that the DSMEP is effective at lowering HbA1c levels from the time the patient enters into the program to the time the patient has received education and is discharged from the program (Karolle, 2011). This study will investigate the significance of changes found in HbA1c levels in the one and two years following the education program. This study will also investigate the significance of changes found in lipid values in the one and two years following the education program.

**Research Questions**

1) Is the SJM Center for Diabetes DSMEP effective at lowering and/or maintaining lowered HbA1c levels at one year and two years after receiving education?

2) Is the SJM Center for Diabetes DSMEP effective at lowering and/or maintaining lowered lipid levels at one year and two years after receiving education?
**Justification and Significance**

It is has been shown that DSMEPs are an important component of patient care for people with diabetes (ADA, 2011). These services have been shown to help reduce the microvascular and macrovascular complications related to diabetes, thus leading to a decrease in hospital stays and the financial burden on health care systems (Funnell, 2007). Lack of DSME services can result in an overall increase in complications that may otherwise have been prevented (Funnell, 2007). This study will observe long-term data on glycemic and lipid control after patients complete the SJM Center for Diabetes DSMEP.

The results from this study may be used to justify the significance of the DSMEP as an effective method of improving health outcomes in patients with diabetes to local physicians and physician groups that are converting to the Patient Centered Medical Home (PCMH) model (Bojadjievski & Gabbay, 2011). The PCMH model follows the Chronic Care Model, “a widely accepted evidence-based guide to quality improvement efforts in the primary care setting” (Bojadjievski & Gabbay, 2011), the goal of which is to provide the patient with a complete and comprehensive health care team within the same facility as the primary care physician (Bojadjievski & Gabbay, 2011).

Patient centered medical home offices generally provide any necessary health education within the primary care setting, often by a Nurse Practitioner (NP; Bojadjievski & Gabbay, 2011). If the results of this study show that the SJM Center for Diabetes DSMEP is effective at lowering and/or maintaining lower HbA1c levels well after the patient completes the program, it may justify a referral outside of the PCP office. The SJM Center for Diabetes DSMEP may be viewed as a helpful adjunct to the education that is done in the primary care setting as a method of maintaining HbA1c levels in their patients over many years.
Individuals that attend the SJM Center for Diabetes DSMEP remain in contact with clinicians for approximately two to three months. After the education is complete, no further follow-ups are planned. If the results from this study show that HbA1c levels rise significantly in the one to two year timeframe after the education, then this may provide the rationale needed to offer multiple follow-ups in the years following the education sessions.
Chapter 2: Review of the Literature

Diabetes Defined

Diabetes is a disease of the endocrine system and can be described as a disorder of metabolism (McCance, 2009). There are various types of diabetes, characterized by the point of failure in the production or utilization of insulin. Type 1 diabetes (T1DM) is a result of the destruction of the beta-cells, the cells that actively produce insulin in the pancreas, which leads to a complete deficiency of endogenous insulin resulting in required exogenous insulin (ADA, 2012). Type 2 diabetes (T2DM) is a progressive decline in the insulin production by the beta cells, where insulin production decreases over time and/or the cells of the body develop a resistance to the endogenous insulin produced (ADA, 2012). Gestational diabetes (GDM) is the diagnosis of diabetes during pregnancy (ADA, 2012).

Diagnostic Criteria

The diagnostic standards for T2DM have changed over the last several years. Until 2009, the method for diagnosis used only: fasting plasma glucose (FPG), a non-fed state of at least 8 hours; multiple random glucose tests, a finger stick glucose test at any time during the pre- or post-prandial state; or the oral glucose tolerance test (OGTT), a medical test that determines how quickly an oral glucose load clears the blood (ADA, 2012). In 2009 it became a diagnostic standard to use the Hemoglobin A1c (HbA1c) value as a method for identifying T2DM (ADA, 2011). The HbA1c, a measure of the glucose that has irreversibly attached to the red blood cell or hemoglobin, known as glycosylated hemoglobin, is a laboratory value obtained from a venipuncture blood sample that assesses the average glucose level from the preceding two to three months (McCance, 2009; ADA, 2012). Once glucose attaches itself to the red blood cell, it remains attached until the death of that cell, which is approximately two to three months (McCance, 2009). The HbA1c measurement indicates the degree of glycosylated hemoglobin
cells currently in the blood stream, and can be converted to an average of blood glucose from the previous two to three months (McCance, 2009).

The American Diabetes Association has several criteria for diagnosing T2DM. A diagnosis can be made with any of the following conditions:

- HbA1c ≥6.5%, an HbA1c within normal limits is between 4-6% (ADA, 2012).
- FPG ≥126 mg/dl (7.0 mmol/l), a FPG within normal limits is less than 100mg/dl (ADA, 2012).
- 2-h plasma glucose ≥200 mg/dl (11.1 mmol/l) during an OGTT. A random glucose level within normal limits is less than 140 mg/dl (ADA, 2012).
- In a patient exhibiting symptoms of hyperglycemia or a random plasma glucose ≥200 mg/dl (11.1 mmol/l) on two separate occasions. A random glucose level within normal limits is less than 140 mg/dl (ADA, 2012).

**Chronic Complications of Diabetes**

Diabetes is a disease that affects every system of the body and can result in various chronic microvascular and macrovascular complications (McCance, 2009). The microvascular complications include neuropathy, nephropathy, and retinopathy (McCance, 2009). Macrovascular diseases include peripheral vascular disease, stroke, and cardiovascular disease (CVD) (1).

Several long-term studies completed to date measure the implications of glycemic control on CVD. The Diabetes Control and Complications Trial (DCCT) followed 1441 individuals with T1DM from 1983-1993 (Nathan et al., 2005). Ninety-three percent of the individuals continued in the follow-up study, the Epidemiology of Diabetes Interventions and Complications (EDIC) until 2005. The DCCT/EDIC study occurred over 20 years, with a mean follow-up of 17 years. The goal of both studies was to obtain a mean HbA1c level of 6.05%. However, the mean
HbA1c obtained at the end of the DCCT was 7.4%, and at the end of the EDIC study was 7.9% for the intensive therapy group (Nathan et al., 2005). At the end of the EDIC study, the intensive therapy group was associated with a 42% reduction in cardiovascular events, when compared with the conventional therapy group, which had a mean HbA1c of 9.1% at the end of the DCCT, and 7.8% at the end of the EDIC study (Nathan et al., 2005).

The original United Kingdom Prospective Diabetes Study (UKPDS) study reported that T2DM patients who received intensive glucose lowering therapy (insulin, sulfonylurea, or metformin) and reached a mean HbA1c of 7.0% were able to improve their microvascular outcomes by 25% over the conventional group, which had a mean HbA1c of 7.9% (UK Prospective Diabetes Study [UKPDS], 1999). Despite the significant reductions in HbA1c values, there were no improvements in macrovascular outcomes (UKPDS, 1999). In addition, there appeared to be no better glycemic control regardless of the therapy used in the intensive group, so the principal factor for microvascular risk reduction lies in general improvement of glycemic control (UKPDS, 1999).

During the 10-year long-term follow up study to the UKPDS, no further interventions occurred; however, the benefits of the original therapy continued for several years after the original intervention (Holman, Paul, Bethel, Matthews & Neil, 2008). The follow-up results support the original findings of reported reductions in microvascular complications (Holman et al., 2008). Only in the long-term follow-up did reductions in macrovascular complications emerge. At this time, differences were found within the intensive therapy groups regarding macrovascular complications. In the sulfonylurea-insulin group, there was a 15% reduction in myocardial infarction, and a 13% decrease in death secondary to any cause compared to the control group (Holman et al., 2008). The metformin group showed a 39% reduction in myocardial infarctions and a 36% decrease in death from any cause (Holman et al., 2008). Both
groups showed similar reductions in microvascular complications. This latent outcome on macrovascular risk has been called the legacy effect, suggesting that the benefits take a longer time to accrue and emerge (Holman et al., 2008). The legacy effect points to the need for continued long-term support and management in patients with T2DM to help maintain lowered glycemic and lipid levels for optimal risk reduction (Holman et al., 2008).

In the Action in Diabetes and Vascular Disease: Preterax and Diamicron Modified Release Controlled Evaluation (ADVANCE) trial, the results were similar to the UKPDS (ADVANCE Collaborative Group [ADVANCE], 2008). The ADVANCE trial had a greater emphasis on lifestyle management in addition to the pharmacological agents studied in the trial. Microvascular reductions were significant at 14% in the intensive therapy group when compared to the standard therapy group (ADVANCE, 2008). Comparable to UKPDS, there was an insignificant decrease in macrovascular events of 6% over the 5-year study period (ADVANCE, 2008). The ADVANCE-ON study is the long-term study currently in progress and expected to continue collecting data until the end of 2013 looking at the continuing implications of the ADVANCE trial (Hamet, 2012). It is anticipated that similar results to the UKPDS 10-year follow-up will appear in macrovascular results, which will further support the legacy effect of optimal glycemic control on macrovascular risk (Hamet, 2012).

The Action to Control Cardiovascular Risk in Diabetes (ACCORD) trial failed to assess whether achieving a target HbA1c level of 6.0% would significantly reduce cardiovascular risk and complications in individuals with T2DM (ACCORD Study Group [ACCORD], 2011). The intensive therapy group of the study was terminated prior to completion because of a high incidence of mortality within the intensive group (ACCORD, 2014). The participants of the ACCORD trial were at a high risk for CVD and were on average older than previous studies (DCCT/EDIC, UKPDS, ADVANCE; ACCORD, 2014). The cause of the higher rate of mortality
in the ACCORD trial is unknown; however, hypoglycemic events were ruled out as the principal factor (ACCORD, 2014). The failure in the ACCORD study suggests that the intensive treatment approach may be an unsuitable treatment option for a high-risk, older population.

Another short-term trial that failed to reproduce the reduction in microvascular and macrovascular risk found in the DCCT and UKPDS was the Veterans Affairs Diabetes Trial (VADT; Duckworth et al., 2009). This trial was completed on veterans, predominately men, who had the diagnosis of T2DM for an average of 11.5 years with uncontrolled glucose levels (Duckworth et al., 2009). The mean HbA1c at the study’s inception was 9.4%. Many of the individuals had already experienced a cardiovascular event; the exclusion was that they did not have an event that had occurred in the past 6 months. The participants in this study were at a higher risk for complications related to the length of diagnosis, present complications, as well as the inadequate response to maximum doses of oral agents or insulin (Duckworth et al., 2009). The mean HbA1c levels at the end of the study were 8.4% for the standard therapy and 6.9% for the intensive therapy (Duckworth et al., 2009). All individuals received the same basic standard of care set forth by the American Diabetes Association (ADA), including education, dietary information, and follow-up. The intensive therapy group received more aggressive oral anti-diabetic agents and/or insulin. Even with the reduction in HbA1c levels for the intensive group, there were no significant differences in the rates of microvascular complications, macrovascular complications, or death from any cause (Duckworth et al., 2009).

These studies propose that complications are more difficult to control and prevent in the patient with T2DM, and more challenging in the uncontrolled, high-risk group. Controlled glycemic levels alone are not enough among individuals with T2DM, especially the high-risk group; there is a need for appropriate management of dyslipidemia and other cardiovascular risk
factors. As a result, the incorporation of related complication risk reduction and management has become a part of many DSME programs (ADA, 2011).

Standards of Care

Diabetes is a chronic condition that can result in multiple acute and long-term complications (ADA, 2011). This chronic disease requires complex continuing medical care as well as self-management, education, and support to help reduce and/or delay the onset of diabetes related complications (ADA, 2011). The Standards of Medical Care in Diabetes have been implemented as a guide for managing the multifaceted care required for the individual with diabetes (ADA, 2011). These standards include recommendations for health care providers for screening, diagnosing, and care planning, which have been known to provide a positive outcome in the health of the patient with diabetes (ADA, 2011).

Diabetes care should provide a complete and comprehensive plan including, but not limited to: ongoing evaluations, physical assessments/examinations, and laboratory evaluations (ADA, 2011). Referrals should be made for annual dilated eye examinations, dental examinations, family planning, Medical Nutrition Therapy (MNT), Diabetes Self-Management Education (DSME), and mental health professionals as needed. The DSME program is an essential piece of the comprehensive care plan and follows the national standards and evidence-based practices in providing education, skill building, and support to people with diabetes (ADA, 2011).

This is a cost-effective method that empowers patients to take an active role in their self-care, which can improve health outcomes overall; however, the research and data on the long-term effectiveness of the DSME on health outcomes remains lacking (ADA, 2011). This study will help to provide some longer-term data about the effectiveness of the SJM Center for
Diabetes DSME program, which is based on the American Association of Diabetes Educators standards that accredit DSME programs (Funnell, 2007).

**Diabetes Self-Management Education Programming**

Because of the diverse nature of the United States population, it is relevant to look at some of the DSMEPs that have proven to be successful in other countries. While the structure of a DSMEP may vary, the goal is to reduce HbA1c levels and ultimately reduce the complications related to T2DM (ADA, 2011). One of the variables in DSMEP structure is the span of time that the patients are in the program. The Joetsu Diabetes Prevention Trial from Joetsu, Japan, is a study that looked at the difference in outcomes between a 2-day hospital stay program and a longer-term outpatient program, when compared to a control group that received no education (Kawahara et al., 2008). It was found that the direct and intensive contact of the 2-day hospital stay was very effective at lowering the risk for developing or delaying the progression of T2DM (Kawahara et al., 2008). It proved to be more effective than the longer term outpatient program, which was far more effective than providing no education at all (Kawahara et al., 2008). The cost effectiveness did not appear to be an issue, based on the health care system in Japan (Kawahara et al., 2008). However, a two-day hospital stay in the U.S. would be entirely cost prohibitive under the current health care system here.

The majority of diabetes education in Japan is provided in the hospital setting and as a result, there are fewer outpatient clinics that provide complete DSME (Adachi et al., 2010). Another on-going study in Japan is investigation the effectiveness of providing more complete DSME by a Registered Dietitian in the general practitioners (GP) medical clinic, which follows similar guidelines and standards as the U.S. national DSME standards (Adachi et al., 2010). The control group received general nutrition guidelines within the medical practice, similar to what would be provided by the GP (Adachi et al., 2010). It is important to note that this is one of the
first cluster randomization studies to be done in Japan, and it is expected that the results from this study will provide favorable health outcomes (Adachi et al., 2010).

More studies from around the world are reporting that the modification of lifestyle is an integral piece in reducing risks related to diabetes. A study from Finland and Australia is looking at the mode of delivery of diabetes education (Oldenburg, Absetz, Dunbar, Reddy & O’Neil, 2011). There are varying barriers to success in individuals around the world. This study looked at programs over the past 10 years and identified that the use of a variety of methods of delivering education are necessary in reaching high-risk individuals with diabetes (Oldenburg et al., 2011). A significant determinant of success for these programs is the governmental support for the resource-poor settings (Oldenburg et al., 2011).

Active Steps for Diabetes is a program in the US that has incorporated physical activity into their DSME (Pariser, Demeuro, Gillette & Stephen, 2010). It has been well known that physical activity is a modifiable lifestyle component that can have a greater impact on the development and progression of diabetes (ADA, 2011). The challenge for many DSME programs is the differing physical capabilities and mobility issues of each patient within the group (Pariser et al., 2010). This program has successfully integrated the physical activity component and has shown some positive results in improving health outcomes and reducing the comorbidities related to diabetes including coronary artery disease as well as increasing overall mobility in patients with such difficulties (Pariser et al., 2010).

One study completed in the UK examined the effects of education on individuals with newly diagnosed T2DM using a three-year follow up after initial diagnosis and intervention (Khunti et al., 2012). The control group did not receive any nutrition education although patients received regular care by the general practice physician while the individuals in the intervention group completed a DSME shortly after they were diagnosed with T2DM (Khunti et al., 2012).
The results at the 3-year follow up reported no significant change in laboratory values, including HbA1c, or health outcomes between the control and intervention group (Khunti et al., 2012).

However, when looking at the long-term follow up study of the Diabetes Prevention Program (DPP) known as the Diabetes Prevention Program Outcomes Study (DPPOS), these results clearly state that lifestyle interventions have a positive impact on the reduction of risk factors that lead to the diagnosis to T2DM (Diabetes Prevention Program Research Group [DPP], 2009). The DPPOS followed individuals who completed the DPP, and reported that the effects of lifestyle intervention can delay diabetes for up to 10 years (DPP, 2009). In addition to the lifestyle intervention, one arm of the study looked at metformin use as a means to delay development of T2DM. The total incidence of diabetes in the lifestyle group was less than the incidence of diabetes in the metformin group (DPP, 2009). It is important to note that both groups were instrumental in delaying the diagnosis of diabetes, but the lifestyle group appeared to have a greater impact over a longer period of time (DPP, 2009). Because of this large, long-term study, the lifestyle interventions and DSME programs deserve an in-depth look in delaying the progression of diabetes, and the reduction of diabetes related complications after diagnosis.

The primary care provider’s office is an increasingly popular delivery site for diabetes education (Whittemore et al., 2010). Nurse Practitioners (NP) are employed more often to provide education not only for diabetes, but for many chronic illnesses, within the primary care office (Whittemore et al., 2010). The results of a pilot study reviewing the delivery of diabetes education by the NP has shown that it can be successful in eliciting behavior change; however, more evidence is needed to determine the effects on lowering HbA1c and lipid levels (Whittemore et al., 2010). A qualitative study reviewed some of the reasons that general practitioners (GP) hesitate to refer patients to an outside DSME program (Sunaert et al., 2011). The general consensus is that GPs needed time to understand the role of the DSME, and develop
a trusting relationship between the groups and understand that their patients care would not be compromised or fragmented by deferring the education to the DSME (Sunaert et al., 2011). Stand-alone diabetes education programs may need to reinforce their effectiveness and provide more long term efficacy data as there is a shift to providing more diabetes education within the primary care setting.

While proving the effectiveness of a DSME is necessary to comply with the evidence-based culture of the U.S. health care system, it is also necessary to show that it is a cost-effective strategy in producing favorable outcomes. One study delineated the top cost-effective interventions for people with T2DM (Li, Zhang, P, Barker, Chowdjury & Zhang, X, 2010). The most cost effective intervention was primary prevention and the use of intensive lifestyle modifications to prevent and delay the diagnosis of T2DM (Li et al., 2010). There was strong evidence supporting the cost-effectiveness of programs like the DPP, and intensive lifestyle interventions for people with newly diagnosed T2DM in maintaining glycemic control (Li et al., 2010). Finally, the DSME proved to be very cost-effective at maintaining glycemic control when compared with individuals who received no diabetes education (Li et al., 2010).

Hospitals and emergency departments stand to see the greatest cost reduction through the use of DSME (Dall et al., 2011). The agency that administers health care benefits for military personnel known as TRICARE has shown that the greatest burden of cost by diabetes patients is from recurring inpatient hospital stays and emergency room visits by individuals with uncontrolled T2DM who have not participated in any DSME (Dall et al., 2011). Individuals who were reported to have uncontrolled T2DM and participated in TRICARE’s, DSME realized better health outcomes, and were associated with lowered medical costs overall (Dall et al., 2011).
The available literature accurately describes the multifaceted nature of diabetes and the complications that can arise. These complexities increase as the individual ages, or develop uncontrolled glucose levels. The DSMEP must be able to meet the complicated needs of the diabetes population. It is now more evident that the DSMEP must address the cardiovascular risk factors as well as optimal glucose control of the individual. Multiple studies support the efficacy and cost-effectiveness of the DSMEP in managing diabetes care. This study will provide longer-term data to support the efficacy of the SJM Center for Diabetes DSMEP in lowering the risks of complications related to diabetes in a cost-effectiveness manner.
Chapter 3: Research Design and Methodology

The primary objective of this study was to determine if the SJM Center for Diabetes DSMEP is effective in lowering or maintaining lowered HbA1c and lipid levels at the one and two-year mark following the education program. This was a quantitative study using existing patient data collected in 2010, 2011, and 2012.

Study Population

The population of this study included patients enrolled in the SJM Center for Diabetes DSMEP in 2010, including all adult (age 18 and older) patients diagnosed with Type 2 Diabetes. The mean age of the study participants was 64 years. Study participant exclusions included participants diagnosed with gestational diabetes, participants diagnosed with Type 1 Diabetes, participants diagnosed with pre-diabetes, participants that did not complete the diabetes education group classes (nine-hours of classroom education), participants that enrolled in the SJM NutriCare (weight management) program, and participants that died during the data collection period.

Ethical Considerations

No live subjects were used in this study. Data were extracted from the SJMH electronic medical record using the participant’s SJMH Medical Record Number (MRN) only. The SJMH MRN# was decoded to protect the names and information of the individuals included in the study. No other personal information was used at any time for the duration of this study. All data collected were kept in a locked cabinet in the locked office of the principal investigator. All electronic data were stored in a password-protected file on the computer of the principal investigator. The principal investigator will destroy all identifiable data at the conclusion of this study. This protocol was approved by the College of Health and Human Services, Human subjects Review Committee, Eastern Michigan University, Ypsilanti, MI (see Appendix 2).
Data Collection

The SJM Center for Diabetes stores participant records in a protected Microsoft Access database. A report query from this database captured all of the patients who participated in diabetes education classes in 2010. The study population was gathered from the report query, exercising the appropriate exclusions. The remaining patients became the study participants.

SJMH uses PowerChart™, an electronic medical record that contains the full medical record of all patients within the SJMH system, including laboratory data collected at any SJMH site. Each study participant had information recorded from PowerChart™ at the following data collection points: Baseline, Post-Program, 1-year Post-Program, and 2-years Post-Program. The laboratory values recorded were: HbA1c, LDL cholesterol, HDL cholesterol, and TC. The Baseline and Post-Program HbA1c values were recorded to verify the initial change in HbA1c levels after completing the group education sessions. Lipid values were recorded for the same Baseline and Post-Program period if available in PowerChart™. The data collected 1-year Post-Program and 2-year Post-Program were used to investigate any further changes in HbA1c, and lipid values. The data were recorded on an excel spreadsheet for each participant.

Data Analysis

The data collected for each individual in the categories, HbA1c, LDL, HDL, and TC were evaluated at baseline, Post-Program, 1-year Post-Program, and 2-years Post-Program. Data analysis was performed using IBM SPSS Statistics 21 software (IBM SPSS Statistics 21.0, 2012, IBM Corporation, Somers, NY) with the assistance of the College of Health and Human Services (CHHS) Inter-Professional Research Office (iPRO). The repeated measures analysis of variance (ANOVA) and sample t-tests were used, with a 95% Confidence Interval, \( p < .05 \), to determine the level of significance in changes from baseline, post-program, 1-year post-program, and 2-
years post-program, then compared to the target ranges recommended by the standards of care for changes for each category in patients that have T2DM.
Chapter 4: Research Results

Demographics

During the year 2010, 299 individuals took part in the SJM Center for Diabetes DSMEP. Of the 299 that took part in the education program, data for 234 individuals was extracted from PowerChart™, the SJMH electronic medical record; 64 individuals did not have laboratory data available and were excluded from the final sample population. One individual died during the study period and was excluded from the sample. The demographical characteristics of the study population (n=234) are: female (n=135) and male (n=99) participants ages 18-99, with a mean age of 64. No distinctions were made for age or race.

HbA1c Values

Demographic characteristics are presented in Table 1. There were 131 individuals with HbA1c values available for all data collection points. Of the 131 individuals, 81 (62%) were females and 50 (38%) were males. Program completion determined by attendance at follow-up visit was 55% (n=72), and 45% (n=59) did not complete the program by not attending the follow-up visit, shown in Table 2.

<table>
<thead>
<tr>
<th>Table 1. Demographic characteristics</th>
<th>Total (n)</th>
<th>% of population</th>
</tr>
</thead>
<tbody>
<tr>
<td>HbA1c Values Available</td>
<td>131</td>
<td>100%</td>
</tr>
<tr>
<td>Gender</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Female</td>
<td>81</td>
<td>62</td>
</tr>
<tr>
<td>Male</td>
<td>50</td>
<td>38</td>
</tr>
</tbody>
</table>

Table 2 presents the HbA1c percent mean values for each data collection point by gender, program completion for both genders, and for all groups. Data were evaluated to see if there were any significant differences in HbA1c percent whether the program was completed or not. Every study participant attended the nine-hour education classes. The program was considered
completed if the individual attended the one-hour individual visit following the nine hours of education classes, 30 minutes with an RD, and 30 minutes with an RN. Table 2 also provides a comparison of HbA1c levels from Baseline to Post-Program, Post Program to 1-year Post-Program, 1-year Post-Program to 2-years Post-Program, and from Baseline to 2-years Post-Program for gender, program completion, and all groups. Repeated measures ANOVA showed that there was a significant effect on HbA1c percent levels for receiving education through the SJM Center for Diabetes DSMEP.

### Table 2: Reported HbA1c percent values for Gender, Program Completion, and all groups at Baseline, Post-Program, 1-year Post-Program, 2-year Post-Program; and the t-test comparison of HbA1c percent levels from Baseline to Post-Program, Post-Program to 1-year Post-Program, and 1-year Post-Program to 2-years Post-Program, and from Baseline to 2-years Post-Program.

<table>
<thead>
<tr>
<th></th>
<th>Baseline HbA1c % Mean ± SD</th>
<th>Post-Program HbA1c % Mean ± SD</th>
<th>Baseline to Post-Program p-value</th>
<th>1-year Post-Program HbA1c % Mean ± SD</th>
<th>Post-Program to 1-year p-value</th>
<th>2-years Post-Program HbA1c % Mean ± SD</th>
<th>1-year to 2-year p-value</th>
<th>Baseline to 2-year p-value</th>
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<tbody>
<tr>
<td><strong>Gender</strong></td>
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</tr>
<tr>
<td>Females (n=81)</td>
<td>8.08 ± 1.82</td>
<td>6.70 ± 0.93</td>
<td>p&lt;0.0001</td>
<td>6.78 ± 1.02</td>
<td>p=0.6025</td>
<td>6.87 ± 1.24</td>
<td>p=0.6232</td>
<td>p&lt;0.0001</td>
</tr>
<tr>
<td>Males (n=50)</td>
<td>8.72 ± 2.14</td>
<td>6.69 ± 1.08</td>
<td>p&lt;0.0001</td>
<td>6.98 ± 1.11</td>
<td>p=0.2003</td>
<td>7.03 ± 1.33</td>
<td>p=0.8259</td>
<td>p&lt;0.0001</td>
</tr>
<tr>
<td><strong>Program Completion</strong></td>
<td></td>
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<tr>
<td>Program Completed (n=72)*</td>
<td>7.97 ± 1.71</td>
<td>6.49 ± 0.91</td>
<td>p&lt;0.0001</td>
<td>6.64 ± 0.90</td>
<td>p=0.3041</td>
<td>6.88 ± 1.14</td>
<td>p=0.1794</td>
<td>p&lt;0.0001</td>
</tr>
<tr>
<td>Program Not Completed (n=59)*</td>
<td>8.76 ± 2.18</td>
<td>6.95 ± 1.02</td>
<td>p&lt;0.0001</td>
<td>7.11 ± 1.18</td>
<td>p=0.4323</td>
<td>6.99 ± 1.43</td>
<td>p=0.6310</td>
<td>p&lt;0.0001</td>
</tr>
<tr>
<td><strong>HbA1c% for all groups (n=131)</strong></td>
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<tr>
<td></td>
<td>8.33 ± 1.97</td>
<td>6.70 ± 0.98</td>
<td>p&lt;0.0001</td>
<td>6.86 ± 1.05</td>
<td>p=0.2112</td>
<td>6.93 ± 1.28</td>
<td>p=0.6044</td>
<td>p&lt;0.0001</td>
</tr>
</tbody>
</table>

SD=Standard Deviation
P is significant at less than .05
* Program completed as determined by attendance at the follow-up visit.
* Includes females and males.
* Includes Program Completed and Not Completed.

The standards of medical care for people with diabetes recommend reaching and maintaining an HbA1c percentage of 7% or below for improved health outcomes (ADA, 2011). The recorded HbA1c percent values provided a mean HbA1c percent for females at Baseline of 8.08%. From Baseline to Post-Program, there was a significant decrease of 1.38% in HbA1c percentage to 6.70% (p<0.0001). The HbA1c percentage for 1-year Post-Program for females was 6.78%, which was a very slight but insignificant increase of 0.08% (p=0.6025) from Post-Program. The HbA1c percentage for 2-years Post-Program for females was 6.87%, which was a
slight but insignificant increase from 1-year Post-Program of 0.09% 9 (p=0.6232). Comparing the change from Baseline to 2-years Post-Program, there was a significant reduction in HbA1c percentage for females of 1.21% (p<0.0001). The mean HbA1c percentage for females reached the target level for HbA1c percentage of <7% (ADA, 2011) at the Post-Program point and remained on target through the 2-years Post-Program point, suggesting that the interventions provided by the SJM Center for Diabetes DSMEP were effective at lowering and maintaining lowered HbA1c levels for females through two years after the program intervention.

The recorded HbA1c percent values provided a mean HbA1c percent for males at Baseline of 8.72%. From Baseline to Post-Program, there was a significant decrease of 2.03% in HbA1c percentage to 6.69% (p<0.0001). The HbA1c percentage for 1-year Post-Program for males was 6.98%, which was a slight but insignificant increase of 0.29% (p=0.2003) from Post-Program. The HbA1c percentage for 2-years Post-Program for males was 7.03%, which was slight but insignificant increase of 0.05% (p=0.8259) from 1 year Post-Program. Comparing the change from Baseline to 2-years Post-Program, there was a significant decrease in HbA1c percentage for males of 1.69% (p<0.0001). Even though the mean HbA1c percentage for males at the 2-years Post-Program was only slightly above the recommended target of <7% (ADA, 2011), there was a significant improvement in HbA1c percentage for males at the 2-year Post-Program point.

For the individuals that completed the program, the Baseline mean HbA1c percentage was 7.97%. There was a significant decrease of 1.48% from Baseline to Post-Program, which was 6.49% (p<0.0001). The 1-year Post-Program HbA1c percentage was 6.64%, which was an insignificant increase of 0.15% (p=0.3041) from Post-Program. The HbA1c percentage for 2-years Post Program for those that completed the program was 6.88%, which was an insignificant increase of 0.24 (p=0.1794) from 1-year Post-Program. Comparing the change from
Baseline to 2-years Post-Program there was a significant decrease in HbA1c of 1.09% (p<0.0001), for those that completed the program by attending the follow up visit.

For the individuals that did not complete the program, the Baseline mean HbA1c percentage was 8.76%. There was a significant decrease of 1.81% from Baseline to Post-Program, which was 6.95% (p<0.0001). The 1-year Post-Program HbA1c percentage was 7.11%, which was an insignificant increase of 0.16% (p=0.4323) from Post-Program. The HbA1c percentage for 2-years Post Program for those that did not complete the program was 6.99%, which was an insignificant decrease of 0.12% (p=0.6310) from 1-year Post-Program. Comparing the change from Baseline to 2-years Post-Program there was a significant decrease in HbA1c of 1.77% (p<0.0001), for those that did not complete the program by not attending the follow up visit.

When combined, looking at all groups together including males, females, those that completed the program by attending the follow up visit and those that did not, the mean HbA1c percentage at Baseline was 8.33%. There was a significant decrease of 1.63% from Baseline to Post-Program, which was 6.70% (p<0.0001) suggesting that the initial intervention was successful at lowering HbA1c levels. There was an insignificant increase of 0.16% from Post-Program to 1-year Post-Program, which was 6.86% (p=0.2112). The 2-year Post-Program mean HbA1c percentage for all groups was 6.93%, which was an insignificant increase of 0.07% (p=0.6044) from 1-year Post-Program. Comparing the change from Baseline to 2-years Post-Program, there was a significant decrease in HbA1c percentage of 1.4% (p<0.0001). The mean HbA1c percentage for all groups showed significant improvement from Baseline to 2-years Post-Program, and was below the target of 7% in the Post-Program points through 2-years Post-Program, showing that the program interventions were successful in lowering HbA1c percentage
levels, as well as maintaining lowered HbA1c percentage levels for the two years following the education program.

**LDL Values**

Table 3 presents the mean LDL (mg/dL) values of each data collection point by gender, program completion, and for all groups. There were 112 individuals with LDL values collected (n=112). Of those 112, 63 (46%) were female and 49 (44%) were male. Table 3 also provides a comparison of LDL (mg/dL) levels from Baseline to Post-Program, Post-Program to 1-year Post-Program, 1-year Post-Program to 2-years Post-Program, and Baseline to 2-years Post-Program for gender, program completion, and all groups. Repeated measures ANOVA show that there was a significant effect on improving LDL (mg/dL) levels from receiving education through the SJMH Center for Diabetes DSMEP.

<table>
<thead>
<tr>
<th>Gender</th>
<th>Baseline LDL (mg/dL) Mean ± SD</th>
<th>Post-Program LDL (mg/dL) Mean ± SD</th>
<th>Baseline to Post-Program p-value</th>
<th>1-year Post-Program LDL (mg/dL) Mean ± SD</th>
<th>Post-Program to 1-year p-value</th>
<th>2-year Post-Program LDL (mg/dL) Mean ± SD</th>
<th>1-year to 2-year p-value</th>
<th>Baseline to 2-year p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Females (n=63)</td>
<td>114.2 ± 35.2</td>
<td>98.4 ± 29.9</td>
<td>0.0076</td>
<td>92.4 ± 26.8</td>
<td>0.2379</td>
<td>90.0 ± 28.5</td>
<td>0.6272</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>Males (n=49)</td>
<td>110.4 ± 35.7</td>
<td>95.6 ± 31.3</td>
<td>0.0315</td>
<td>90.5 ± 31.3</td>
<td>0.4219</td>
<td>92.7 ± 39.8</td>
<td>0.7617</td>
<td>0.0226</td>
</tr>
</tbody>
</table>

**Program Completion**

Program Completed (n=62)

<table>
<thead>
<tr>
<th>Program Completed (n=62)</th>
<th>Baseline LDL (mg/dL) Mean ± SD</th>
<th>Post-Program LDL (mg/dL) Mean ± SD</th>
<th>Baseline to Post-Program p-value</th>
<th>1-year Post-Program LDL (mg/dL) Mean ± SD</th>
<th>Post-Program to 1-year p-value</th>
<th>2-year Post-Program LDL (mg/dL) Mean ± SD</th>
<th>1-year to 2-year p-value</th>
<th>Baseline to 2-year p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Program Completed (n=62)</td>
<td>112.1 ± 33.4</td>
<td>98.3 ± 31.4</td>
<td>0.0193</td>
<td>87.9 ± 28.1</td>
<td>0.0543</td>
<td>88.4 ± 36.2</td>
<td>0.9317</td>
<td>0.0002</td>
</tr>
<tr>
<td>Program Not Completed (n=50)</td>
<td>113.2 ± 37.9</td>
<td>95.8 ± 29.4</td>
<td>0.0118</td>
<td>96.1 ± 29.1</td>
<td>0.9592</td>
<td>94.6 ± 30.5</td>
<td>0.8019</td>
<td>0.0081</td>
</tr>
</tbody>
</table>

**LDL (mg/dL) for all groups (n=112)**

<table>
<thead>
<tr>
<th>LDL (mg/dL) for all groups (n=112)</th>
<th>Baseline LDL (mg/dL) Mean ± SD</th>
<th>Post-Program LDL (mg/dL) Mean ± SD</th>
<th>Baseline to Post-Program p-value</th>
<th>1-year Post-Program LDL (mg/dL) Mean ± SD</th>
<th>Post-Program to 1-year p-value</th>
<th>2-year Post-Program LDL (mg/dL) Mean ± SD</th>
<th>1-year to 2-year p-value</th>
<th>Baseline to 2-year p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>All groups (n=112)</td>
<td>112.5 ± 35.4</td>
<td>97.2 ± 30.4</td>
<td>0.0006</td>
<td>91.6 ± 28.7</td>
<td>0.1577</td>
<td>91.2 ± 33.8</td>
<td>0.9240</td>
<td>&lt;0.0001</td>
</tr>
</tbody>
</table>

SD=Standard Deviation

* P is significant at less than .05

* Program completed as determined by attendance at the follow-up visit.

* Includes females and males.

* Includes Program Completed and Not Completed.

The target LDL (mg/dL) for people with diabetes is <100 mg/dL (Buse et al., 2007). The recorded LDL (mg/dL) values provided a mean LDL (mg/dL) for females at Baseline of 114.2 mg/dL. The Post-Program mean LDL was 98.4 mg/dL, which was a significant decrease of 15.8
mg/dL from Baseline (p=0.0076). The 1-year Post-Program LDL (mg/dL) was 92.4 mg/dL, which was an insignificant decrease of 6 mg/dL (p=0.2379) from Post-Program. The 2-year Post-Program LDL (mg/dL) for females was 90.0 mg/dL, which was an insignificant decrease of 2.4 mg/dL (p=0.6272) from 1-year Post-Program. Comparing the Baseline and 2-years Post-Program LDL (mg/dL) for females, there was a significant decrease of 24.2 mg/dL (p<0.0001). LDL (mg/dL) levels continued to improve through each collection point. Females reached the target LDL (mg/dL) range in the Post-Program point and remained below the target range through the 2-years Post-Program point, suggesting that the SJM Center for Diabetes DSMEP was effective in lowering and maintaining lowered LDL (mg/dL) levels for females.

The recorded LDL (mg/dL) values provided a mean LDL (mg/dL) for males at Baseline of 110.4 mg/dL. The Post-Program mean LDL was 95.6 mg/dL, which was a significant decrease of 14.8 mg/dL from Baseline (p=0.0315). The 1-year Post-Program LDL (mg/dL) was 90.5 mg/dL, which was an insignificant decrease of 5.1 mg/dL (p=0.4219) from Post-Program. The 2-year Post-Program LDL (mg/dL) for males was 92.7 mg/dL, which was an insignificant increase of 2.2 mg/dL (p=0.7617) from 1-year Post-Program. Comparing the Baseline and 2-years Post-Program LDL (mg/dL) for males, there was a significant decrease of 17.7 mg/dL (p=0.0226). LDL (mg/dL) levels improved from Baseline through 1-year Post-Program and then showed an increase at 2 years Post-Program. Even though the LDL (mg/dL) levels increased very slightly at the 2-year Post-Program point, males reached the target LDL (mg/dL) range in the Post-Program point and remained below the target range through the 2-years Post-Program, again supporting the initial effectiveness of the SJM Center for Diabetes DSMEP.

For the individuals that completed the program, the Baseline mean LDL (mg/dL) was 112.1 mg/dL. There was a significant decrease of 13.8 mg/dL from Baseline to Post-Program, which was 98.3 mg/dL (p=0.0193). The 1-year Post-Program LDL (mg/dL) was 87.9 mg/dL,
which was an insignificant decrease of 10.4 mg/dL (p=0.0543) from Post-Program. The LDL (mg/dL) for 2-years Post Program for those that completed the program was 88.4 mg/dL, which was an insignificant increase of 0.5 mg/dL (p=0.9317) from 1-year Post-Program. Comparing the change from Baseline to 2-years Post-Program there was a significant decrease in LDL (mg/dL) of 23.7 mg/dL (p=0.0002), for those that completed the program by attending the follow up visit, and all Post-Program points were below the target range.

For the individuals that did not complete the program, the Baseline mean LDL (mg/dL) was 113.2 mg/dL. There was a significant decrease of 17.4 mg/dL from Baseline to Post-Program, which was 95.8 mg/dL (p=0.0118). The 1-year Post-Program LDL (mg/dL) was 96.1 mg/dL, which was an insignificant increase of 0.3 mg/dL (p=0.9592) from Post-Program. The LDL (mg/dL) for 2-years Post Program for those that did not complete the program was 94.6 mg/dL, which was an insignificant decrease of 1.5 mg/dL (p=0.8019) from 1-year Post-Program. Comparing the change from Baseline to 2-years Post-Program there was a significant decrease in LDL (mg/dL) of 18.6 mg/dL (p=0.0081), for those that did not complete the program by attending the follow up visit, and all Post-Program points were again below the target range for LDL (mg/dL).

Comparing all groups together, both genders, those that completed the program by attending the follow up visit and those that did not, the mean LDL (mg/dL) at Baseline was 112.5 mg/dL. There was a significant decrease of 15.3 mg/dL from Baseline to Post-Program, which was 97.2 mg/dL (p=0.0006). There was an insignificant decrease of 5.6 mg/dL (p=0.1577) from Post-Program to 1-year Post-Program, which was 91.6 mg/dL. The 2-year Post-Program mean LDL (mg/dL) for all groups was 91.2 mg/dL, which was an insignificant decrease of 0.4 mg/dL (p=0.9240) from 1-year Post-Program. Comparing the change from Baseline to 2-years Post-Program, there was a significant reduction in LDL (mg/dL) of 21.3 mg/dL (p<0.0001). The
mean LDL (mg/dL) for all groups was below the target of 100 mg/dL in all of the Post-Program points through 2-years Post-Program, again showing the success of the interventions provided in the SJM Center for Diabetes DSMEP.

**HDL Values**

Table 4 presents the mean HDL values at each data collection point for gender and a comparison of mean HDL levels for gender between each of the data collection points. HDL values were available for 117 individuals (n=117) for all data collection points. Of the 117 individuals, n= 63 (54%) were female and n= 54 (46%) were male. Table 4 also provides a comparison of HDL (mg/dL) levels from Baseline to Post-Program, Post-Program to 1-year Post-Program, 1-year Post-Program to 2-years Post-Program, and Baseline to 2-years Post-Program for gender, program completion, and all groups. Repeated measures ANOVA showed that there was a significant effect on HDL levels after receiving education through the SJMH Center for Diabetes DSMEP.
Table 4. Reported HDL (mg/dL) values for Gender, Program Completion, and all groups at Baseline, Post-Program, 1-year Post-Program, 2-year Post-Program; and the t-test comparison of HDL (mg/dL) levels from Baseline to Post-Program, Post-Program to 1-year Post-Program, 1-year Post-Program to 2-years Post-Program, and Baseline to 2-years Post-Program.

<table>
<thead>
<tr>
<th>Gender</th>
<th>Baseline HDL (mg/dL) Mean ± SD</th>
<th>Post-Program HDL (mg/dL) Mean ± SD</th>
<th>Baseline to Post-Program p-value</th>
<th>1-year Post-Program HDL (mg/dL) Mean ± SD</th>
<th>2-years Post-Program HDL (mg/dL) Mean ± SD</th>
<th>1-year to 2-year p-value</th>
<th>Baseline to 2-year p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Females (n=63)</td>
<td>46.7 ± 13.7</td>
<td>49.2 ± 12.2</td>
<td>p=0.2815</td>
<td>51.3 ± 13.2</td>
<td>p=0.3556</td>
<td>52.8 ± 11.9</td>
<td>p=0.5042</td>
</tr>
<tr>
<td>Males (n=54)</td>
<td>37.7 ± 8.5</td>
<td>40.0 ± 9.2</td>
<td>p=0.1801</td>
<td>44.4 ± 13.0</td>
<td>p=0.0448</td>
<td>45.0 ± 12.3</td>
<td>p=0.8059</td>
</tr>
</tbody>
</table>

Program Completion

<table>
<thead>
<tr>
<th>Gender</th>
<th>Baseline HDL (mg/dL) Mean ± SD</th>
<th>Post-Program HDL (mg/dL) Mean ± SD</th>
<th>Baseline to Post-Program p-value</th>
<th>1-year Post-Program HDL (mg/dL) Mean ± SD</th>
<th>2-years Post-Program HDL (mg/dL) Mean ± SD</th>
<th>1-year to 2-year p-value</th>
<th>Baseline to 2-year p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Program Completed (n=64)</td>
<td>43.6 ± 14.3</td>
<td>45.6 ± 13.4</td>
<td>p=0.4156</td>
<td>49.3 ± 15.0</td>
<td>p=0.1436</td>
<td>50.2 ± 14.2</td>
<td>p=0.7280</td>
</tr>
<tr>
<td>Program Not Completed (n=53)</td>
<td>41.2 ± 9.6</td>
<td>44.3 ± 9.6</td>
<td>p=0.0995</td>
<td>46.7 ± 11.4</td>
<td>p=0.2437</td>
<td>48 ± 10.7</td>
<td>p=0.5463</td>
</tr>
</tbody>
</table>

HDL (mg/dL) for all groups (n=117)†, ‡, §

<table>
<thead>
<tr>
<th>Gender</th>
<th>Baseline HDL (mg/dL) Mean ± SD</th>
<th>Post-Program HDL (mg/dL) Mean ± SD</th>
<th>Baseline to Post-Program p-value</th>
<th>1-year Post-Program HDL (mg/dL) Mean ± SD</th>
<th>2-years Post-Program HDL (mg/dL) Mean ± SD</th>
<th>1-year to 2-year p-value</th>
<th>Baseline to 2-year p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>42.5 ± 12.4</td>
<td>45.0 ± 11.8</td>
<td>p=0.1155</td>
<td>48.1 ± 13.5</td>
<td>p=0.0627</td>
<td>49.2 ± 12.7</td>
<td>p=0.5215</td>
</tr>
</tbody>
</table>

SD=Standard Deviation
P is significant at less than .05
† Program completed as determined by attendance at the follow-up visit.
‡ Includes females and males.
§ Includes Program Completed and Not Completed.

The target recommended HDL (mg/dL) for females with diabetes is >50 mg/dL (Buse et al., 2007). The goal for HDL (mg/dL) levels is to increase and remain above the target level. The recorded HDL (mg/dL) values provided a mean HDL (mg/dL) for females at Baseline of 46.7 mg/dL. The Post-Program mean HDL was 49.2 mg/dL, which was an insignificant increase of 2.5 mg/dL (p=0.2815) from Baseline. Although it was statistically insignificant, any increase in HDL values from baseline would be considered beneficial. The 1-year Post-Program HDL (mg/dL) was 51.3 mg/dL, which was an insignificant increase of 2.1 (p=0.3556) mg/dL from Post-Program. However, the increased HDL levels from 49.2 mg/dL at Post-Program to 51.3 mg/dL at 1-year Post-Program shows that patients reached the target level in the 1-year Post-program period. The 2-year Post-Program HDL (mg/dL) for females was 52.8 mg/dL, which was an insignificant increase of 1.5 mg/dL (p=0.5042) from 1-year Post-Program. Comparing the Baseline and 2-years Post-Program HDL (mg/dL) for females, there was a significant increase of 6.1 mg/dL (p<0.0086). HDL (mg/dL) levels continued to improve through each collection point. Females reached the target HDL (mg/dL) range in the 1-year Post-Program point and remained
above the goal through the 2-years Post-Program point, further supporting the success of interventions provided.

The target recommended HDL (mg/dL) for males with diabetes is >40 mg/dL (Buse et al., 2007). The recorded mean HDL (mg/dL) values for males at Baseline were 37.7 mg/dL and the Post-Program mean HDL was 40.0 mg/dL, which was statistically insignificant (p=0.1801) when compared to baseline, however, the increased HDL value from 37.7mg/dL to 40mg/dL shows patients reached the recommendation in the Post-Program period. The 1-year Post-Program HDL (mg/dL) was 44.4 mg/dL, which was a statistically significant increase of 4.4 mg/dL (p=0.0448) from Post-Program. The 2-year Post-Program HDL (mg/dL) for males was 45.0 mg/dL, which was an insignificant increase of 0.6 mg/dL (p=0.8059) from 1-year Post-Program. Comparing the Baseline and 2-years Post-Program HDL (mg/dL) for males, there was a significant increase of 7.3 mg/dL, (p=0.0005). HDL (mg/dL) levels increased from Baseline through 2-years Post-Program. Males reached the target HDL (mg/dL) range in the Post-Program point and remained above the target range through the 2-years Post-Program point.

For the individuals that completed the program, the Baseline mean HDL (mg/dL) was 43.6 mg/dL. There was an insignificant increase of 2.0 mg/dL (p=0.4158) from Baseline to Post-Program, which was 45.6 mg/dL. Again, even though the changes were insignificant, increases in HDL mg/dL levels would be considered beneficial. The 1-year Post-Program HDL (mg/dL) was 49.3 mg/dL, which was an insignificant increase of 3.7 mg/dL (p=0.1436) from Post-Program. The HDL (mg/dL) for 2-years Post Program for those that completed the program was 50.2 mg/dL, which was an insignificant increase of 0.9 mg/dL (p=0.7280) from 1-year Post-Program. Comparing the change from Baseline to 2-years Post-Program there was a significant increase in HDL (mg/dL) of 6.6 mg/dL, (p=0.0099), for those that completed the program by attending the follow up visit.
For the individuals that did not complete the program, the Baseline mean HDL (mg/dL) was 41.2 mg/dL. There was an insignificant increase of 3.1 mg/dL (p=0.0995) from Baseline to Post-Program, which was 44.3 mg/dL. The 1-year Post-Program HDL (mg/dL) was 46.7 mg/dL, which was an insignificant increase of 2.4 mg/dL (p=0.2437) from Post-Program. The HDL (mg/dL) for 2-years Post Program for those that did not complete the program was 48 mg/dL, which was an insignificant increase of 1.3 mg/dL (p=0.5463) from 1-year Post-Program.

Comparing the change from Baseline to 2-years Post-Program there was a significant increase in HDL (mg/dL) of 6.8 mg/dL, (p<0.0008), for those that did not complete the program by attending the follow up visit.

Combining all groups together, including males, females, those that completed the program by attending the follow up visit and those that did not, the mean HDL (mg/dL) at Baseline was 42.5 mg/dL. There was an insignificant increase of 2.5 mg/dL (p=0.1155) from Baseline to Post-Program, which was 45 mg/dL. There was an insignificant increase of 3.1 mg/dL (p=0.0627) from Post-Program to 1-year Post-Program, which was 48.1 mg/dL. The 2-year Post-Program mean HDL (mg/dL) for all groups was 49.2 mg/dL, which was an insignificant increase of 1.1 mg/dL (p=0.5215) from 1-year Post-Program. Comparing the change from Baseline to 2-years Post-Program, there was a significant increase in HDL (mg/dL) of 6.7 mg/dL (p<0.0001). The effects of dietary and exercise modifications can be seen in the elevations of HDL (mg/dL) levels for all groups throughout each collection point, which can result in positive health outcomes.

**Total Cholesterol Values**

Table 5 presents the mean TC values of each data collection point for gender, program completion, and for all groups. There were 116 individuals with TC values collected (n=116). Of those 116, 62 (53%) were female and 54 (47%) were male. Table 5 also presents a comparison of
TC (mg/dL) levels from Baseline to Post-Program, Post-Program to 1-year Post-Program, 1-year Post-Program to 2-years Post-Program, and Baseline to 2-years Post-Program for gender, program completion, and all groups. Repeated measures of ANOVA showed that patients benefitted greatly by receiving education through the SJM Center for Diabetes DSMEP for controlling TC (mg/dL) levels.

Table 5: Reported TC (mg/dL) values for Gender, Program Completion, and all groups at Baseline, Post-Program, 1-year Post-Program, 2-year Post-Program; and the t-test comparison of TC (mg/dL) levels from Baseline to Post-Program, Post-Program to 1-year Post-Program, 1-year Post-Program to 2-years Post-Program, and Baseline to 2-years Post-Program.

<table>
<thead>
<tr>
<th>Gender</th>
<th>Baseline TC (mg/dL) Mean ± SD</th>
<th>Post-Program TC (mg/dL) Mean ± SD</th>
<th>Baseline to Post-Program p-value</th>
<th>1-year Post-Program TC (mg/dL) Mean ± SD</th>
<th>Post-Program to 1-year p-value</th>
<th>2-years Post-Program TC (mg/dL) Mean ± SD</th>
<th>1-year to 2-year p-value</th>
<th>Baseline to 2-year p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Females (n=62)</td>
<td>191.1 ± 39.6</td>
<td>174.0 ± 34.5</td>
<td>0.0116</td>
<td>172.5 ± 32.1</td>
<td>0.8025</td>
<td>170.7 ± 32.3</td>
<td>0.7561</td>
<td>0.0021</td>
</tr>
<tr>
<td>Males (n=54)</td>
<td>182.4 ± 44.0</td>
<td>163.3 ± 39.6</td>
<td>0.0195</td>
<td>162.1 ± 37.0</td>
<td>0.8711</td>
<td>169.2 ± 45.0</td>
<td>0.3725</td>
<td>0.1262</td>
</tr>
<tr>
<td>Program Completed (n=64)</td>
<td>184.3 ± 42.7</td>
<td>167.5 ± 39.2</td>
<td>0.0220</td>
<td>161.3 ± 35.6</td>
<td>0.3507</td>
<td>167.0 ± 43.3</td>
<td>0.4175</td>
<td>0.0245</td>
</tr>
<tr>
<td>Program Not Completed (n=52)</td>
<td>190.5 ± 40.7</td>
<td>170.8 ± 34.7</td>
<td>0.0092</td>
<td>175.4 ± 32.4</td>
<td>0.4863</td>
<td>173.6 ± 31.9</td>
<td>0.7759</td>
<td>0.0203</td>
</tr>
<tr>
<td>TC for all groups (n=116)</td>
<td>187.0 ± 41.7</td>
<td>169.0 ± 37.2</td>
<td>0.0006</td>
<td>167.7 ± 34.8</td>
<td>0.7837</td>
<td>170.0 ± 38.6</td>
<td>0.6341</td>
<td>0.0015</td>
</tr>
</tbody>
</table>

SD=Standard Deviation
P is significant at less than .05
a Program completed as determined by attendance at the follow-up visit.
b Includes females and males.
c Includes Program Completed and Not Completed.

The target TC (mg/dL) for people with diabetes is <200 mg/dL (Buse et al., 2007). The recorded TC (mg/dL) values provided a mean TC (mg/dL) for females at Baseline of 191.1 mg/dL. The Post-Program mean TC was 174.0 mg/dL, which was a significant decrease of 17.1 mg/dL (p=0.0116) from Baseline. The 1-year Post-Program TC (mg/dL) was 172.5 mg/dL, which was an insignificant decrease of 1.5 mg/dL (p=0.8025) from Post-Program. The 2-year Post-Program TC (mg/dL) for females was 170.7 mg/dL, which was an insignificant decrease of 1.8 mg/dL (p=0.7561) from 1-year Post-Program. Comparing the Baseline and 2-years Post-Program TC (mg/dL) for females, there was a significant decrease of 20.4 mg/dL (p=0.0021). Total Cholesterol (mg/dL) levels continued to decline through each collection point. Females
were below the target TC (mg/dL) range at baseline and remained below the target range through the 2-years Post-Program point, suggesting that the SJM Center for Diabetes DSMEP is effective at maintaining TC levels below the target range.

The recorded TC (mg/dL) values provided a mean TC (mg/dL) for males at Baseline of 182.4 mg/dL. The Post-Program mean TC was 163.3 mg/dL, which was a significant decrease of 19.1 mg/dL (p=0.0195) from Baseline. The 1-year Post-Program TC (mg/dL) was 162.1 mg/dL, which was an insignificant decrease of 1.2 mg/dL (p=0.8711) from Post-Program. The 2-year Post-Program TC (mg/dL) for males was 169.2 mg/dL, which was an insignificant increase of 7.1 mg/dL (p=0.725) from 1-year Post-Program. Comparing the Baseline and 2-years Post-Program TC (mg/dL) for males, there was an insignificant decrease of 13.2 mg/dL (p=0.1262). TC (mg/dL) levels declined from Baseline through 1-year Post-Program and then showed an increase at 2 years Post-Program. Even though the TC (mg/dL) levels increased slightly at the 2-year Post-Program point, males remained below the target range from Baseline through the 2-years Post-Program.

For the individuals that completed the program, the Baseline mean TC (mg/dL) was 184.3 mg/dL. There was a significant decrease of 16.8 mg/dL (p=0.0220) from Baseline to Post-Program, which was 167.5 mg/dL. The 1-year Post-Program TC (mg/dL) was 161.3 mg/dL, which was an insignificant decrease of 6.2 mg/dL (p=0.3507) from Post-Program. The TC (mg/dL) for 2-years Post Program for those that completed the program was 167 mg/dL, which was an insignificant increase of 5.7 mg/dL (p=0.4175) from 1-year Post-Program. Comparing the change from Baseline to 2-years Post-Program there was a significant decrease in TC (mg/dL) of 17.3 mg/dL (p=0.0245), for those that completed the program by attending the follow up visit, and all collection points were below the target range for TC (mg/dL).
For the individuals that did not complete the program, the Baseline mean TC (mg/dL) was 190.5 mg/dL. There was a significant decrease of 19.7 mg/dL (p=0.0092) from Baseline to Post-Program, which was 170.8 mg/dL. The 1-year Post-Program TC (mg/dL) was 175.4 mg/dL, which was an insignificant increase of 4.6 mg/dL (p=0.4863) from Post-Program. The TC (mg/dL) for 2-years Post Program for those that did not complete the program was 173.6 mg/dL, which was an insignificant decrease of 1.8 mg/dL (p=0.7759) from 1-year Post-Program. Comparing the change from Baseline to 2-years Post-Program there was a significant decrease in TC (mg/dL) of 16.9 mg/dL (p=0.0203), for those that did not complete the program by attending the follow up visit, and again, all Post-Program points were again below the target range for TC (mg/dL).

When looking at all groups together, including males, females, those that completed the program by attending the follow up visit and those that did not, the mean TC (mg/dL) at Baseline was 187 mg/dL. There was a significant decrease of 18 mg/dL (p=0.0006) from Baseline to Post-Program, which was 169 mg/dL, suggesting that the SJM Center for Diabetes DSMEP is effective at lowering TC levels. There was an insignificant decrease of 1.3 mg/dL (p=0.7837) from Post-Program to 1-year Post-Program, which was 167.7 mg/dL. The 2-year Post-Program mean TC (mg/dL) for all groups was 170 mg/dL, which was an insignificant increase of 2.3 mg/dL (p=0.6341) from 1-year Post-Program. Comparing the change from Baseline to 2-years Post-Program, there was a significant decrease in TC (mg/dL) of 17 mg/dL (p=0.0015). The mean TC (mg/dL) for all groups was below the target of 200 mg/dL in all of the collection points, again showing significant improvements in TC (mg/dL). The TC levels for all groups remained below the target level from Baseline through 2-years Post-Program again supporting the success of education interventions at maintaining TC levels below the target range.
Chapter 5: Discussion

Question One: Is the SJM Center for Diabetes DSMEP effective at lowering and/or maintaining lowered HbA1c levels at one year and two years after receiving education?

Previous data collected on the SJM Center for Diabetes DSMEP supports the effectiveness of the program by demonstrating lowered HbA1c levels in individuals that attended the education classes (Karolle, 2011). Previous studies have also shown that the DSMEP can be a cost-effective method of maintaining glycemic control when compared with individuals who do not receive diabetes education (Li et al., 2010). The results of this study further support the effectiveness of the SJM Center for Diabetes DSMEP by reporting a significant decrease in HbA1c levels of 1.63% from the time an individual enters the program (Baseline) to the time that they complete the education classes (Post-Program).

The results also support a positive answer to the question of whether the SJM Center for Diabetes DSMEP is effective at maintaining lowered HbA1c levels at one and two years after receiving education services. Individuals in this study received services in 2010. Results from the Post-Program to 1-year Post-Program (2011) showed there was a modest but insignificant increase in mean HbA1c levels of 0.16%. There was again a slight, but insignificant increase in mean HbA1c levels from 1-year Post-Program to 2-years Post-Program of 0.07%, suggesting that the mean HbA1c levels stabilize and the slight trend upward was at a slower rate. While there were increases in HbA1c levels from the Post-Program to 1-year Post-Program and 2-years Post-Program, it is important to note that the mean HbA1c levels for all three Post-Program collection points were below the recommended HbA1c level for people with T2DM of 7.0% (ADA, 2011). The slight, but trending rise in HbA1c levels from the subsequent years may indicate a need for continued follow-up for each year after the initial education program,
however, further long-term studies with HbA1c levels will determine if the follow-up visits have a positive impact.

The results show the mean HbA1c level is lower, overall, in individuals who complete the program, though not to a significant degree. Further studies may indicate whether this is due to the education program, or the likelihood of general increased compliance in the group that completes the program.

**Question Two: Is the SJM Center for Diabetes DSMEP effective at lowering and/or maintaining lowered lipid levels at one year and two years after receiving education?**

This study provided some mixed results therefore it is necessary to review each of the lipid values separately.

**Mean LDL levels** for all groups from Baseline were 112.5 mg/dl and significantly decreased to 97.2 mg/dl at the Post-Program collection point. LDL levels continued to decrease from Post-Program to 1-Year Post-Program, and 2-years Post-Program. All of the post program levels were below the recommended LDL level of 100 mg/dl (Buse, 2007) and continued to trend lower from year to year. Therefore, LDL levels were initially lowered, and then were sustained throughout each of the data collection points.

LDL levels were not significantly different between genders. They were slightly higher in women, which may be a result of cholesterol levels rising as women age, increasing during and after menopause, associating the increased risk for CVD in women (Papdopoulou & Kaski, 2013). LDL levels continued to decrease from Post-Program to 1-year-Post Program and 2-years Post-Program for females. Males showed an initial decrease from Baseline to Post-Program, and from Post-Program to 1-year Post-Program. LDL levels began to rise insignificantly from 1-year Post-Program to 2-Years Post-Program.
The mean LDL levels were not significantly different between those that completed the program from those that only completed the nine-hours of classroom education. The group that completed the program had slightly lower LDL levels, but not to a significant degree. Again, further research will determine if this slight difference is related to increased compliance overall in the individuals who completed the program.

**HDL levels** showed no significance in change from Baseline to Post-Program for all groups. The levels did increase from Baseline to Post-Program, as well as from Post-Program to 1-year Post-Program, and again from 1-year Post-Program to 2-years Post-Program. While these levels trended higher throughout each of the data collection points, none of the changes were reported as significant; however, it is also essential to report that females and males reached their target HDL level.

HDL levels in all of the data collection points were significantly higher for women than for men. This may be attributed to the naturally occurring increased cholesterol levels in women throughout the study (Papdopoulou & Kaski, 2013). The combined gender mean HDL levels trended upward consistently from year to year. The target levels for HDL cholesterol are >40 mg/dL for men and >50 mg/dL for women (Buse, 2007). When looking at the differences for men and women, men met their target level in the Post-Program data collection point of 40.0 mg/dL and remained above target level into 1-year and 2-years Post-Program with 44.4mg/dL and 45.0 mg/dL. Women reached their target HDL level at 1-year Post-Program and remained in target at 2-Years Post-Program, with 51.3 mg/dl and 52.8 mg/dl respectively. Although there were no significant changes in HDL levels from Baseline to Post-Program between genders, whether the program was completed or not, and for all groups, it is important to note that the HDL levels continued to trend higher throughout each of the data collection points.
**Total Cholesterol levels** for all groups were below the goal of <200 mg/dl and remained below goal for the duration of the study (Buse, 2007). From Baseline to Post-Program, there was a significant decrease in mean TC levels of 18.0 mg/d. The TC levels for all groups decreased slightly and insignificantly, from Post-Program to 1-year Post-Program. The levels increased insignificantly from 1-year Post-Program to 2-years Post-Program. The insignificant change in TC levels suggest that they remained relatively stable after the initial lowering from Baseline to Post-Program.

TC levels were overall lower for men than women, this again may be attributed to the natural rise in cholesterol levels as women age, similar to the LDL and HDL levels (Papdopoulou & Kaski, 2013). TC levels continued to decrease from Post-Program to 1-year-Post Program and 2-years Post-Program for females. Males showed an initial decrease from Baseline to Post-Program, and from Post-Program to 1-year Post-Program. TC levels began to rise insignificantly from 1-year Post-Program to 2-Years Post-Program. This is a similar trend found in LDL cholesterol levels between genders. Further research will be needed to determine if there is any significance to this trend, and how it may further the advancement in reducing risks on heart disease for women and men.

The results from the lipid values suggest that the SJM Center for Diabetes DSMEP is an effective adjunct to a comprehensive therapy program in lowering and maintaining lowered LDL and TC levels, while increasing and maintaining increased HDL levels at 1 and 2-years following the program. These improved lipid levels can be instrumental in reducing macrovascular disease, as opposed to just HbA1c levels alone. Longer-term lipid values like these may also shed more light on the legacy effect discussed in the UKPDS (UKPDS, 1999) and EDIC (Nathan et al., 2005) studies for the long-term reduction in macrovascular disease.
Application to Practice

The UKPDS and the 10-year follow up showed that improvements in glycemic control could help reduce microvascular and macrovascular complications related to T2DM (Holman et al., 2008). The patients in the UKPDS studies received dietary and/or pharmacological interventions. The more recent ADVANCE (ADVANCE, 2008) trial also suggests that these interventions may continue to help reduce microvascular complications, and the results of the ADVANCE-ON follow up study may show similar promise for macrovascular complications if the legacy effect is true, which could reproduce results similar to the UKPDS 10-year follow-up study (Holman et al., 2008; ADVANCE, 2008; Hamet, 2012). Continued long-term observational studies on patients that enter the SJM Center for Diabetes DSMEP would be helpful in determining additional complication reduction potential.

The ACCORD study’s intensive arm was halted because aggressive intervention with medications was shown to increase mortality in high-risk, elderly patients with T2DM (ACCORD, 2011). The participants in this study receive both educational and pharmacological interventions. Similarly, the VADT study did not yield any positive results for intensive therapy on microvascular and macrovascular outcomes (Duckworth, 2009). This high risk, elderly population may benefit more from programs like SJM Center for Diabetes DSMEP, where the focus is on lifestyle instead of intensive control from pharmacological agents. Given the mean age of the study population of 64, it is possible that many individuals who enter the SJM Center for Diabetes DSMEP could fall under these characteristics and would likely be inappropriate for intensive therapy.

Program Planning

Program planning decisions are based on health outcomes of the patients, including HbA1c level reduction. Once the nine hours of education classes are complete, there is only one
follow-up visit planned, which is typically three to six weeks after the classes are completed. If
the patient does not attend that follow-up visit, the program is incomplete, and no further follow-
up occurs. Those that completed the program had overall improved levels in every category
when compared to those that did not complete the program. Considering the slight, but
significant increases in HbA1c levels and slight but insignificant increase in TC levels from Post-
Program to 1-year Post-Program and 2-years Post-Program, regularly continued follow-up visits
may result in maintained lowered HbA1c and lipid levels. Piloted follow-up visits with data
collection and analysis would be helpful in determining if regular post-program follow-up visits
would prevent any increase in HbA1c and TC levels.

Given the effectiveness of the SJM Center for Diabetes DSMEP, physician offices who
are changing to the PCMH model may continue to rely on the DSMEP to help patients reach
target health outcomes. As the climate of health care continues to change, it is important to keep
patient care at the forefront of any model. As health care reimbursement changes, the SJM
Center for Diabetes DSMEP may continue to be a cost-effective way of delivering much needed
education and support to individuals with diabetes.

**Limitations of this Study**

There were several variables not controlled for in this study include pharmacotherapy
agents prescribed by the patient’s physician, barriers to receiving services, and education or
information received by other means. These variables require acknowledgement as possible
contributors to compliance with lifestyle changes and increased blood glucose and lipid control.

The data collected on study participants may be affected by pharmacotherapy agents
prescribed by the patient’s physician. Understanding that the DSME is often an adjunct therapy
to pharmacotherapies prescribed by physicians, the goal is to help reduce microvascular and
macrovascular complications by decreasing the modifiable risk factors by all therapies necessary,
which may result in multiple concomitant therapies used, including the DSMEP (McCance, 2009).

This study reports a benefit from attending the SJM Center for Diabetes DSMEP; however, participants in the DSMEP may have had fewer barriers to self-care and more likely to improve their HbA1c and lipid levels. Barriers may be economical, physical, psychological, cultural, or social in nature. Barriers may affect an individual’s compliance to pharmacological therapy, behavior modification, and overall self-care. Individuals with difficult or multiple barriers may be less likely to attend a DSMEP. Some specific barriers may have been addressed individually, however are not accounted for in the scope of this study.

Patients may receive education or find information from multiple sources around them including the primary physician’s office, endocrinologist’s office, friends, family, as well as the abundance of information found on the internet when using reputable sources. Patients may also receive the emotional or social support needed to make necessary changes, overall affecting HbA1c and lipid values.

Not all laboratory values were available in the electronic medical record; values collected were obtained at the discretion of the individual’s physician. Individuals who have regular primary care appointments and laboratory values may be more likely to be successful in other self-management behaviors. St. Joseph Mercy Center for Diabetes does not collect any blood samples to address any missing data that would be helpful in assessing long-term effectiveness.
Chapter 6: Conclusions

Conclusions

The results of this study show that the SJM Center for Diabetes DSMEP is effective as part of a comprehensive therapy program in lowering HbA1c levels in people with diabetes from the time an individual enters the program to the end of the program. The results of this study also suggest that the SJM Center for Diabetes DSMEP is effective at improving LDL and TC levels from the beginning to the end of the program. Furthermore, the SJM Center for Diabetes DSMEP appears to be effective in sustaining improvements of HbA1c, LDL, HDL, and TC for at least two years after services were provided. There were no significant differences between the group that completed the program versus the group that did not complete the program, however in each of the data collection points there was a trend toward improvement for those who did complete the program. It is unknown whether this difference is related to the program, or other general compliance factors. The reductions in HbA1c percent and improvements in lipid levels are correlated with improved health outcomes in individuals with diabetes (ADA, 2011; McCance, 2009; Funnell, 2007), which is the main goal in providing diabetes education self-management programs. The results of this study further support the evidence suggesting that individuals with diabetes who attend a DSME program have better glycemic control, as well as improved lipid profiles, higher quality of life, and increased knowledge and understanding about diabetes and self-management skills (Brennan, Hwang, & Phelps, 2011; Khanna et al, 2012).

Implications for Saint Joseph Mercy Center for Diabetes

The current content of the SJM Center for Diabetes DSMEP covers not only methods to obtain and maintain optimal glucose levels, it also covers methods to obtain and maintain optimal lipid levels. The results from this study support the continued use of the current curriculum, updated regularly as new evidence-based material comes available. The slight
increase at one and two years in HbA1c and TC levels and the long-term intervention required to positively impact microvascular and macrovascular complications suggest a need for continued follow-up consisting of education and support in years following the initial education program. Long-term studies suggest a sustained benefit from initial interventions; however, microvascular and macrovascular risks may further be lowered from continued contact with the DSMEP.

**Future Research**

Future research could continue in a similar manner at SJM Center for Diabetes. The current Microsoft Access database used contains only pre and post program HbA1c levels that are available in PowerChart™ at the time the patient chart is audited and closed. Lipid values may be available and could be collected at the same time as the HbA1c by the clinician. If patients have continued follow-up visits at the SJM Center for Diabetes, the appropriate changes to the database could be made to capture this ongoing data as the patient returns for follow-ups. Annual queries are made in the database to evaluate pre- and post-program HbA1c levels; queries could be made at the same time to evaluate lipid levels.

As more physicians are using the EMR, more laboratory values will become available. As patients continue to follow-up with the SJM Center for Diabetes, longer-term data will become available. This data may be helpful in assessing long-term microvascular and macrovascular risk reductions associated with the SJM Center for Diabetes DSMEP.

Further studies that could be done within the SJM Center for Diabetes could be looking at the changes in HbA1c and lipid levels in the individuals that do not attend all of the education classes, or for the individuals that come in for one visit and do not return. Studies in this area could review the effectiveness of the initial contact point.
Another area of study could be the comparison of the DSMEP to the education received in the physician’s office. This may be an important area to study with the increased use of the PCMH, where more education is likely to be provided in the primary care setting.

An important undertaking will be in defining the numerous barriers that may be preventing individuals from attending or completing the education program, or taking part in basic diabetes self-care management. Understanding and addressing these barriers will aid in the development of strategies to overcome or manage them, while ultimately improving the level of glucose control and reducing overall health risks.
References


February 13, 2013

Clisty Kinlin, RD, CDE
St. Joseph Mercy Hospital
620 Byron Rd
Howell, MI 48843

Dear Clisty Kinlin:

On behalf of the SJMHS Institutional Review Board, expedited approval was granted on February 13, 2013 confirming that the following meets the requirements for expedited review and approval per 45 CFR 46.110(b) for the following new study. The number listed below has been assigned to this protocol.

**R-13-1438** The Effectiveness of the St. Joseph Mercy Center for Diabetes Education Program at 1 and 2 years post program completion. (New Study: Retrospective data review)

Your study was approved for 12 months with waiver of authorization. Your study’s continuing review approval will expire on **February 13, 2014**.

Federal regulations require that the IRB review each research project at least annually. It is your responsibility to submit the continuing review report in a timely manner so that IRB review can occur prior to the expiry date. **In approximately one year, or upon completion of your research project, a report will need to be submitted to the IRB that addresses the following points:**

1. The current status of the investigation (completed or continuing);
2. A list of subjects/record participating (included) in the project since its beginning, (using initials, code number or other means to maintain anonymity), and the date of entry for each subject/record;
3. A description of the experience of the subjects, including adverse reactions, complications, benefits and/or withdrawals from the study as applicable
4. A summary of the research results thus far;
5. A current assessment of the risks and benefits based on study results, including any new information that has come to light since the IRB’s last review;
6. A copy of the current consent form, if applicable.

**You should be aware that if the report is delinquent it is IRB policy to close the study and withdraw any intramural funding.** You should also know that the IRB periodically audits
research projects as part of its quality review process; your agreement to cooperate fully with such an audit is condition of approval.

All changes/amendments to your protocol or consent form require review and approval by the IRB prior to implementation. You are also required to submit a written description for any serious adverse reactions, unexpected events or deaths to the IRB Chairman and appropriate regulatory agencies within 72 hours of the occurrence. You are responsible for complying with these and all other policies and procedures of the SJMH Institutional Review Board.

The SJMHS IRB operates in accordance with the Good Clinical Practice Guidelines and applicable laws and regulations. If there is any aspect of the policies and procedures about which you would like further information please visit the SJMHS IRB website at http://www.sjmercyhealth.org/body.cfm?d=873. Failure to comply with SJMH policy is in violation of federal regulations and could result in withdrawal of approval and/or funding for your project.

Sincerely,

Digitally signed by Darlene Wahlberg
DN: cn=Darlene Wahlberg, c=US, o=SJMHS, ou=IRB Office, email=wahlberd@trinity-health.org
Reason: I am the author of this document
Location: Reichert Health Building Suite 6017
Date: 2013.02.13 10:25:17 -05'00'
Darlene Wahlberg, MBA
Saint Joseph Mercy Health System
Reichert Health Building Suite 6017
Ypsilanti, MI 48197

CC Kathleen Kasperek-Korelis
February 14, 2014

Clusty Kinlin, RD, CDE
St. Joseph Mercy Hospital
620 Byron Ed
Howell, MI 48843

Dear Ms. Kinlin:

On behalf of the SJMHS Institutional Review Board #1, expedited review was conducted on February 14, 2014 for the continuing review report confirming that the following meets the requirements for expedited review and approval per 45 CFR 56.110(b) and 21 CFR 56.110(b):.

R-13-1438 The Effectiveness of the St. Joseph Mercy Center for Diabetes Education Program at 1 and 2 years post program completion - 301 Records reviewed - CLOSED TO ACCURAL. This continuing review was sent to the IRB Office on January 23, 2014. It was filed incorrectly by the IRB Office (placed in wrong email folder) and it was discovered on 2/14/14. The study’s approval had expired on February 13, 2014 but the study is closed to accrual and is a retrospective data endeavor and the risk/benefit parameters are not affected by the 24 hour expiry.

Continuing Review Approval: February 14, 2014
Continuing Review Expiry: February 14, 2015
IRB Action: Annual review was approved for 12 months with waiver of authorization.

Federal regulations require that the IRB review each research project at least annually. In approximately one year, you will receive a reminder from the IRB Office. You should be aware that if the report is delinquent it is IRB policy to close the study and withdraw any intramural funding, if applicable. It is your responsibility to submit this report form in a timely manner. You should also know that the IRB periodically audits research projects as part of its quality review process; your agreement to cooperate fully with such an audit is condition of approval.

The SJMHS IRB operates in accordance with the Good Clinical Practice Guidelines and applicable laws and regulations. SJMHS IRB policies and procedures can be located via the following link: http://www.stjoesannarbor.org/irb. You are responsible for complying with these and all other policies and procedures of the SJMHS IRB. Failure to comply with SJMHS policy is in violation of federal regulations and could result in withdrawal of approval and/or funding.
Appendix 2 – Eastern Michigan University College of Health and Human Services Human Subjects Approval

**Date**: Tue Apr 16 2013  
**Subject**: MS #1116 - College of Health and Human Services Human Subjects  
**From**: Gretchen Dahl Reeves  
**Decision**: Accept Submission

Dear Clisty,

Congratulations! After careful review, your proposal "The Effectiveness of The St. Joseph Mercy Center for Diabetes Education Program at 1 and 2 years Post Program Completion." has been approved by the College of Health and Human Services Human Subjects committee. We stress that you do not stray from your proposed plan. Good luck with your research effort.

The current version of your paper is available here:
http://commons.emich.edu/cgi/preview.cgi?article=1116&context=chhs_hs

Sincerely,

Gretchen Dahl Reeves, PhD  
Chair, CHHS-HSRC
Appendix 3 – The SJM Center for Diabetes Service Request Form

<table>
<thead>
<tr>
<th>Appendix 3 – The SJM Center for Diabetes Service Request Form</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>PATIENT INFORMATION</strong></td>
</tr>
<tr>
<td>Patient Name:</td>
</tr>
<tr>
<td>Date of Birth:</td>
</tr>
<tr>
<td>Sex: M/F</td>
</tr>
<tr>
<td>Insurance:</td>
</tr>
</tbody>
</table>

**Services for patients WITH DIABETES:**

<table>
<thead>
<tr>
<th>DIAGNOSIS</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Type 2 Diabetes</td>
<td>Type 1 Diabetes</td>
</tr>
<tr>
<td>Pre Diabetes</td>
<td>FBS 100-125</td>
</tr>
</tbody>
</table>

**DIABETES SERVICES:**

<table>
<thead>
<tr>
<th>Nutrition and Diabetes Education</th>
<th>Type 1 or Type 2 diabetes (5-7 visits or classes/10-11 hours)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pre-diabetes Education</td>
<td>Individual visits and classes for weight loss</td>
</tr>
</tbody>
</table>

**Specialty Diabetes Education Services:**

<table>
<thead>
<tr>
<th>Start New Injectable Medication</th>
<th>Insulin, Byetta® or Symlin® Instruction – RN only</th>
</tr>
</thead>
<tbody>
<tr>
<td>Non-urgent</td>
<td>(1-2 visits / 1-2 hours)</td>
</tr>
<tr>
<td>Urgent</td>
<td>(within 7 days)</td>
</tr>
<tr>
<td>Instructions for oral agents</td>
<td>When above is begun</td>
</tr>
<tr>
<td>Nutrition Education Only</td>
<td>For patients with Type 1 or Type 2 diabetes – RD only</td>
</tr>
<tr>
<td>Diabetes Education Review</td>
<td>RD &amp; RN for patients who have previously attended diabetes</td>
</tr>
<tr>
<td>Blood glucose meter instruction</td>
<td>Only (1 visit / 1 hour)</td>
</tr>
<tr>
<td>Multiple Daily injection</td>
<td>RN &amp; RD – develop or assist with insulin algorithm</td>
</tr>
<tr>
<td>Pump Algorithm Adjustment</td>
<td>RN &amp; RD – problem solving and algorithm (4-8 visits / 4-10 hours)</td>
</tr>
<tr>
<td>Pump Education Review</td>
<td>RN only – assistance with sites or pump features (2-4 visits / 2-6 hours)</td>
</tr>
<tr>
<td>Pump Upgrade</td>
<td>RN only – advancement to new pump (1-2 visits / 1-2 hours)</td>
</tr>
<tr>
<td>Continuous Glucose Monitoring</td>
<td>CGM – RN only – Education, trial and/or initiation of CGM and</td>
</tr>
<tr>
<td>dawnload of data</td>
<td>(3-5 visits / 3-5 hours)</td>
</tr>
</tbody>
</table>

**SUPPORTING LABWORK:**

<table>
<thead>
<tr>
<th>Please complete the following or attach a copy of most recent lab results</th>
<th>Other</th>
</tr>
</thead>
<tbody>
<tr>
<td>FBS mg/dl Cholesterol mg/dl LDL mg/dl HDL mg/dl HbA1C % TGH mg/dl</td>
<td></td>
</tr>
<tr>
<td>Microalbumin mg/dl Creatinine mg/dl</td>
<td></td>
</tr>
</tbody>
</table>

**SERVICES FOR PREGNANT WOMEN:**

<table>
<thead>
<tr>
<th>Diagnosis: Gestational Diabetes or Impaired Glucose Tolerance during Pregnancy</th>
<th>Pre-existing diabetes with pregnancy</th>
<th>Pregnancy, does not have diabetes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Service requested: Diabetes and Education for diabetes during pregnancy – RN &amp; RD – Includes nutrition and monitoring education (2-3 visits / 34 hours)</td>
<td>Blood glucose monitoring instruction only – RN only (1 visit, 1/2 - 1 hour)</td>
<td>Prevention care for diabetes – RN &amp; RD (1-2 visits / 2-3 hours)</td>
</tr>
<tr>
<td>Insulin Instruction – Please specify type of insulin, dose and schedule</td>
<td>Healthy eating for pregnancy or pre-natal nutrition (no diabetes)</td>
<td></td>
</tr>
</tbody>
</table>

**Supporting Labwork:**

<table>
<thead>
<tr>
<th>1 hour OGGT - Fasting 1 hour 2 hour 3 hour</th>
</tr>
</thead>
<tbody>
<tr>
<td>3 hour OGGT</td>
</tr>
</tbody>
</table>

**PHYSICIAN INFORMATION:**

<table>
<thead>
<tr>
<th>Referring Physician:</th>
<th>Phone #:</th>
<th>Fax #:</th>
</tr>
</thead>
<tbody>
<tr>
<td>I certify that I am managing the above patient's diabetes or other medical condition(s) and that the diabetes self-management training or MNT requested is needed to ensure therapy compliance or provide the beneficiary with skills and knowledge to help manage their condition.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Signature of Referring Physician: Medicaid requires physician signature</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Fax completed form to (734) 712-1380</td>
<td>To schedule call 800-396-1313, option #3</td>
<td>For more information, call Phone: Diabetes (734) 712-2431 or (517) 545-6125, NutriCare (734) 712-5800</td>
</tr>
</tbody>
</table>

18001-935 R 10/08 (MD)
Appendix 4 – The SJM Center for Diabetes program outline.

Saint Joseph Mercy Center for Diabetes
Diabetes Self-Care Education Program

Family members and other support people are encouraged to attend with you. Please feel free to bring food or a drink with you.

First Visit
   Health History
   Diet History
   Meal Plan

Class #1. Diabetes Skills (3 hours)
**Bring glucometer and supplies to this class
   Meal Planning
   Medications
   Low Blood Sugar
   Blood Sugar Monitoring

Class #2. Diabetes Overview and Long Term Care for Diabetes (3 hours)
   What is Diabetes?
   Exercise
   High Blood Sugar
   Sick Day Management
   Diabetes Complications
   Hygiene and Foot Care
   Community Resources

Class #3. Nutrition for Diabetes (3 hours)
   Disease Prevention
   Dining Out
   Sweeteners
   Label Reading
   Goal Setting

Last Visit (1/2 hour with dietitian, 1/2 hour with nurse)
**Bring glucometer and blood sugar records to this visit
   Review of meter, blood sugar records, meal plan and exercise plan
   Behavior Goals
   Foot Care and Foot Exam

Ann Arbor classes are held Thursdays 5-8pm and Fridays 9am-12pm. Livingston classes are held Thursdays 1-4pm and 5-8pm. Registration is required. Please call us at (734) 712-1313 to schedule.