

CASE STUDY AND EVALUATION OF A PRE-DIABETES
SELF-MANAGEMENT EDUCATION PROGRAM

by

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DISSERTATION APPROVAL

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AN ABSTRACT OF THE DISSERTATION OF

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TITLE: CASE STUDY AND EVALUATION OF A PRE-DIABETES SELF-MANAGEMENT EDUCATION PROGRAM

MAJOR PROFESSOR: Dr. Roberta Ogletree

The primary purpose of this research study was to provide an in-depth analysis of a pre-diabetes self-management education program located in a Midwest health care center and to evaluate the effectiveness of the program. The study was designed to answer the following research questions: (1) How was the DSME program developed and how is it being implemented? (2) To what extent do the program's elements align with the *National Standards for Diabetes Self-Management Education?* (3) What factors affect completion of the entire program by participants? (4) What factors affect non-completion of the entire program by participants? (5) How do participants perceive their experience in the program? (6) What are the immediate effects of the program in terms of weight loss and exercise adoption? (7) What are the long-term effects of the program in terms of maintenance of weight loss, maintenance of physical activity, and prevention of T2D? (8) To what extent are the *AADE Standards for Outcome Measurement of DSME* being met?

Effective DSME programs are typically those that meet nationally recognized guidelines and outcomes measures. Data were collected to determine the effectiveness of this program using the following methods: interviews, document reviews, observations, and a survey.

Descriptive statistics in the form of frequencies and percentages were used to describe the results. Analysis of the qualitative data was conducted and themes emerged. Recommendations were provided as to how the program can be improved upon to make it more effective.

ACKNOWLEDGEMENTS

TBD

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CHAPTER ONE

INTRODUCTION

Background

Diabetes is an epidemic in the United States. Approximately 25.8 million Americans have diagnosed or undiagnosed diabetes, including 1.9 million newly diagnosed cases in 2010 (Centers for Disease Control and Prevention [CDC], 2011b). Diabetes contributes to debilitating complications, including diseases of the cardiovascular and nervous systems, failure of the eyes and kidneys, non-traumatic amputations, and complications of pregnancy. Diabetes was the seventh leading cause of death in the U.S. in 2007 and remained in that ranking for preliminary data for 2009 (CDC, 2011b; Kochanek, Xu, Murphy, Minino, & Kung, 2011). The most recent data show the economic cost of diabetes exceeded \$174 billion in 2007. Type 1, type 2 and gestational are the three major types of diabetes. The term pre-diabetes also has been quantified for diagnosis and is used to describe someone at increased risk for developing diabetes (CDC, 2011b).

Type 1 diabetes (T1D) is an autoimmune disease in which the body's own immune system destroys the cells in the pancreas responsible for the production of insulin. Insulin is a hormone that is required to regulate blood glucose levels (CDC, 2011b). Since the pancreas does not produce insulin and insulin is necessary for survival, T1D used to be referred to as insulin-dependent diabetes mellitus. T1D is usually diagnosed at a young age, thus it was also known as juvenile-onset diabetes. T1D accounts for about 5% of all diagnosed diabetes cases. There is no known way to prevent or cure T1D (American Diabetes Association [ADA], 2011; CDC, 2011b).

Type 2 diabetes (T2D) is the most prevalent type of diabetes (ADA, 2011; CDC, 2011b) and is the focus of this study. This type accounts for 90%-95% of all diagnosed diabetes cases (CDC, 2011b). T2D can be prevented and/or managed through certain lifestyle behaviors, such as maintaining a healthy body weight and getting appropriate exercise (ADA, 2011; CDC, 2011b). When cells in the body do not use insulin properly, it is called insulin resistance. T2D usually begins with insulin resistance. Because the pancreas produces insulin in most people with T2D, it was previously known as non-insulin-dependent diabetes mellitus. The pancreas, however, tries to compensate for the body's inability to use insulin properly by producing more. Eventually, the pancreas loses the ability to make more insulin. The inability of the pancreas to continue producing insulin results in insulin-dependent diabetes mellitus (CDC, 2011b).

Gestational diabetes only occurs in women during pregnancy (ADA, 2011; CDC, 2011b). It is a result of glucose intolerance. Generally, gestational diabetes affects 2%-10% of pregnancies and these women have a 35-60% chance of developing diabetes within the next 10-20 years (CDC, 2011b).

Pre-diabetes describes a condition in which the blood glucose level is higher than normal, but not high enough to be considered diabetes (ADA, 2011; CDC, 2011b). It is estimated that 35% of all adults in the U.S. had pre-diabetes in 2005-2008. Applying that value to the population in 2010 would yield an estimated 79 million U.S. adults with pre-diabetes (ADA, 2011; CDC, 2011b). Individuals with pre-diabetes are similar to those with diabetes in that they have an increased risk of developing various chronic diseases, such as T2D (Marrero, Ackermann, Hoskin, Gallivan, Ruggiero & Kriska, 2009). According to the American Association of Diabetes Educators (AADE), a 5- to 15-fold higher risk of developing T2D exists

in those with pre-diabetes as compared to those with normal blood glucose levels (Marrero et al., 2009).

Although there is no cure for diabetes, treatments for diabetes and prevention of onset of diabetes are numerous. Taking medications, following a healthy diet, exercising regularly, and losing weight are the major treatments available (AADE, 2010). While medications have been shown to be effective in most cases, interventions to prevent or delay T2D have been shown to be more reliable and cost-effective. Diabetes self-management education (DSME) programs are designed to facilitate the development of those behaviors and skills necessary to prevent and/or manage diabetes and related risks (Mulcahy, Maryniuk, Peeples, Peyrot, Tomkey, Weaver et al., 2003b). The ADA declared in the *Standards of Medical Care in Diabetes* (2010) that counseling of patients with or at-risk for diabetes is important for the success of the prevention or delay of T2D. Additionally, the ADA (2010) states that the individual's plan "should recognize diabetes self-management education (DSME) and on-going diabetes support as an integral component of care" (p. S16). The effectiveness of DSME is determined by whether certain standards have been met and whether certain outcomes have been measured. These standards and outcomes have been defined by the AADE and the ADA (AADE, 2010).

Statement of the Problem

The AADE and the ADA convened a task force in 2006 to review and revise the *National Standards for Diabetes Self-Management Education*, which were originally developed in 1983 as the *National Standards for Diabetes Patient Education Programs*. These *National Standards for Diabetes Self-Management Education* define what a quality DSME is and how to provide evidence-based practices to ensure an effective program (Funnell, Brown, Childs, Haas, Hosey, Jensen et al., 2010). Furthermore, in 2003, the AADE and the ADA defined five standard

outcomes measures called the *Standards for Outcomes Measurement of Diabetes Self-Management Education* (AADE, 2003). The AADE and ADA state that patient self-care behaviors should be measured at least before and after the intervention (AADE, 2003). Meeting the *Standards for Outcomes Measurement of Diabetes Self-Management Education* ensures the success of the program (Funnell et al., 2010).

A local Midwest health care center provides a DSME program. The program was modeled after the existing cardiac rehabilitation program within that same department. Patients are referred to the program by their doctors if they meet the criteria for pre-diabetes. The DSME program is an open program with rolling enrollment. Patients who enroll in the program attend weekly exercise sessions during which information about diabetes prevention and management is disseminated through lectures, videos, and handouts. It was unknown if this DSME program meets the *National Standards for Diabetes Self-Management Education* or if the recommended measures for outcomes are conducted. This case study describes the DSME program. The research was designed to then determine if the DSME program meets the *National Standards for Diabetes Self-Management Education* and the *Standards for Outcomes Measurement of Diabetes Self-Management Education* and whether it is an effective program as defined by the standards. This evaluation exposed the necessary areas for improvement as well as the elements that are effective in the program.

Purpose of the Study

The purpose of this research study was to provide an in-depth analysis of a DSME program at a Midwest health care center and to evaluate the effectiveness of the DSME program. The specific objectives of this study were: (1) to describe the program from inception to how it is currently implemented, (2) to determine if the *National Standards for Diabetes Self-Management*

Education are being met, (3) to determine what factors affect completion and non-completion of the program by participants, and (4) to determine the impact and outcome of the program. The remainder of this chapter provides an overview of the research was conducted to answer the research questions.

Significance of the Study

Health educators are charged with the responsibility to conduct evaluation and research related to health education. The results then must be interpreted to “compare evaluation results to other findings” and to “report effectiveness of programs in achieving proposed objectives” (National Commission for Health Education Credentialing [NCHEC], 2011). This case study of this DSME was essential to determine how the program operates and whether or not it is effective. The county that is served by this program has a higher prevalence of diagnosed diabetes (7.4%) than the national prevalence rate (6.4%) (CDC, 2011c; CDC, 2011b), so an effective program can help people in the area prevent and manage diabetes. Results were interpreted and compared to *National Standards for Diabetes Self-Management Education* and *Standards for Outcomes Measurement of Diabetes Self-Management Education* which are defined by major organizations for diabetes prevention and management. Results were then interpreted and reported as to the effectiveness of the program in achieving the objectives outlined within *National Standards for Diabetes Self-Management Education* and *Standards for Outcomes Measurement of Diabetes Self-Management Education*. Quality DSME programs are essential to help people learn to prevent, manage, and treat diabetes (Funnell et al., 2010). This case study is significant because these results may then be generalized to other similar programs. The results of this study may contribute to a foundation of best practices overall for DSME programs.

Research Questions

The following research questions directed this study:

1. How was the DSME program developed and how is it being implemented?
2. To what extent do the program's elements align with the *National Standards for Diabetes Self-Management Education*?
3. What factors affect completion of the entire program by participants?
4. What factors affect non-completion of the entire program by participants?
5. How do participants perceive their experience in the program?
6. What are the immediate effects of the program in terms of weight loss and exercise adoption?
7. What are the long-term effects of the program in terms of maintenance of weight loss, maintenance of physical activity, and prevention of T2D?
8. To what extent are the *AADE Standards for Outcome Measurement of DSME* being met?

Research Design & Methodology

This research is a case study of a DSME program at a Midwest health care center. It involves an in-depth description of the program as well as the impact and outcomes of the program. Both a formative and a summative evaluation of the DSME program were conducted. The formative evaluation provided evidence as to the process of how the program was developed and how it is being implemented. It also established the extent to which the DSME aligns with the *National Standards for Diabetes Self-Management Education*. The summative evaluation provided evidence as to program impact and outcomes. Program impact is defined as: 1) meeting the goals of achieving the adoption of at least 150 minutes of aerobic physical activity

each week and 2) losing 5-7% of excess body fat. Program outcome is defined as maintaining those goals and, ultimately, preventing T2D.

Data Collection

Data collection included multiple methods. Document reviews were conducted to obtain both data on the history of how the program was developed and how it is currently being implemented. Document reviews provided information that could not be observed or obtained through interviews about the program, such as unofficial correspondence to and from the Program Directors, information about the participants' initial session, etc. Additionally, document reviews allowed data collection about the extent to which the program meets the *National Standards for Diabetes Self-Management Education*. Interviews with the DSME director and participants were conducted to obtain rich, in-depth information on the program development and implementation that could not be determined by program documents and to obtain unique perspectives about the program. Interviews with the participants additionally provided data as to what factors affect completion and non-completion of the program. Observations of the DSME sessions were arranged to collect data about how the sessions are structured, the roles and activities of the program staff and participants, and other elements of the DSME program that could not be found in documents. Finally, a survey developed by this researcher was distributed to DSME participants to determine the impact and outcomes of the program.

Data Analysis

Much of the data collection is qualitative in nature. Results of data analyses yielded descriptions of the case being studied. The information allowed an alignment of the DSME to the *National Standards for Diabetes Self-Management Education* and the *AADE Standards for*

Outcome Measurement of DSME. Recorded interviews were transcribed verbatim. Content analysis was used to analyze interviews to determine emerging themes as to the factors that affect completion and non-completion of the program by participants. Descriptive statistical analyses were conducted on document review data and survey data from participants regarding the impact and outcome goals of weight loss, physical activity, and prevention of T2D. Results of univariate analyses were reported in averages and frequencies.

Limitations

The limitations of this study may include the following:

1. Program documents may be incomplete or inaccurate.
2. The DSME director may present biased information about the program.
3. Participants who choose to participate in the interview and complete the survey may have experienced the program differently than those who choose not to participate.
4. Participants may over-report or under-report their actual level of physical activity and body weight.
5. Participants may choose socially desirable responses when answering questions about their perception of the program and about the adoption and maintenance of the lifestyle behavior changes.
6. Results may not be generalized to other DSME programs in similar settings.
7. The researcher's opinions and perceptions may influence analysis and reporting of the case study.
8. The researcher may affect the situation being observed in unknown ways.

Delimitations

The study was characterized by the following delimitations:

1. The case study will focus on one DSME program at a health care center in the Midwest.
2. Participants for the interviews and survey will be recruited from that particular DSME program.
3. Participation in the interview and completion of the survey will be voluntary.
4. Observations of the program sessions will be selected based on the time and frequency of session delivery.
5. The primary method selected for this program is a qualitative approach.

Assumptions

The following assumptions are made for this study:

1. Access will be granted to program documents.
2. Observations of the program sessions will be granted.
3. Participants in the program will volunteer to serve as interviewees.
4. The DSME director and participants will answer interview questions honestly and to the best of their abilities.
5. Surveys will be completed honestly and returned by program participants.
6. The instruments selected will be adequate to answer the research questions.

Definitions of Terms

The following terms have special meaning to this study:

1. *Aerobic exercise*: exercise that lasts longer than a few minutes and requires oxygen for the production of energy necessary to sustain the activity (American College of Sports Medicine [ACSM], 2007).

2. *Anaerobic exercise*: exercise that lasts longer than a few seconds, but not more than a few minutes, and does not require oxygen for the production of energy necessary to sustain the activity (ACSM, 2007).
3. *Autoimmune disease*: “a disease in which the body’s own immune system destroys essential body tissue because it has mistakenly identified it as a foreign invader of the body” (Petit & Adamec, 2002, p. 36)
4. *Blood glucose level*: “the amount of glucose in a given amount of blood. It is noted in milligrams in a deciliter, or mg/dL” (ADA, 2011).
5. *Diabetes*: a disease in which the blood glucose levels are elevated due to inadequate insulin action or production (CDC, 2011b).
6. *DSME*: “the ongoing process of facilitating the knowledge, skill, and ability necessary for diabetes self-care. This process incorporates the needs, goals, and life experiences of the person with diabetes and is guided by evidence-based standards.” (Funnell et al., 2010, p. 599).
7. *Glycemic control*: “a description of overall blood glucose control” (Petit & Adamec, 2002, p. 142).
8. *Hemoglobin A1C*: “a test that measures a person’s average blood glucose level over the past 2 to 3 months. Hemoglobin (HEE-mo-glo-bin) is the part of a red blood cell that carries oxygen to the cells and sometimes joins with the glucose in the bloodstream. Also called hemoglobin A1C or glycosylated (gly-KOH-sih-lay-ted) hemoglobin, the test shows the amount of glucose that sticks to the red blood cell, which is proportional to the amount of glucose in the blood” (ADA, 2011).

9. *Impaired fasting glucose (IFG)*: “a condition in which a blood glucose test, taken after an 8- to 12-hour fast, shows a level of glucose higher than normal but not high enough for a diagnosis of diabetes. IFG, also called pre-diabetes, is a level of 100 mg/dL to 125 mg/dL” (ADA, 2011).
10. *Impaired glucose intolerance (IGT)*: “a condition in which blood glucose levels are higher than normal but are not high enough for a diagnosis of diabetes. IGT, also called pre-diabetes, is a level of 140 mg/dL to 199 mg/dL 2 hours after the start of an oral glucose tolerance test. Most people with pre-diabetes are at increased risk for developing type 2 diabetes. Other names for IGT that are no longer used are ‘borderline, subclinical, chemical, or latent’ diabetes” (ADA, 2011).
11. *Individualized medical nutrition therapy*: “the use of specific nutrition services to treat an illness, injury, or condition” (American Dietetic Association, 1994, p. 838).
12. *Insulin*: “a hormone that helps the body use glucose for energy. The beta cells of the pancreas make insulin” (ADA, 2011).
13. *National Standards for DSME*: “are [standards] designed to define quality diabetes self-management education and to assist diabetes educators in a variety of settings to provide evidence-based education. Because of the dynamic nature of health care and diabetes-related research, these Standards are reviewed and revised approximately every 5 years by key organizations and federal agencies within the diabetes education community” (Funnell, 2010, p. S89).
14. *Pre-diabetes*: “a condition in which blood glucose levels are higher than normal but are not high enough for a diagnosis of diabetes. People with pre-diabetes are at increased risk for developing Type 2 diabetes and for heart disease and stroke. Other

- names for pre-diabetes are impaired glucose tolerance and impaired fasting glucose” (ADA, 2011).
15. *Type 1 diabetes mellitus*: “a condition characterized by high blood glucose levels caused by a total lack of insulin. Occurs when the body's immune system attacks the insulin-producing beta cells in the pancreas and destroys them. The pancreas then produces little or no insulin. Type 1 diabetes develops most often in young people but can appear in adults” (ADA, 2011).
16. *Type 2 diabetes mellitus*: “a condition characterized by high blood glucose levels caused by either a lack of insulin or the body's inability to use insulin efficiently. Type 2 diabetes develops most often in middle-aged and older adults but can appear in young people” (ADA, 2011).

Summary

Chapter one provided the background and rationale for the study. Limitations, delimitations, assumptions and definitions were provided as well. Chapter two will provide a review of pertinent literature and chapter three will describe the methodology for this research.

CHAPTER TWO

REVIEW OF RELATED LITERATURE

Purpose

The purpose of this research study was to provide an in-depth analysis of a Diabetes Self-Management Education [DSME] program at a Midwest health care center and to evaluate the effectiveness of the DSME program. This chapter describes literature relevant to this study. The literature is divided into the following sections: diabetes prevalence and risk factors, impact of diabetes, types of diabetes, prevention of diabetes, treatment and management of diabetes, Diabetes Self-Management Education, effectiveness of DSME, case study research, and evaluation research.

Diabetes Prevalence and Risk Factors

Diabetes is a disease that is affecting the United States in epidemic proportions. The number of people diagnosed with diabetes has more than tripled over the last 25-30 years (CDC, 2010). From 1980 through 2008, the number of diagnosed diabetes cases rose from 5.5 million to 18.0 million respectively (CDC, 2010) (Figure 1). According to the CDC (2011b), there are approximately 18.8 million people with diagnosed diabetes in the United States. Also, it is projected that 7.0 million more people have diabetes but are not yet diagnosed (CDC, 2011b). New cases of diagnosed diabetes have increased significantly. Adults aged 18-79 years have seen more than a three-fold increase in the number of new diabetes cases from 1980 – 2009. While the number of new cases has increased significantly since the early 1990's, the overall number of new diabetes cases has risen from 493,000 in 1980 to more than 1.8 million in 2009 (CDC, 2010) (Figure 2).

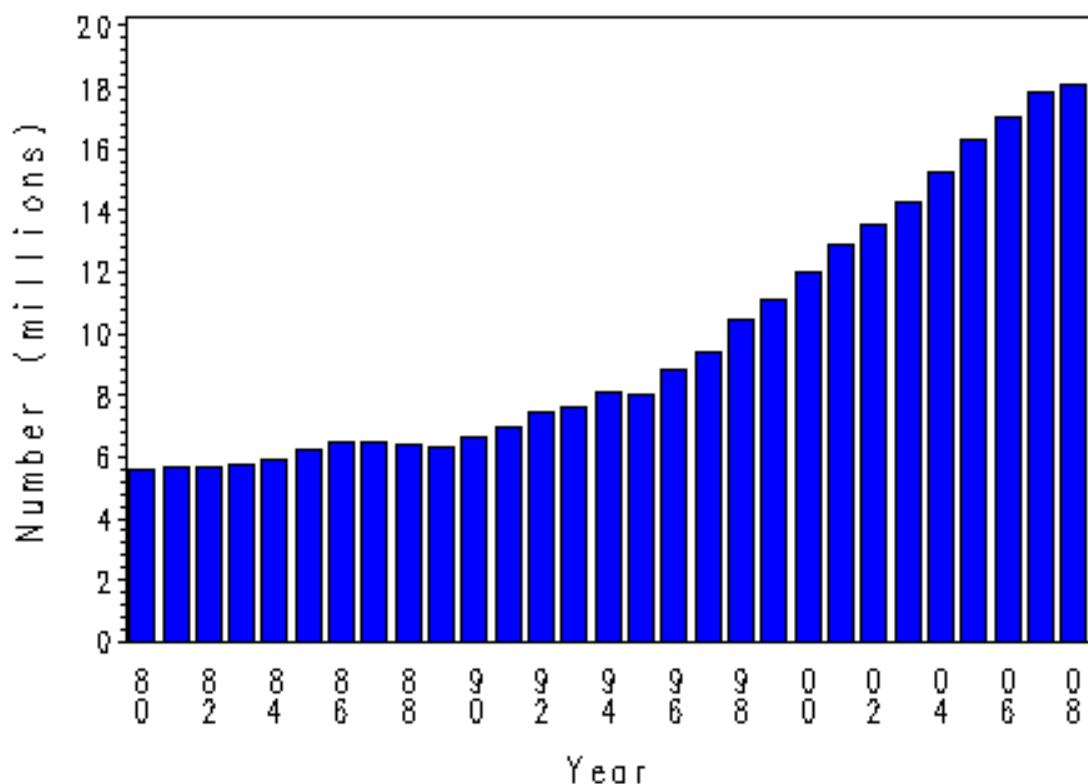


Figure 1. Number (in Millions) of Civilian, Non-institutionalized Adults with Diagnosed Diabetes, United States, 1980–2008 (CDC, 2010).

Risk factors for the development of diabetes include: “older age, obesity, family history of diabetes, history of gestational diabetes, impaired glucose metabolism, physical inactivity, and race/ethnicity” (CDC, 2011b). Obesity and physical inactivity are risk factors that are typically controllable. The increase in obesity rate in the United States has contributed to the increase in diabetes rate (CDC, 2010) (Figure 3). Flegal & colleagues (2010) reported the trend in obesity rate in the United States from 1999 – 2008. Obesity is defined as having a body mass index $\geq 30 \text{ kg/m}^2$. In 1999 – 2000, the percentage of obese men and women 20 years or older in the United States was 27.5% and 33.4%, respectively. By 2007-2008, the percentages of obese men and women increased to 32.2% and 35.5%, respectively (Flegal, Carroll, Ogden, & Curtin, 2010).

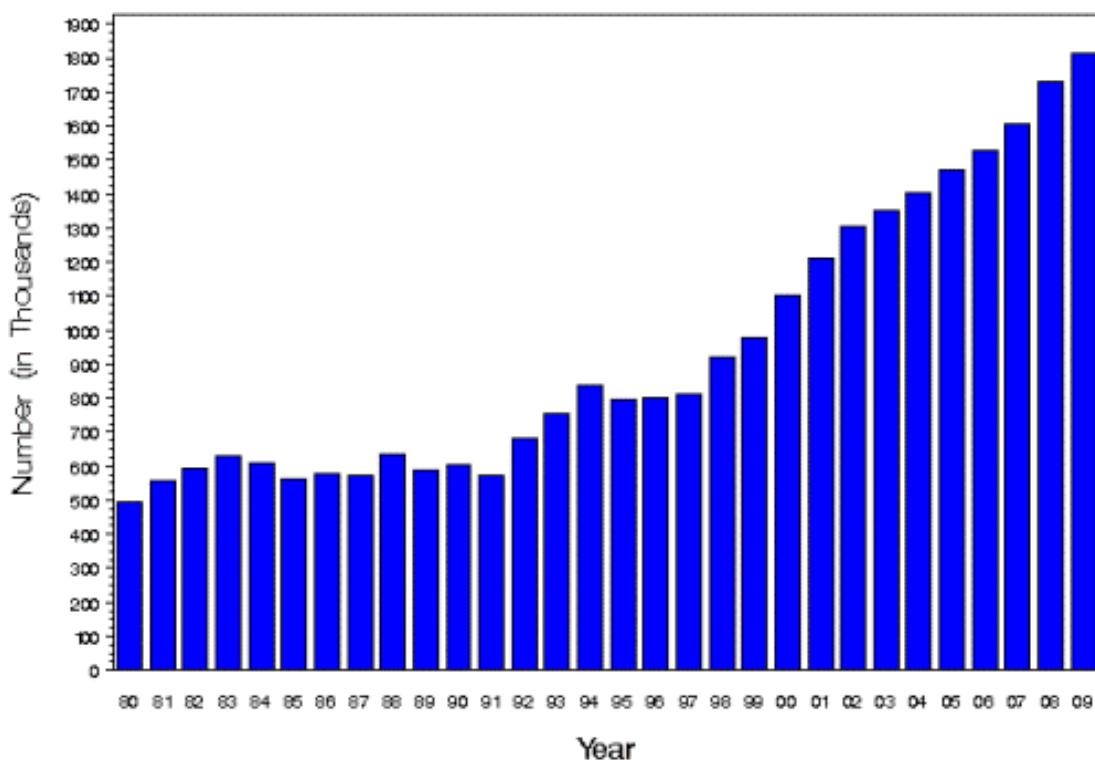


Figure 2. Annual Number (in Thousands) of New Cases of Diagnosed Diabetes Among Adults Aged 18–79 Years, United States, 1980–2009 (CDC, 2010)

Research has demonstrated that those at high risk who lose weight and increase their physical activity levels can significantly reduce the risk of developing diabetes (Eriksson & Lindgarde, 1991; Knowler, Barrett-Conner, Fowler, Hamman, Lachin, Walker, & Nathan, 2002; Norris, Zhang, Avenell, Gregg, Bowman, Schmid, & Lau, 2005; Pan, Li, Hu, Wang, Yang, An et al., 1997; Tuomilehto, Lindstrom, Eriksson, Valle, Hamalainen, Ilanne-Parikka, et al., 2001).

Impact of Diabetes

Diabetes can be extremely debilitating. The CDC (2011b) attributes the following complications to diabetes: cardiovascular disease, hypertension, blindness, nephropathy, nervous system disease, amputations, dental disease, and complications of pregnancy to name a few. In

the “National Diabetes Fact Sheet, 2011” document, the most recent information on the prevalence for the various complications is reported. Prevalence rates for heart disease and

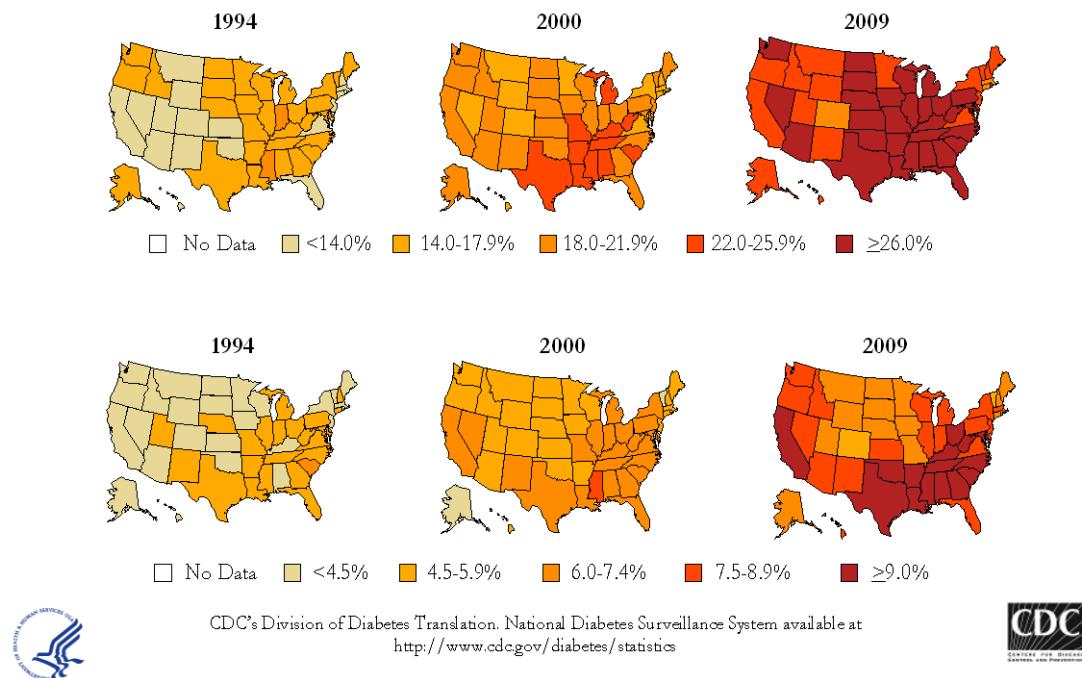


Figure 3. Age-adjusted percentage of U.S. adults who were obese (top pictures) or who had diagnosed diabetes (bottom pictures) (CDC, 2010).

stroke are two to four times higher in people with diabetes than in those without diabetes. It was reported that 67% of those with diabetes had hypertension as defined by a blood pressure greater than or equal to 140/90 mmHg (CDC, 2011b). Additionally, the leading cause of blindness is attributed to diabetes accounting for approximately 4.2 million cases between 2005 and 2008. Forty-four percent of the new cases of kidney failure in 2008 were attributed to diabetes. Approximately 60-70% of people with diabetes have nervous system damage and in 2006, they experienced 65,700 lower-limb amputations. Dental disease is twice as prevalent and birth

defects and spontaneous abortions occur in 5-10% and 15-20% of pregnancies, respectively (CDC, 2011b).

In addition to the detriment to the overall health of people with diabetes, diabetes affects Americans economically as well. The CDC's most recent estimate concluded that medical costs and decreased productivity due to diabetes totaled \$174 billion in 2007 (CDC, 2011b). People with diabetes access health care more often and have higher medical costs up to 2-3 times that of people without diabetes (Dall, Mann, Zhang, Martin, Chen, & Hogen, 2008). Additionally, the estimated economic cost due to undiagnosed diabetes in the United States in 2007 exceeded \$18 billion (Zhang, Dall, Mann, Chen, Martin, Moore et al., 2009)

Types of Diabetes

There are various types of diabetes mellitus including T1D, T2D, gestational diabetes, and pre-diabetes. Other names commonly used include juvenile-onset diabetes, adult-onset diabetes, insulin-dependent diabetes mellitus, and non-insulin dependent diabetes mellitus (CDC, 2011b)

Type 1 Diabetes Mellitus

T1D was previously referred to as juvenile onset diabetes. Researchers realized that, in addition to children, adolescents and adults could also develop this form of diabetes, so the name was changed. T1D was also previously referred to as insulin-dependent diabetes mellitus until researchers realized that people with T2D diabetes may develop the need to take insulin, so the name was changed for that reason as well (Petit & Adamec, 2002). T1D is believed to be an autoimmune disease in which the pancreatic beta cells are mistakenly destroyed by the body. These beta cells are responsible for the production of insulin (Petit & Adamec, 2002). When the beta cells are destroyed, insulin is no longer produced. Insulin is a hormone that aids in the

movement of glucose from the blood into the cells (CDC, 2011b). It is necessary to move glucose from the blood into the cells in order to produce energy. Energy is necessary for all processes within the body, including exercise and other biological and chemical activities (ACSM, 2007). Without insulin, the body cannot survive. A person with T1D must inject insulin into the body every day (CDC, 2011b).

T1D accounts for about 5% of all diagnosed diabetes cases in the United States. It generally develops in children or adolescents. T1D in adults accounts for about 5 percent of all diagnosed cases of diabetes (National Diabetes Information Clearinghouse [NDIC], 2011). While the exact cause of T1D is unknown, risk factors include the environment and genetics. Currently there is no prevention or cure for T1D (CDC, 2011b).

Type 2 Diabetes Mellitus

T2D was previously referred to as non-insulin dependent diabetes mellitus. The name was changed because it is possible for someone with T2D to require insulin therapy later in life due to the cessation of insulin production by the pancreas (Petit & Adamec, 2002). It is the most common form of diabetes accounting for 90-95% of all diagnosed diabetes cases (CDC, 2011b). It usually develops as a person ages, which is why it is used to be referred to as adult-onset diabetes; however, diagnosis of T2D among children has been increasing (Petit & Adamec, 2002). T2D begins as insulin resistance. Cells in the body do not respond normally to insulin and, therefore, glucose cannot be delivered to the cells to be stored or used for energy (Medline Plus, 2011b; Petit & Adamec, 2002). Fat cells are thought to resist the action of insulin which is why being overweight or obese increases one's risk of developing T2D. Most people diagnosed with T2D are overweight at the time of diagnosis (Medline Plus, 2011b).

T2D develops gradually over time due to various risk factors. Uncontrollable risk factors include having a family history of diabetes, having a history of gestational diabetes, older age, and race/ethnicity such as African Americans, Hispanic/Latino Americans, American Indians, and some Asian Americans and Native Hawaiians or other Pacific Islanders. Controllable risk factors include obesity and a sedentary lifestyle (CDC, 2011b). “The majority of people with type 2 diabetes are obese” (Petit & Adamec, 2002, p. 241).

Gestational Diabetes Mellitus

Gestational diabetes occurs in pregnant women. Roughly 2-10% of pregnancies are affected by gestational diabetes. Women who experience gestational diabetes have an approximate 35-60% increased chance of developing diabetes in the following 10-20 years. Obese women, those with a family history of diabetes, and women who are African American, Hispanic/Latino American, and American Indian are at a higher risk of developing gestational diabetes (CDC, 2011b). Additionally, women who are over age 25, who previously gave birth to a large infant, and who had problems with previous pregnancies such as still-births or miscarriages are also prone to gestational diabetes (Petit & Adamec, 2002). Uncontrolled diabetes during pregnancy can result in increased chance of needing a C-section, preeclampsia, miscarriage or stillbirth, and early or preterm birth. Uncontrolled diabetes during pregnancy can result in birth defects, increased birth weight, low blood sugar after birth, and an increased risk of developing obesity and diabetes later in life for the baby (CDC, 2011a).

Pre-diabetes

Pre-diabetes is a condition in which blood glucose levels are above the healthy range, but not yet high enough to be diagnosed as diabetes. The diagnosis of pre-diabetes results from having impaired fasting glucose or impaired glucose tolerance (CDC, 2011b). A normal fasting

blood glucose level should be below 100 mg/dL. A person with diabetes has a fasting blood glucose level above 126 mg/dL. Someone who has a fasting blood glucose level between 100 and 126 mg/dL is identified as having pre-diabetes (CDC, 2011b). Similarly, normal glucose tolerance would result in a blood glucose level below 140 mg/dL after a 2-hour glucose tolerance test. A person with diabetes has a blood glucose level of 200 mg/dL or higher after a 2-hour glucose tolerance test. Those for whom the level is between 140 and 199 mg/dL are identified as having pre-diabetes (CDC, 2011b). The CDC projected that approximately 79 million Americans had pre-diabetes in 2010. People with pre-diabetes have an increased risk of developing T2D, as well as an increased risk of cardiovascular disease and stroke (CDC, 2011b).

Prevention of Diabetes

A sedentary lifestyle and obesity have been shown to significantly increase one's risk of developing T2D (CDC, 2011b). Typically, these are controllable risk factors for developing diabetes. Several landmark studies demonstrate the significance of lifestyle intervention on declines in T2D risk, including weight reduction and regular physical activity (Hu, Manson, Meir, Colditz, Liu, Solomon, & Willett, 2001; Knowler et al., 2002; Lindstrom, Ilanne-Parikka, Peltonen, Aunola, Eriksson, Hemio et al., 2006; Lindstrom, Lauheranta, Mannelin, Rastas, Salminen, Eriksson, Uusitupa & Tuomilehto, 2003; Tuomilehto et al., 2001). An overview of those studies and the results follows.

The Finnish Diabetes Prevention Study Group demonstrated that those with impaired glucose tolerance can significantly reduce their risk of developing diabetes by affecting the modifiable risk factors of obesity and sedentary lifestyle (Tuomilehto et al., 2001). Between 1993 and 1998, 522 subjects with impaired glucose tolerance were randomly assigned to an intervention group or a control group. The main goals for the intervention group were to achieve

a reduction in weight of 5% or more and to exercise at a moderate intensity for at least 30 minutes per day. The overall incidence of diabetes in the intervention group as compared to the control group was reduced by 58%; this included a 63% reduction among men and a 54% reduction among women (Tuomilehto et al., 2001). This landmark study was one of the first of its kind to demonstrate how significantly lifestyle changes reduce the risk of developing T2D.

Hu and colleagues (2001) demonstrated similar results in a study of 84,941 female nurses selected from the Nurses' Health Study data. The nurses were followed for 16 years during which 3300 new cases of T2D were diagnosed. Overweight or obesity measured by body mass index was determined to be the most important predictor of the development of diabetes. After adjustment for the body mass index, however, other factors such as sedentary lifestyle, poor diet, smoking status, and the absence of limited alcohol use were all associated with a significantly higher risk of diabetes development. Obtaining and maintaining an appropriate weight, exercising regularly, consuming a healthy diet, and consuming limited amounts of alcohol were recommendations derived from this study to reduce the risk of developing T2D (Hu et al., 2001).

The Diabetes Prevention Program Research Group compared incidence of diabetes in persons with high risk who made lifestyle changes and those who took the medication metformin (Knowler et al., 2002). Metformin is a medication commonly used to increase the sensitivity of cells to the action of insulin, thus reducing insulin resistance (Skidmore-Roth, 2000). Researchers randomly assigned 3234 non-diabetic people into three groups – intensive lifestyle-modification group, metformin group and control group. The intensive lifestyle modification group had a goal to achieve at least a 7% weight loss and accumulate at least 150 minutes of physical activity per week. The metformin group took the medication twice daily and received standard lifestyle recommendations. The control group took a placebo twice daily and received

standard lifestyle recommendations. Results demonstrated that both lifestyle-modification and metformin reduced one's risk of developing T2D; however, the lifestyle intervention demonstrated a 58% reduction while the metformin group demonstrated a 31% reduction overall (Knowler et al., 2002).

A follow-up study to the Finnish Diabetes Prevention Study was conducted to determine the impact of the lifestyle intervention. Physical activity, dietary intake, and various other clinical and metabolic measures were assessed after one and three years following the conclusion of the original study. The one and three-year results indicated that the intervention group continued to show significantly greater improvements over the control group. Long-term benefits were achieved in physical activity level; dietary changes, various clinical and metabolic indices, as well as diabetes risk (Lindstrom et al., 2003).

Lindstrom et al. (2006) conducted another follow-up to the original Finnish Diabetes Prevention Study. Participants were tracked for a median total of seven years. Results of the seven years total follow-up showed a relative risk reduction for the development of T2D of 43%, compared to the original study results of 58%. Results demonstrated that “an intensive lifestyle intervention lasting for a limited time can yield long-term benefits in reducing the risk of type 2 diabetes in high-risk individuals” (Lindstrom et al., 2006, p. 1677).

The aforementioned studies demonstrate the magnitude of achieving and maintaining a small amount of weight loss as well as regular physical activity in order to reduce the risk of developing T2D. These and other self-care behaviors have been identified as strategies for the treatment and management of diabetes.

Treatment and Management of Diabetes

The American Association of Diabetes Educators [AADE] has identified seven self-care behaviors essential for the treatment and management of diabetes. The seven self-care behaviors, identified as *AADE 7* are: “healthy eating, being active, monitoring, taking medication, problem solving, reducing risks and healthy coping” (AADE, 2010). Several review studies were conducted that provide the evidence base for these self-care behaviors (Boren, Gunlock, Schaefer & Albright, 2007a; Fisher, Thorpe, DeVellis, B., & Devellis, R., 2007; Funnell, 2007; Hill-Briggs & Gemmell, 2007; Kavookjian, Elswick & Whetsel, 2007; Odegard & Capoccia, 2007; Povey & Clark-Carter, 2007;). Those review studies are described within each self-care behavior section below. Additional information about each of the AADE 7 is provided by Mulcahy and colleagues (2003a) from a technical review of the published evidence.

Healthy Eating

Healthy eating contributes to the management of diabetes. Factors affecting decisions about what to eat, when to eat, and how much to eat include food availability, family eating patterns, habits, emotions, food preferences, blood glucose control, and knowledge regarding how food affects diabetes control and overall health (Mulcahy, Maryniuk, Peeples, Peyrot, Tomkey, Weaver et al., 2003a). Clinical studies report better glucose control and a decrease in LDL cholesterol in those with pre-diabetes and diabetes who follow individualized medical nutrition therapy (ADA, 2007). Medical nutrition therapy is defined as the use of specific nutrition services to treat an illness, injury, or condition (Pastors, 2002, p. 608). Medical nutrition therapy assists in weight control (ADA, 2007). Povey & Clark-Carter (2007) reviewed literature pertaining to healthy eating and the impact on the treatment and management of diabetes. They began with 497 potential studies and narrowed them down to 23 peer-reviewed

studies published from 1990 through March 2006. The researchers discovered that, although standardization among these studies was limited, overall, the results showed that a healthy plan of eating improves diabetes management (Povey & Clark-Carter, 2007). These results support the ADA position statement on nutrition recommendations and interventions. The ADA (2007) recommends individualized medical nutrition therapy provided by a registered dietician for anyone with pre-diabetes or diabetes. Additionally, the ADA (2007) recommends nutrition counseling for the individual.

Skills necessary to successfully change behavior to adopt healthy eating include carbohydrate and fat gram counting, label reading, and measuring foods for portion control (Mulcahy et al., 2003a). The DSME program is charged with facilitating the adoption of these skills for improved metabolic control. Evaluation of eating behavior can be done through patient self-report. Standard assessments include the 24-hour recall and food frequency questionnaire. Data should be collected regarding blood glucose levels, food records, skill checks, food choices, amounts eaten, and the timing of meals. The effect of food on blood glucose should be measured at baseline, 2 to 4 weeks, and then every 3 to 6 months (Mulcahy et al., 2003a).

Being Active

Regular physical activity has been shown to significantly decrease one's risk for the development of diabetes (Hu et al., 2001; Knowler et al., 2002; Lindstrom et al., 2003; Lindstrom et al., 2006; Tuomilehto et al., 2001). Kavookjian & colleagues (2007), however, reported that the lifestyle change of physical activity remains problematic for most people with diabetes or pre-diabetes. They reviewed twelve electronic databases to assess evidence in the literature regarding physical activity as an intervention for those with diabetes. Ultimately, the

researchers reported that evidence revealed that exercise aided in control of blood glucose levels as well as diabetes-related complications (Kavookjian et al., 2007).

Aerobic physical activity should be performed optimally for 20-30 minutes, 3 to 5 times per week at a moderate intensity. However, to obtain better control of blood glucose levels, the duration of aerobic exercise should be up to 40 minutes and it should be completed 3 to 4 times weekly. For weight control, the duration should be 45 to 60 minutes, 4 to 5 times weekly. People with diabetes should have a baseline of knowledge with regard to physical activity including the type, duration, frequency, and intensity of aerobic exercise as well as appropriate food intake and monitoring blood glucose levels before and after activity. Additionally, they should adopt physical activity as a lifestyle behavior. Assessment of physical activity should be measured at baseline, at 2 to 4 weeks, and then every 3 to 6 months. Data is frequently collected through self-report, observation, and other physical activity instruments such as a pedometer (Mulcahy et al., 2003a).

Monitoring

It is recommended for patients who have diabetes and use insulin to monitor blood glucose levels. However, physicians are divided as to whether or not patients should self-monitor blood glucose levels if they have T2D and do not use insulin (Funnell, 2007). Funnell (2007) reviewed research published on self-monitoring of blood glucose on patients with T2D who do not use insulin and found the results of the research to be mixed. The researcher commented that, although strong supportive evidence for this population is lacking, some studies have shown that self-monitoring of blood glucose can improve a person's long-term blood glucose levels if only to help that person make better decisions with regard to diet, exercise, and taking medications (Funnell, 2007). Monitoring of blood glucose has also been shown to

decrease acute complications of diabetes, such as hypoglycemia (Mulcahy et al., 2003a).

Diabetes educators train patients to make such decisions with regard to the treatment and management of diabetes; therefore, it is suggested that diabetes educators can help convince the patient of the importance of self-monitoring of blood glucose, although the optimal frequency of monitoring blood glucose levels for those with T2D is unknown (Funnell, 2007).

Patients should be assessed at baseline, at 2 to 4 weeks, and then every 3 to 6 months for blood glucose monitoring behavior. Such behavior includes the method, technique and frequency of monitoring. Barriers to attainment of this behavior change should be assessed as well. Self-report, logs, and stored data in glucose meters are methods of assessment for this behavior change (Mulcahy et al., 2003a).

Taking Medication

In 2006, the ADA added the medication metformin to lifestyle changes of physical activity and weight loss as the initial treatment plan for a person upon diagnosis of T2D. It was noted that metformin provided benefit in the management of blood glucose of an additional 1-2% decrease in hemoglobin A1C without significant disadvantages (Nathan, Buse, Davidson, Ferrannini, Holman, Sherwin et al., 2009). As stated earlier, hemoglobin A1C is a test that measures the average amount of glucose in the blood over a period of time. It is a method to determine how well the blood glucose levels have been managed over time (Medline Plus, 2011a). Adherence to diabetes medication therapy, however, is poor and ranges from 36% to 85% adherence (Odegard & Capoccia, 2007). Odegard & Capoccia (2007) reviewed 283 published articles from 1990 through May 2007 with regard to taking oral diabetes medications, compliance, and adherence. Thirty-six of the original 283 articles were included in their review. Researchers summarized many of the most common barriers to following the medication

regimen, including complexity of the regimen, failure to remember doses and refills, fear of adverse effects, self-confidence, and depression (Odegard & Capoccia, 2007). Medication therapy is an essential part of diabetes self-management. Diabetes educators need to identify the barriers to following a medication regimen, help patients develop strategies to overcome such barriers, and provide opportunities for follow-up assessments to ensure that patients are taking the medication properly (Odegard & Capoccia, 2007).

Necessary medication taking behaviors for effective glucose control include: administration at recommended time(s) of day; frequency of doses; correct dose preparation, selection, or calculation; administration technique and skills; consistency over time; adjustment for delayed or missed doses; management or recognition of adverse effects; and recognition of drug failure by interpreting self-monitoring of blood glucose results or symptoms. Assessment of medication taking behavior should be completed at baseline and disparities should be addressed at that time with the patient. Additional assessments should be completed at least annually. Assessment data can be obtained through direct observation of the behavior. Role-playing with the patient can provide additional assessment of other skills, such as what to do in the case of hypoglycemia, etc. Other measures include reviewing self-report diaries, measuring the amount of drug used/unused, and checking refill profiles (Mulcahy et al., 2003a).

Problem Solving

To adequately manage diabetes, patients need to go beyond having the knowledge and skills to carry out appropriate behaviors. One must overcome barriers to following the appropriate treatment and management techniques. “Problem solving is a learned skill that is most commonly characterized as involving a sequence of rational steps” (Hill-Briggs & Gemmell, 2007, p. 1047). Hill-Briggs & Gemmell (2007) reviewed 52 studies to assess the

association between problem solving and diabetes self-management. Results provided consistent evidence that an adult with good problem-solving abilities had more control and showed improvement in hemoglobin A1C levels.

Goals for problem solving include educational and behavioral goals. Educational goals incorporate knowledge of individual blood glucose levels, recognition of physical signs and symptoms, and appropriate treatment for high and low blood glucose levels. Behavioral goals include developing appropriate problem-solving skills for responding to blood glucose readings and the associated implications of blood glucose levels. Data can be collected through patient self-report and blood glucose monitoring data, medical charts and patient self-report for clinical care in cases of hyper- or hypo-glycemia, and patient self-report of days missed from work, school, or other activities due to diabetes-related issues (Mulcahy et al., 2003a).

Reducing Risks

Complications from diabetes are numerous. Diabetes-related complications include having a 2-4 times higher rate of death due to heart disease and a 2-4 times higher risk of stroke, as well as higher rates of hypertension, blindness, kidney disease, nervous system disease, nontraumatic lower-limb amputations, dental disease, complications of pregnancy, and other illnesses (CDC, 2011b; Petit & Adamec, 2002). Reducing the risks of developing complications from diabetes is essential for diabetes self-management. Boren & colleagues (2007a) reviewed 39 published articles between 1990 and 2007 for evidence to support this claim. Their research focused on the following risk-reduction topics: smoking cessation, eye examination, foot care, oral health, vaccination, cardiovascular risk reduction, and comprehensive risk reduction (Boren et al., 2007a). Recommendations from this review include having clinicians work collaboratively with patients to identify the particular risks, developing a plan of care, and

communicating with the patient what is expected of him or her to maximize reduction of risk. Empowering individuals to take control of their care is a recommendation of this study (Boren et al., 2007a).

Risk-reduction behaviors can be assessed through self-report, questionnaires, or other written maintenance schedules. Verification of these behaviors can be assessed through demonstration by the patient and laboratory data. Data should be collected at baseline, at 2 to 4 weeks, and every 3 to 6 months (Mulcahy et al., 2003a).

Healthy Coping

Psychological and social factors impact diabetes management and metabolic control. Learning to cope with the barriers to diabetes self-management and with psychological and social stressors, described by the AADE as healthy coping, can help a person more effectively manage diabetes. Identifying effective interventions for healthy coping was the goal of the review conducted by Fisher and colleagues (2007). The researchers searched for published articles from 1990 through July 2006 and identified 186 supporting articles. The review was divided into three parts. Part 1 dealt with the interrelationship between diabetes management, health status, quality of life and psychosocial factors. Part 2 dealt with psychosocial and emotional issues and the impact on diabetes management. Part 3 dealt with evidence for healthy coping interventions on metabolic control and diabetes management. The researchers concluded that healthy coping through coping/problem-solving interventions, treatment of depression, support groups, and therapy, among other strategies, improved metabolic control and quality of life (Fisher et al., 2007).

The ultimate goal of healthy coping is to improve one's quality of life. Psychological distress, quality of life, psychological adjustment, and health-related beliefs and perceptions

should be assessed at baseline, at 2 to 4 weeks, and every 3 to 6 months. Methods of data collection include specific tools for measuring each of the above mentioned measurements. For psychological distress, a questionnaire, such as the Zung/Beck Depression Scale, can be used. SF-36/SF-12 can be used to measure quality of life. The P.A.I.D., D-SMART, and various other tools are also available (Mulcahy et al., 2003a).

Diabetes Self-Management Education

“A central purpose of DSME is to help patients make informed decisions and to facilitate their self-care behavior” (Mulcahy et al., 2003a, p. 774). Lifestyle behavior change, including being physically active and reducing risks, is of utmost importance in DSME programs. Behaviors identified by the AADE for self-management of diabetes are behaviors that can be learned. DSME programs are designed to teach people the most effective behaviors and skills to manage diabetes and related risks. In order for DSME programs to successfully train patients in self-care, they must be effective in helping patients change behavior (Mulcahy et al., 2003b).

Several documents have been developed to guide DSME program administrators to ensure the effectiveness of DSME programs. They are (1) *National Standards for Diabetes Self-Management Education*, (2) *National Standards, Essential Elements and Interpretive Guidance*, and (3) *AADE Standards for Outcomes Measurement of Diabetes Self-Management Education*. “The *National Standards for DSME* are designed to define quality diabetes self-management education and to assist diabetes educators in a variety of settings to provide evidence-based education” (Funnell et al., 2010, p. S89). The *National Standards, Essential Elements and Interpretive Guidance* checklist (Appendix A) is a tool developed by the AADE to be used by administrators seeking accreditation for their program. It is based on the *National Standards for*

Diabetes Self-Management Education and provides information about the essential elements necessary within a program to meet each of the national standards (AADE, 2010).

Finally, the *AADE Standards for Outcomes Measurement of Diabetes Self-Management Education* were developed as a complement to the version of the *National Standards for Diabetes Self-Management Education* that was published in 2000 (AADE, 2003). The purpose of the *AADE Standards for Outcomes Measurement of Diabetes Self-Management Education* is to support what is now standard 6 (previously standard 7 in the 2000 version) and standard 10 (similar to 2000 version) of the revised *National Standards for Diabetes Self-Management Education* (AADE, 2003). Standard 6 of the *National Standards for Diabetes Self-Management Education* states,

A written curriculum reflecting current evidence and practice guidelines, with criteria for evaluating outcomes, will serve as the framework for the DSME entity. Assessed needs of the individual with pre-diabetes and diabetes will determine which of the content areas...are to be provided. (Funnell et al., 2010, p. S90)

Standard 10 of the *National Standards for Diabetes Self-Management Education* states “The DSME entity will measure the effectiveness of the education process and determine opportunities for improvement using a written continuous quality improvement plan that describes and documents a systematic review of the entities’ process and outcome data” (Funnell et al., 2010, p. S92). In order to determine effectiveness, outcomes must be measured. “Diabetes educators can use the core measures to determine their effectiveness with individuals and populations, compare their performance with established benchmarks, and establish the unique contribution of DSME in the overall context of diabetes care (Mulcahy et al., 2003a, p. 768).

National Standards for Diabetes Self-Management Education

The *National Standards for Diabetes Self-Management Education* were developed to provide evidence-based practices for diabetes educators in order for them to deliver quality diabetes education programs (Funnell et al., 2010). These standards originated from the 1983 *National Standards for Diabetes Patient Education Programs*. In 1993, a task force of representatives from nine major organizations, including the American Diabetes Association, the Centers for Disease Control and Prevention, and the American Association of Diabetes Educators, was charged with reviewing and revising the *National Standards for Diabetes Patient Education Programs*. Based on research and health trends at that time, the task force revised the standards to what became known as the *National Standards for Diabetes Self-Management Education* (Task Force, 1995). Since then, the *National Standards for Diabetes Self-Management Education* have been reviewed several times. The current *National Standards for Diabetes Self-Management Education* were approved in March 2007. They will continue to be reviewed and revised approximately every 5 years (Funnell et al., 2010).

“Quality diabetes self-management education programs can be measured in terms of structure, process, and outcomes” (Task Force, 1995, p. 189). The current *National Standards for Diabetes Self-Management Education* are based on these three main components. Within each of these three components are specific standards which comprise quality DSME programs. Standards 1 through 4 address the structure of a DSME program and standards 5 through 8 address the process of a DSME program. Standards 9 and 10 address outcomes (Funnell et al., 2010).

The AADE and the ADA identified the *National Standards for Diabetes Self-Management Education* (Figure 4) as:

Structure

Standard 1: The DSME entity will have documentation of its organizational structure, mission statement, and goals and will recognize and support quality DSME as an integral component of diabetes care.

Standard 2: The DSME entity shall appoint an advisory group to promote quality. This group shall include representatives from the health professions, people with diabetes, the community, and other stakeholders.

Standard 3: The DSME entity will determine the diabetes educational needs of the target population(s) and identify resources necessary to meet these needs.

Standard 4: A coordinator will be designated to oversee the planning, implementation and evaluation of diabetes self-management education. The coordinator will have academic or experiential preparation in chronic disease care and education and in program management.

Process

Standard 5: DSME will be provided by one or more instructors. The instructors will have recent educational and experiential preparation in education and diabetes management or will be a certified diabetes educator. The instructor(s) will obtain regular continuing education in the field of diabetes management and education. At least one of the instructors will be a registered nurse, dietitian, or pharmacist. A mechanism must be in place to ensure that the participant's needs are met if those needs are outside the instructors' scope of practice and expertise.

Standard 6: A written curriculum reflecting current evidence and practice

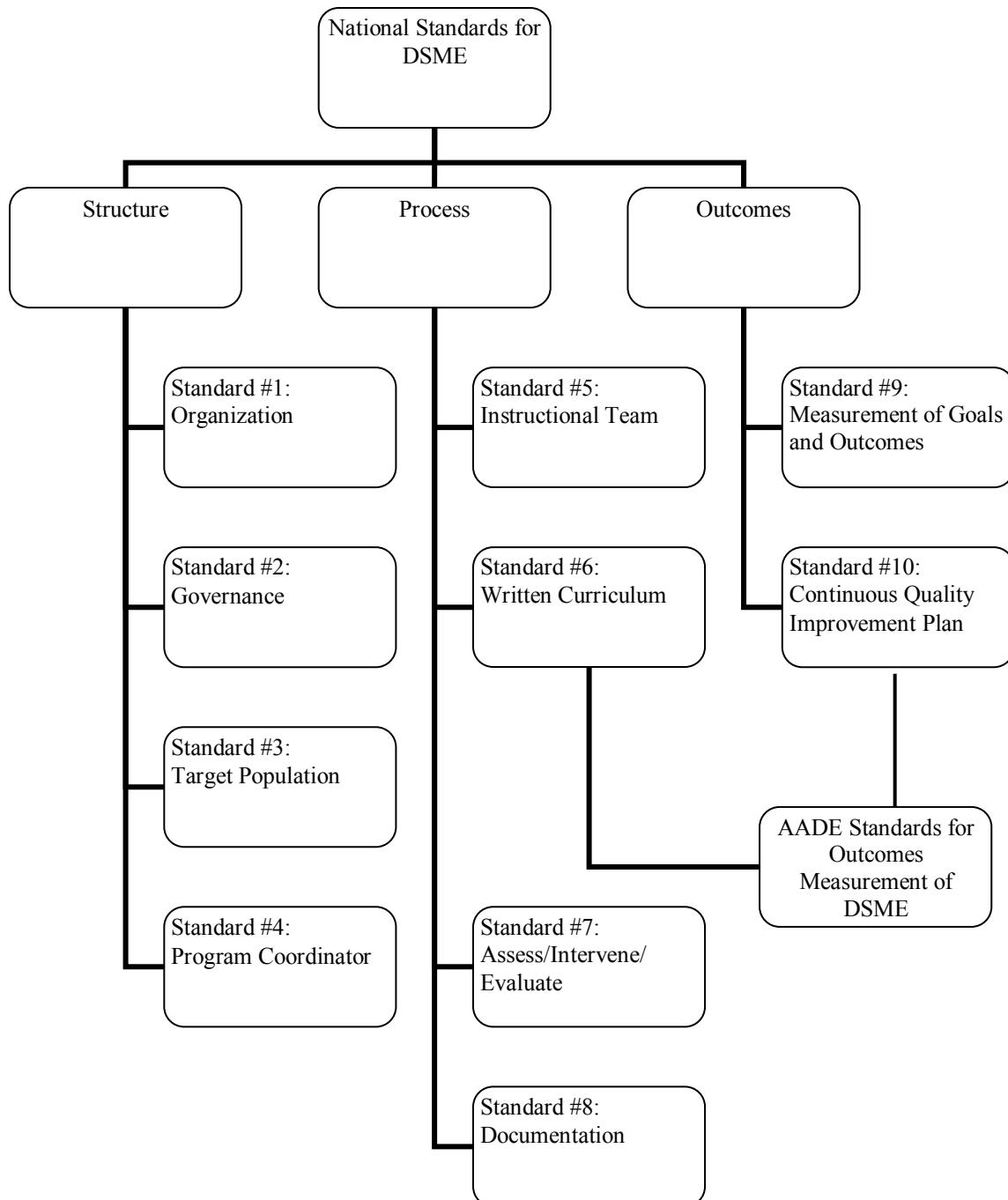


Figure 4. Organization of National Standards for DSME and AADE Standards for Outcomes Measurement of DSME (AADE, 2003).

guidelines, with criteria for evaluating outcomes, will serve as the framework for the DSME entity. Assessed needs of the individual with pre-diabetes and diabetes will determine which of the content areas are to be provided.

Standard 7: An individual assessment and education plan will be developed collaboratively by the participant and instructor(s) to direct the selection of appropriate educational interventions and self-management support strategies. This assessment and education plan and the intervention and outcomes will be documented in the education record.

Standard 8: A personalized follow-up plan for ongoing self management support will be developed collaboratively by the participant and instructor(s). The patient's outcomes and goals and the plan for ongoing self management support will be communicated to the referring provider.

Outcomes

Standard 9: The DSME entity will measure attainment of patient-defined goals and patient outcomes at regular intervals using appropriate measurement techniques to evaluate the effectiveness of the educational intervention.

Standard 10: The DSME entity will measure the effectiveness of the education process and determine opportunities for improvement using a written continuous quality improvement plan that describes and documents a systematic review of the entities' process and outcome data. (Funnell, 2010, S89-S92)

Funnell and colleagues (2010) state, "The overall objectives of DSME are to support informed decision-making, self-care behaviors, problem-solving and active collaboration with the health care team and to improve clinical outcomes, health status, and quality of life" (p. S89). The

National Standards for Diabetes Self-Management Education must be met and evaluated to determine the effectiveness of the DSME (Mulcahy et al., 2003a).

AADE Standards for Outcomes Measurement of DSME

The AADE (2010) defines DSME as, “...a collaborative process through which people with or at risk for diabetes gain the knowledge and skills needed to modify behavior and successfully self-manage the disease and its related conditions”. In support of measuring outcomes to ensure the effectiveness of DSME programs, the AADE defined the *AADE Standards for Outcomes Measurement of DSME* that must be met by a DSME to evaluate not only what the DSME delivers but also what it achieves (Mulcahy et al., 2003a).

The *AADE Standards for Outcomes Measurement of DSME* are:

1. Behavior change is the unique outcome measurement for diabetes self-management education.
2. Seven diabetes self-care behavior measures determine the effectiveness of diabetes self-management education at individual, participant, and population levels.
3. Diabetes self-care behaviors should be evaluated at baseline and then at regular intervals after the education program.
4. The continuum of outcomes, including learning, behavioral, clinical, and health status, should be assessed to demonstrate the inter-relationship between DSME and behavior change in the care of individuals with diabetes.
5. Individual patient outcomes are used to guide the intervention and improve care for that patient. Aggregate population outcomes are used to guide programmatic

services and for continuous quality improvement activities for the DSME and the population it serves. (AADE, 2003, p. 809-814)

Measuring outcomes allows the diabetes educators to determine the effectiveness of the program, to determine the impact of the program on the participants, and to determine areas of improvement (Mulcahy et al., 2003b). Mulcahy and colleagues (2003a) state that the process of consistently and frequently measuring outcomes at various intervals is essential, as is utilizing the data to make educational and clinical decisions.

Effectiveness of DSME

Despite its proven success, only around 50% of Americans with diabetes participate in formal diabetes education and the Healthy People 2010 policy goal is to increase the proportion of people receiving formal diabetes education from the 1998 baseline of 45% to 60% by 2010. (Duncan, Birkmeyer, Coughlin, Li, Sherr, & Boren, 2009, p. 753)

Of course, for people to participate, a DSME program needs to be implemented in the community. Additionally, a DSME program needs to be designed to be effective at either preventing T2D in those at high risk and/or reducing the severity or other risks of complications due to diabetes. There are documented reports in the literature that demonstrate the effectiveness of these community-based programs (Makrيلakis, Liatis, Grammatikou, Perrea, & Katsilambros, 2010; Kulzer, Hermanns, Gorges, Schwarz, & Haak, 2009). A review of two such programs follows.

Makrيلakis & colleagues (2010) conducted the “Diabetes in Europe – Prevention using Lifestyle Physical Activity and Nutritional Intervention” (DE-PLAN) study on a sample in Athens, Greece. The DE-PLAN study was initiated by the Department of Public Health,

University of Helsinki with the goal to create a model DSME program in Europe. Additionally, the researchers wanted to ensure that the DSME being proposed would be feasible and cost-effective. Since this was the first program of its kind in Greece, the initial goal was to identify those at risk for T2D (Makrilakis et al., 2010).

The researchers utilized the *Finnish Type 2 Diabetes Risk Score Questionnaire* to identify those at high risk for T2D. The questionnaire was distributed in twelve locations; six primary-care settings and six occupational settings. Of the 3240 completed questionnaires, 620 people were identified as high-risk for developing T2D. The high-risk individuals were invited to undergo an oral glucose tolerance test to identify those with unknown diabetes. Three-hundred eighteen individuals agreed to participate and of those, 67 were discovered as having diabetes. The remaining individuals were asked to participate in the lifestyle intervention and 191 agreed. The intervention consisted of six group sessions over the course of 1 year. The goal of the intervention was to educate participants about the risk of developing diabetes and to provide motivation to make lifestyle changes, particularly in the areas of nutrition and physical activity. One hundred twenty-five participants completed the intervention and follow-up oral glucose tolerance test. The results demonstrated that for those who attended 4-6 intervention sessions, weight loss was significant. Additionally, glycemic status was improved in those individuals overall (Makrilakis et al., 2010).

A study conducted by Kulzer & colleagues (2009) developed a *Prevention of Diabetes Self-Management Program (PREDIAS)* based on the *Diabetes Prevention Program*. This program included 12 lessons that lasted about one year. After the intervention was completed, a follow-up was conducted utilizing the same examination as at baseline, including: an oral glucose tolerance test, lipid, glucose, and A1C levels, weight, height, waist circumference, blood

pressure, physical activity assessment, nutrition assessment, and anxiety and psychological well-being assessments (Kulzer et al., 2009).

Results were positive for those members of the intervention group versus the control group. Significant weight loss, increased physical activity, improved nutrition, improved fasting glucose, reduced total cholesterol and triglycerides, reduced systolic and diastolic blood pressure, increased psychological well-being, and decreased anxiety and depressive symptoms were all reported in the intervention group and were significant compared to the control group (Kulzer et al., 2009).

Cost Effectiveness of DSME

Within the health care arena, it has become increasingly important to measure health outcomes as well as economic outcomes of the services provided. The information obtained from a population-based evaluation helps to identify interventions that are most appropriate and cost effective for a given population (Mulcahy et al., 2003a). Educating people with diabetes and those at risk for diabetes is effective for improving their quality of life. Norris and colleagues (2001) reviewed multiple studies on the effectiveness of self-management training in T2D published between 1980 and 1999. They reported on knowledge, self-care, lifestyle behaviors, psychological and quality of life outcomes, glycemic control, cardiovascular disease risk factors, and economic and health-care utilization outcomes from the 72 studies they reviewed. The overall conclusion was that there was sufficient evidence to support the effectiveness of self-management training for people with T2D (Norris, Engelgaue & Narayan, 2001).

Additionally, Boren and colleagues (2009) report that DSME is cost effective. Their study was a review of published literature from 1991-2006 accessed through a search using the

Medline database and Google. The researchers identified 26 papers that met the criteria for the study, specifically those that addressed the costs and benefits of DSME. The overall conclusion of the study was that the benefits of a DSME program outweigh the costs associated with the program (Boren, Fitzner, Panhalkar, & Specker, 2009).

Duncan and colleagues (2009) researched the impact of DSME on the cost of patient care. Administrative claims data compiled from members of commercial and Medicare Advantage health plans were evaluated. Health plan members from these two plans totaled over 8.7 million. The researchers delimited the procedure codes that were specific to diabetes care and prevention. Additionally, the researchers made a concerted effort to reduce any potential bias that could occur within the sample. The results of the analysis demonstrated that members with diabetes who participate in diabetes education incur lower overall health costs than those who do not. The commercially insured member cost was reduced by 5.7% and the Medicare member cost was reduced by 14% in those members with diabetes who participated in DSME (Duncan et al., 2009).

Case Study Research

Case study research is a research methodology. Case study research can be both quantitative and qualitative. The end product of case study research provides a rich description of the case being evaluated (Merriam, 2009). Stake (1995) defines a case study as, "...the study of the particularity and complexity of a single case, coming to understand its activity within important circumstances" (p. xi). Merriam (2009) defines a case study as "...an in-depth description and analysis of a bounded system (p. 40). The case is generally a person or a program. It is of interest to determine how the case compares to established benchmarks as well as what is unique to that particular case. While it can be argued that generalizations cannot be

made from a single case, the primary purpose of a case study is to understand the case itself (Stake, 1995).

Case study research involves objective recording from the field and examination of its meaning from which the researcher will draw conclusions. In this type of qualitative research, the researchers are given privilege to determine what is meaningful within the case study. Researchers interpret meaningful conclusions drawn from past experiences and knowledge of the topic or case. Methods of data collection include observation and examination of records. These methods are the most non-invasive methods of gathering data. At times, however, it is essential to also test and interview the individuals being studied (Stake, 1995).

Yin (2003) defines a case study as a research strategy "...used in many situations to contribute to our knowledge of individual, group, organizational, social, political, and related phenomena" (p. 1). He describes six sources of evidence for conducting case studies. According to Yin (2003), documentation, archival records, interviews, direct observations, participant-observation, and physical artifacts are the six sources for collecting data.

Documentation and archival records information can take many forms. Letters, agendas, minutes of meetings, written reports, organizational records, personal records and other administrative documents are examples (Yin, 2003). Stake (1995) reports that document reviews can provide information that cannot be observed directly. Some of the strengths of these types of data collection include that the information can be reviewed repeatedly, the methods are virtually unobtrusive, the information generally contains adequate detail, and information can be collected in this method covering a broad span of time. Weaknesses may include accessibility issues, reporting bias, and incomplete documentation (Merriam, 2009; Yin, 2003).

Interviews are described by Yin (2003) as “one of the most important sources of case study information...” (p. 89). He describes them as “...guided conversations rather than structured queries...” (p. 89). Interview data can provide important insights into the case study and are targeted to the particular case (Yin, 2003). Interviewing provides another perspective of the case study that cannot be directly observed. It provides an opportunity to derive how others perceive or interpret the case being studied (Merriam, 2009). According to Stake (1995) the purpose of the interview is to obtain the multiple views of the case by people involved in the case. Each interviewee is expected to have a unique perspective and therefore, the same questions are rarely asked of each subject. Obtaining good interviews can be difficult. Interviewer bias can occur with poorly constructed questions and interviewee bias can occur in the responses. Additionally, the interviewee may respond to the interview in a manner in which he/she believes the interviewer wants him/her to respond (Yin, 2003).

Direct observations allow the researcher to collect data in “real time”. The observations can be formal or casual. These observations provide a context for the information (Yin, 2003). Stake (1995) describes two approaches to observation – a qualitative and a quantitative approach. The quantitative approach focuses on categories or key events. Interpretations of relationships are avoided and repeated observations are necessary to substantiate the data. The qualitative approach provides a description of the event. This approach reveals the unique complexities of the case (Stake, 1995). Merriam (2009) provides the following checklist of elements to observe in any setting: the physical setting, the participants, activities and interactions, conversation, subtle factors – such as what does not happen or informal and unplanned activities, and your own behavior – is the researcher affecting the scene he/she is observing? The downside to direct observations includes the time-consuming nature of the process as well as the selective nature of

which or how many observations to make. Reflexivity is also a factor, which Yin (2003) describes as an alteration in the proceedings of the event being observed because of the fact that it is being observed.

Participant observations provide real-time data and a context for the information similar to direct observations. The researcher participates in the event being studied. This method provides a unique perspective, but not without significant issues. The potential of researcher bias is great as is the potential of the researcher as participant to change the event merely by participating in it. Additionally, the researcher may be so involved in participating that he/she is not able to take adequate notes (Yin, 2003).

Physical artifacts are the final sources of evidence that Yin (2003) discusses in a case study. These artifacts may be collected or observed. Artifacts may include a cultural work of art, a tool or instrument used in the setting, or other physical evidence. Data collected from the artifacts provides insight into cultural features of the case study; however, the availability and selectivity of the artifacts remain a weakness of this evidence (Yin, 2003).

Evaluation Research

The seven areas of responsibility of a health educator have been defined by the National Commission for Health Education Credentialing, Inc. (NCHEC). Area IV involves the responsibility to conduct evaluation and research related to health education (NCHEC, 2011). Health educators are responsible for evaluating programs and reporting the strengths and limitations of the programs. Additionally, health educators are responsible for comparing the results of the research to other findings. Implications to the profession of Health Education include exposing the necessary areas for improvement as determined by the evaluation as well as determining elements that are effective. These results can then be generalized to other similar

populations and contribute to a foundation of best practices overall for programs such as DSME programs (NCHEC, 2011).

Patton (2002) states “...evaluations examine and judge the processes and outcomes aimed at attempted solutions” (p. 218). He further affirms that the purpose of evaluation research is to improve the program (Patton, 2002). A formative, or process, evaluation is generally conducted to inform the managers and staff members if the program is working, what needs improvement, and how it should be changed. Formative evaluation is useful when a program may serve as a model for best practices and allows for dissemination and replication of the program. “By describing and understanding the details and dynamics of program processes, it is possible to isolate critical elements that have contributed to program successes and failures (Patton, 2002, p. 160). A formative, or process, evaluation has been described by Patton (2002) as a particularly appropriate qualitative application. The purpose of the formative evaluation is to “...serve the purpose of improving a specific program...” (Patton, 2002, p. 220). Formative evaluations typically use qualitative methods. Conversely, a summative evaluation is usually conducted to determine program effectiveness, who was affected, what was effective, and whether or not it was cost-effective. This type of evaluation generally involves some type of quantitative approach (Patton, 2002).

Summary

Diabetes is a debilitating disease that affects millions of people in the United States. Additionally, millions more have pre-diabetes, a condition that significantly increases the risk of developing T2D. Overwhelming evidence supports the use of healthy lifestyle changes to help prevent the development of this disease. Decreasing body weight and increasing physical activity are two main healthy changes that must be adopted to prevent and/or manage diabetes.

Such behavior changes are the targets for DSME programs, which can be effective at decreasing the risk and severity of diabetes. It is imperative for those at risk for diabetes to participate in DSME programs for effective training on prevention and management of the disease. Equally important is an evaluation of the DSME program to determine which aspects are effective and which aspects need improvement. That is the focus of this research study. Chapter two provided a review of literature pertinent to this research study. Chapter three describes the methodology for this research.

CHAPTER THREE

METHODOLOGY

Purpose

The purpose of this research study was to provide an in-depth analysis of a Diabetes Self-Management Education [DSME] program at a Midwest health care center and to evaluate the effectiveness of the DSME program. This chapter describes the methods that were used to address the research questions with sections devoted to research design and methodology, data collection, and data analysis.

Research Questions

The following research questions directed this study:

1. How was the DSME program developed and how is it being implemented?
2. To what extent do the program's elements align with the *National Standards for Diabetes Self-Management Education*?
3. What factors affect completion of the entire program by participants?
4. What factors affect non-completion of the entire program by participants?
5. How do participants perceive their experience in the program?
6. What are the immediate effects of the program in terms of weight loss and exercise adoption (impact)?
7. What are the long-term effects of the program in terms of maintenance of weight loss, maintenance of physical activity, and prevention of T2D (outcome)?
8. To what extent have the *AADE Standards for Outcome Measurement of DSME* been met?

Research Design & Methodology

Yin (2003) described a research design as “...the logical sequence that connects the empirical data to a study’s initial research questions and, ultimately, to its conclusions” (p. 20). Descriptive research was the design chosen for this research project. Descriptive research design was appropriate for this study because it provided the opportunity to collect the appropriate data to answer the research questions. This study was designed using a qualitative, case study methodology.

A case study approach was utilized to describe how the chosen DSME was established, to describe how it is being implemented, and to evaluate the effectiveness of the program when compared to *National Standards for Diabetes Self-Management Education*. Simons (2009) described a case study as a method that involves conducting systematic, critical inquiry into a phenomenon and generating understanding to contribute to the body of knowledge of the topic. Simons (2009) specifically defined a case study as,

An in-depth exploration from multiple perspectives of the complexity and uniqueness of a particular...programme... in a ‘real life’ context. It is research-based, inclusive of different methods and is evidence-led. The primary purpose is to generate in-depth understanding of a specific...programme... (p. 21)

Stake (1995) defined a case study as “...the study of the particularity and complexity of a single case, coming to understand its activity within important circumstances...” (p. xi). These definitions of a case study provide support for the methodology chosen in order to answer the research questions for this study.

This research project used a case study methodology in order to describe how the DSME program was established, to describe the uniqueness of the particular program, and to add to the

body of knowledge for DSME. It involves an in-depth description of the specific program as well as the process and outcomes of the program. Both a formative and a summative evaluation of the DSME program was conducted as part of this research project; therefore, the case study includes an element of evaluation research as well. The research described in this paper is a case study of a single DSME program that incorporates an evaluation of the effectiveness of the DSME program.

For the purpose of this study, a formative evaluation was used to determine the extent to which the DSME program aligns with the *National Standards for Diabetes Self-Management Education* and to determine how the DSME is being implemented. Specifically, the formative evaluation determined whether or not the DSME program meets standards 1 through 8 of the *National Standards for Diabetes Self-Management Education*. Additionally, the formative evaluation provided evidence as to what factors affect completion and non-completion of the entire program by participants. It also provided insight into how participants perceive their experience in the program.

The purpose of the summative evaluation used in this study was to determine the immediate effects of the program in terms of weight loss and exercise adoption (impact), to determine the long-term effects of the program in terms of maintenance of weight loss, maintenance of physical activity, and prevention of T2D (outcome), and to establish the extent to which the *AADE Standards for Outcome Measurement of Diabetes Self-Management Education* have been met. Specifically, the summative evaluation determined whether or not the DSME program meets standards 9 and 10 of the *National Standards for Diabetes Self-Management Education*.

Case studies involve multiple methods and are not defined by any one particular method (Simons, 2009). This case study incorporated both qualitative and quantitative methods (Figure 5). Document reviews, interviews with the Program Director and participants, observations, and a survey of the program participants were the various methods that were used. This descriptive methodology provided rich, comprehensive information about the program.

Data Collection

After approval from the SIUC Human Subjects Committee, the Ethics Board at the health care center, and the doctoral dissertation committee, information was collected about the program through a review of DSME documents, interviews with the Program Director and participants, observations of DSME sessions, and a survey.

Instrumentation

The AADE created an instrument to determine the extent to which a DSME program's elements align with the *National Standards for Diabetes Self-Management Education*. This instrument can be used by DSME programs to prepare for accreditation by the AADE. The instrument, titled *National Standards, Essential Elements and Interpretive Guidance* (Appendix A), defines essential elements for each of the *National Standards for Diabetes Self-Management Education* that should be included in a quality DSME program (AADE, 2009). This instrument was used in this study to guide the collection of data. The DSME program was thoroughly analyzed to determine if each of the essential elements defined on the *National Standards, Essential Elements and Interpretive Guidance* is met for each of the *National Standards for Diabetes Self-Management Education*. Therefore, the instrument was used as a checklist by which to determine whether or not the DSME program is meeting each standard.

Interview questions for the DSME Program Director (Appendix B) were structured to obtain a historical perspective of the program, how it was developed, and how it is being implemented. Additional questions were structured to obtain data that may not have been found through other data collection methods about the extent to which the program meets the *National Standards for Diabetes Self-Management Education* as well as the extent to which the program meets *AADE Standards for Outcomes Measurement of DSME*.

Interview questions for the participants (Appendix C) were structured to determine what factors affected completion and non-completion of the program by participants. The questions were developed by the researcher to obtain information that lead to an understanding of why some complete the program while others do not complete the program. Other questions prompted participants to describe their perception of their experiences in the program.

The survey that was used to ascertain information about the impact and outcome of the DSME program was developed by the researcher (Appendix D). The survey was structured to obtain information about whether or not the participant has met (impact) or has maintained (outcome) the goals of the DSME program in terms of 5-7% weight loss and 150 minutes of aerobic physical activity per week as well as whether or not the participant prevented T2D or if he/she was diagnosed with T2D.

A form adopted from Mulcahy and colleagues (2003a) and modified by the current researcher to allow for field notes was used to determine whether or not each of the *AADE Standards for Outcomes Measurement of DSME* has been met (Appendix F). Each of the five *AADE Standards for Outcomes Measurement of DSME* is listed on the form as well as the criteria for each standard as defined by AADE (2003) and Mulcahy and colleagues (2003a). Data were collected to determine the extent of which each of these standards is being met within the

	Research Questions	TOOL/METHOD	ANALYSIS/REPORTING OF DATA
Formative	How is the DSME program being implemented?	Document reviews Interview with Program Director Observation of DSME sessions	Description of DSME program; historical and current
	To what extent do the DSME's elements align with the <i>National Standards for DSME</i> ?	National Standards, Essential Elements and Interpretive Guidance checklist Document reviews Interview with Program Director	Comparison of DSME program vs. essential elements for each National Standards; data were analyzed to determine which elements are being met within each standard
	What factors affect completion of the entire program by participants?	Interviews with participants who completed the program.	Emerging themes were determined and described
	What factors affect non-completion of the entire program by participants?	Interviews with participants who did not complete the program.	Emerging themes were determined and described
	How do participants perceive their experience in the program?	Interviews with participants who did and who did not complete the program.	Emerging themes were determined and described
Summative	IMPACT: What are the immediate effects of the DSME program (i.e., weight loss of 5-7%, exercise adoption of 150 min/wk)?	Document reviews Survey	Frequencies were reported as to the number of participants who adopted weight goals and physical activity goals; Univariate analysis
	OUTCOME: What are the long-term effects of the program (maintenance of weight loss, maintenance of exercise, prevention of type 2 diabetes?) To what extent does DSME program meet AADE Standards for Outcome Measurement of DSME (5)?	Survey (Self-report weight; Self-report physical activity, Self-report diagnosis of T2D) AADE Standards for Outcome Measurement of DSME checklist; document reviews	Frequencies were reported as to the number of participants who maintained weight goals and physical activity goals; Univariate analysis Comparison of DSME program vs. outcomes standards; data were analyzed to determine which of the measurements are assessed and at what intervals

Figure 5. Case Study and Evaluation of a Pre- Diabetes Self-Management Education Program

DSME program.

Document Reviews

Reviews of the program documents were part of the case study. “These kinds of documents provide the evaluator with information about many things that cannot be observed” (Patton, 2002, p. 293). Documents and records reviewed included grant applications, marketing propaganda, patient files, the curriculum, patient medical records, and patient attendance records. Access to the documents was requested from the Ethics Board of the health care facility, the department manager, and the Program Director. The *National Standards, Essential Elements, and Interpretive Guidance* form (Appendix A) and the *AADE Standards for Outcomes Measurement of DSME* form (Appendix F) were used to guide the document reviews.

AADE has defined *Standards for Outcomes Measurement of DSME*. They are: behavior change, seven self-care behaviors, measurement interval, outcomes continuum, and individual & aggregate outcomes (AADE, 2003). Within each *AADE Standards for Outcomes Measurement of DSME* there are procedures and elements deemed necessary by the AADE for a quality DSME. The *AADE Standards for Outcomes Measurement of DSME* form (Appendix F) was used to guide the collection of data from the document reviews to determine whether or not the DSME program is meeting standards 1 through 4 of the *AADE Standards for Outcomes Measurement of DSME* and to determine what outcomes measures are being collected within the DSME program. Document reviews and an interview with the DSME Program Director were used to determine whether or not standard 5 is being met. Standard 5 describes the process by which the outcomes are used to guide program changes. A descriptive process comparing information obtained in the methods outlined above to the *AADE Standards for Outcomes Measurement of DSME* determined whether or not each standard is being met. The extent to which the DSME measures

these outcomes will determine the effectiveness of this program and enable the educators to compare the outcomes of this program with established benchmarks (AADE, 2003).

Additionally, data from the document reviews were collected about the process by which the program was developed and to what it is today. Such documents included grant or funding applications and proposals. The data allowed the researcher to provide a thorough description of the program starting with a historical perspective of the program as well as insights into the development, modifications, and challenges encountered in DSME program process.

The immediate effects of the program (impact) in terms of weight loss of at least 5% and adoption of at least 150 minutes per week of aerobic physical activity were assessed by reviewing the files of the current program participants and by the survey completed by those who graduated within the last 3 months. Access to these files was requested from the DSME Program Director. Participant's initial weight and initial self-reported physical activity status as well as the participant's current weight and physical activity status and number of sessions attended comprised the data collected.

Documents provide a wealth of information that cannot be observed. Review of documents allows data to be collected that provide an in-depth analysis of the process of the program development and the interactions between the program staff and administration (Patton, 2002). Document reviews however, may stimulate inquiries that may only be acquired through interviews and observations.

Interviews

First, an interview with the DSME director was conducted. The DSME director was contacted personally for an in-depth interview intended to reveal additional information not found in the document review as to what extent the *National Standards for Diabetes Self-*

Management Education have been met, how the program was developed and how it is currently being implemented. The interview took place in a quiet office within the medical center and took about an hour. Just before the interview, informed consent was obtained. The semi-structured interview questions for the Program Director were based on the *National Standards, Essential Elements, and Interpretive Guidance* form (Appendix B). Interview data provided rich, in-depth information that generally is not attainable from written documents. Data was recorded using a voice recorder and field notes with permission of the Program Director.

Semi-structured interviews with program participants were conducted. Interviews enabled the researcher to obtain rich data and direct quotes regarding the participants' perspectives and how participants perceived their experiences in the program. In addition, data were obtained to provide information as to what factors affect program completion or non-completion. Additional questions for participants were structured from the *AADE Diabetes Education Core Outcomes Measures for Diabetes Self-Care Behaviors* as defined by Mulcahy and colleagues (2003). The interview questions were piloted prior to using them on the study sample. The primary purpose for a DSME program is the development of self-care behaviors, which were defined previously (Mulcahy et al., 2003).

A list of participants who completed the program (graduated) and of those who did not complete the program (quit) was generated by reviewing documents in the Program Director's files. Participants who either graduated or quit in the last 18 months were targeted. This time frame was used because the Program Director said that at about that time some changes were made with regard to information collected on the participants when they had their orientation session. A pre-/ post- test of diabetes knowledge was one thing that was eliminated from the orientation session and the last attended session, because the Program Director realized it was

not an effective tool to measure of knowledge. Currently there is no other method used to measure knowledge of diabetes pre- or post- participation in the DSME program.

Once all of the contact information was gathered for the participants on the list, an interview request sheet (Appendix E) was mailed with a survey, which is described below. A cover letter (Appendix I) described the research and solicited participation in the interview. Participants were requested to fill in their preferred phone number and email address if they were interested in volunteering for an interview. Those who were interested mailed back the interview request sheet in the addressed, stamped envelope that accompanied the cover letter and survey. Follow-up phone calls or emails were conducted to arrange the interviews and to solicit interviews from those who did not respond.

Consent was given at the interview site prior to beginning the interview. Interviews were conducted at the health care center or other convenient public location at a time that was convenient for the participants. Six participants who completed the program (graduated) and four participants who did not complete the program (quit) were interviewed. Each interview lasted about one hour. Interviews were recorded using a voice recorder with permission of the interviewees. Interviews were transcribed and content analysis was conducted.

Survey

Immediate effects of the program (impact) and long-term effects of the program (outcome) in terms of weight loss and physical activity were assessed through distribution of a survey that included a self-report of participants' current weight and physical activity level (Appendix D). The survey was distributed to all participants who completed or quit the program within the last 18 months. Some of these participants were the same as those recruited for the interviews. Surveys were mailed to participants with a cover letter explaining the research and

included a stamped, addressed, return envelope by which to mail it back. Those who did not return the survey within two to three weeks of initial mailing were contacted by phone to solicit them to complete the survey. Some participants requested an additional copy of the materials be mailed to them as they claimed either to not have received it or they threw it away not realizing what it was. Additionally, the same data were collected on current participants in the program by reviewing their class documents, such as their initial weight, current weight, and number of sessions completed. Data provided evidence as to whether or not the impact goals of 5% weight loss and 150 minutes of aerobic physical activity were achieved for those who recently graduated or quit. Data collected on those who have been out of the program longer provided evidence as to whether or not the outcomes have been met with regard to maintenance of weight loss, physical activity, and prevention of T2D.

Observations

Observations of DSME sessions provided data as to how the DSME program is being implemented. The DSME Program Director was contacted to arrange times for observation during normally scheduled sessions. Permission to observe and to document findings from the sessions was requested from the DSME Program Director. Since observations were made of the group, individual consent was not necessary. Four observations for the duration of each session were conducted. Data about how sessions were structured were collected. Field notes were written based on what was observed. “Field notes contain the description of what has been observed. They should contain everything that the observer believes to be worth noting” (Patton, 2002, p. 302). The session times, days of the week, activities and interactions of the staff and participants, educational presentations, protocols, and roles of the DSME Program Director/staff and participants were documented.

Data Analysis

“Data analysis is a complex process that involves moving back and forth between concrete bits of data and abstract concepts, between inductive and deductive reasoning, between description and interpretation” (Merriam, 2009, p 176). “The much preferred way to analyze data in a qualitative study is to do it simultaneously with data collection” (Merriam, 2009, p. 171). Case study analysis involves a comprehensive description of a single, bounded unit. All material from the various data collections methods – document reviews, interviews, observations, surveys - must be organized together. Patton (2002) described information from the various forms of data collection as case data. Once the raw data have been accumulated from the various methods of collection, it may be written as a case record in which the information is pulled together and organized into a comprehensive, primary resource package (Patton, 2002). Data must be organized chronologically or topically. Data may also be organized into categories, themes, models, or theory (Merriam, 2009).

The method by which the DSME program is being implemented was analyzed using descriptive statistics. Data from document reviews, an interview with the DSME director, and observations provided the basis of information to provide a rich, comprehensive description of how the program began and how it has developed over time. Content analyses were conducted on the data from the interviews.

The extent to which the program’s elements align with the *National Standards for Diabetes Self-Management Education* was determined by descriptive univariate analysis, primarily percentages. Data collected from document reviews and interviews with the DSME Program Director were compared against the *National Standards for Diabetes Self-Management Education* using the *National Standards, Essential Elements and Interpretive Guidance* checklist

(Appendix A). Each standard has essential elements that must be met for program success, as defined by the AADE (2010). For each of the ten *National Standards for Diabetes Self-Management Education*, an examination was made as to whether or not the DSME program meets each of the essential elements for each standard. A descriptive univariate analysis, in the form of percentages and averages, of the number of elements actually met for each standard was reported in the results.

Factors that affect completion and non-completion of the entire program by participants were determined by interviewing. Interviews were transcribed soon after they were completed. Additional notes about the interviewees were documented as well. These notes included observations during the interviews and reflections about the context of what was said during the interviews. Data collected from the interviews were examined and categorized. The process was inductive in that the categories and themes came from the data. Pieces of data were analyzed from the derived tentative categories. As the categories emerged, subsequent deductive analysis of the data provided an opportunity to “test” the category against the data. Some categories remained and others did not. Toward the end of the data analysis, a point of saturation was reached whereby no new information was obtained (Merriam, 2009). Additional themes emerged through participant interviews with regard to how participants perceive their experience in the program. The process to answer this research question was the same as described above.

Immediate and long-term effects of the program in terms of weight loss and exercise adoption and the long-term effect of prevention of T2D were determined by analyzing data from document reviews and surveys. Univariate analysis, reported in frequencies and percentages, was conducted on data to determine the number of participants who adopted and/or maintained the

weight loss goal of 5% and the physical activity goal of 150 minutes or more per week, as well as the prevention of T2D.

Initial weight, derived from the health history questionnaire that was completed on the orientation date, and end weight, derived from the last session attended were used to calculate whether or not a 5% weight loss was attained. For those who completed the survey, the initial weight, from the health history questionnaire, and the self-reported current weight was used to calculate whether or not a 5% weight loss was maintained since participation in the program ended. The number and percent of participants who achieved and maintained the weight were reported.

Survey data provided evidence as to whether or not participants had adopted and maintained at least 150 minutes of aerobic activity each week. The amount and intensity of aerobic exercise and anaerobic exercise was self-reported; however, only the aerobic exercise was used in the analysis. Individual and aggregate data were reported for those who met this goal. For those who did not return the survey, and for those who were currently participating in the program, data was insufficient to determine if they met or maintained the exercise goal. Survey data also provided self-reported evidence as to whether or not participants had developed T2D. The number and percentage of participants, who completed the survey, who did or did not develop T2D were reported.

The extent to which the *AADE Standards for Outcome Measurement of DSME* are being met was determined through descriptive univariate analysis and reported in percentages and averages. Data from document reviews, observations and an interview with the DSME Program Director were compared against the guidelines for measuring outcomes as defined by AADE (2010). The *AADE Standards for Outcome Measurement of DSME* form (Appendix F) was used

as a checklist. Data were compared against the guidelines and the extent to which the guidelines are met was determined. A descriptive univariate analysis of the number of elements actually met for each outcome standard was reported in the data analysis.

Summary

Chapter three outlined the methods that were used to answer the research questions. Descriptive research was the design chosen for this study. The method is a case study and an evaluation of a single DSME program at a Midwest health care center. Data collection included document reviews, observations of DSME sessions, interviews, and a survey. Data collected were analyzed and reported descriptively. Chapter four describes the results from this research.

CHAPTER FOUR

RESULTS

Purpose

The purpose of this research study was to provide an in-depth analysis of a Diabetes Self-Management Education [DSME] program at a Midwest health care center and to evaluate the effectiveness of the DSME program. This chapter describes the results from data collection methods that were used to address the research questions. There are sections devoted to: background, program development and implementation, alignment with *National Standards for Diabetes Self-Management Education*, factors affecting completion, factors affecting non-completion, participant perceptions, impact and outcome, and alignment with *AADE Standards for Outcome Measurement of DSME*.

Research Questions

The following research questions directed this study:

1. How was the DSME program developed and how is it being implemented?
2. To what extent do the program's elements align with the *National Standards for Diabetes Self-Management Education*?
3. What factors affect completion of the entire program by participants?
4. What factors affect non-completion of the entire program by participants?
5. How do participants perceive their experience in the program?
6. What are the immediate effects of the program in terms of weight loss and exercise adoption (impact)?
7. What are the long-term effects of the program in terms of maintenance of weight loss, maintenance of physical activity, and prevention of T2D (outcome)?

8. To what extent have the *AADE Standards for Outcome Measurement of DSME* been met?

Background

The DSME program is housed in a department within a 128-bed health care center (hospital) which is nestled in a small community in the Midwest. The department was established in 1983 and has delivered cardiac rehabilitation and stress testing services to the people within the community who have been afflicted with heart disease. Over the years, the department has grown to include rehabilitation services for people with pulmonary disease; now it includes services for people with pre-diabetes and diabetes, as well. The department is staffed by one part-time and five full-time Registered Nurses, two full-time Exercise Physiologists, one full-time Exercise Specialist, one part-time Respiratory Therapist, one Department Manager, and one clerical staff person. Rehabilitation services are in the form of monitored exercise sessions during which education is provided. Rehabilitation patients are assigned to a specific class. The classes meet either two or three times per week at a specific time and last one hour. Patients attend as many sessions as are covered by insurance, typically 36, or as many sessions as they are willing to pay for out-of-pocket. The department offers cardiac rehabilitation classes on Mondays, Wednesdays, and Fridays at 5:30 a.m., 7:00 a.m., 8:00 a.m., 9:00 a.m., 10:15 a.m., 12:30 p.m., 1:30 p.m., and 2:30 p.m. On Tuesdays and Thursdays cardiac classes meet at 7:00 a.m., 8:00 a.m., 9:00 a.m., and 10:15 a.m. Pulmonary rehabilitation classes are offered on Mondays, Tuesdays, and Thursdays at 11:15 a.m. and on Tuesdays and Thursdays at 12:30 p.m. and 1:30 p.m. The pre-diabetes sessions are offered on Tuesdays and Thursdays at 4:35 p.m. and on Wednesdays and Fridays at 11:15 a.m. The diabetes classes meet on Tuesdays and Thursdays at 2:30 p.m. and 3:30 p.m. A variety of other services besides rehabilitation/ prevention of cardiac and pulmonary diseases and diabetes are provided through this department as well. Stress

testing, pulmonary clinic, pulmonary function testing, EKG's, and a pacemaker clinic are offered within the department. Off-site programs, such as Heart Smart for Teens, Body Smart, and Heart Smart for Women are offered as well. These programs are out-reach programs that target specific populations and offer education and guidance to help people prevent chronic disease.

Facility

When walking into the DSME program facility, one will observe a large counter to the right (east) that runs the length of that segment of the wall. Above half of the counter, a large bulletin board is decorated for the holiday. A large dry erase board is mounted above the other part of the counter. Heart rate conversions for converting 10-second heart rates to 60-second heart rates are written on the dry erase board. A list of birthdays for the month (participants and staff) and general information for participants is written on the board as well. Under the counter are large file drawers and cabinets. The drawers store files for current participants. Each patient has his/her own file and they are organized by class. Exercise records are kept in the files. When participants begin the pre-diabetes program, they are given an exercise record sheet (Appendix J). They record their own information on the sheet. Information recorded includes: pre- and post-exercise heart rate and blood pressure, body weight, and exercises completed. Participants record the information on each date they attend the class. Continuing down the east side of the room, at the end of the counter is a hall that extends further east. Coat hooks, a weight scale, a place to put on an EKG monitor for cardiac patients, a water fountain and a men's bathroom and a women's bathroom are all located within the hall. Inside the bathrooms there is one toilet stall, sink, mirror, and a shower with changing area. The last part of the east side of the room is made up of eighteen chairs arranged in a U-shaped formation. This is the patient waiting area. A counter-height wall separates the west side of the patient waiting area from the rest of the exercise room.

On top of the counter-height wall is a ledge where many participants set their clipboards during the exercise session.

The entire north side of the room is made of floor to ceiling windows. There is a view of part of the parking lot and the entrance to the emergency department. There is a nicely landscaped area in between with flowers, bushes, and a grassy area. Most of the equipment is arranged so that participants are facing away from the windows. The west side of the room has a half wall and then the top half is made of windows. Through the windows participants can see into a separate room where resistance training equipment is organized. This equipment is used by the cardiac patients and by hospital staff. Finally, the south side is a solid wall. In the center of the wall, a large screen drops down from the ceiling. Onto this screen, images are projected from a unit that hangs down from the ceiling. It is connected to a netbook. The netbook is on a podium at the front of the room. It is from this position that the Program Director stands and gives presentations to the pre-diabetes class while they are exercising. A large sound system is mounted to the wall. Staff members play CDs in the player during the warm-up session before participants exercise. Additionally, two large televisions are mounted to a support beam in the middle of the room; each is facing a different direction. The Program Director occasionally shows the participants a video on specific educational topics.

To the left of the main entrance to the room is a U-shaped staff area. This is from where staff observes a class, such as a cardiac rehabilitation class, that needs to have EKGs monitored during the exercise session. There are file drawers full of patient files for each rehabilitation patient. Within the open shelves above the desk area one can see reference books and models to be used for presentations such as plastic food to show appropriate serving sizes, a heart, and a blood vessel with plaque buildup in it. Three computers and two large printers sit on top of the

desk space. Other items include desk supplies, fresh flowers in a vase which were given to the staff members from a patient, hand sanitizer, lotion, and bottles of water. There are decorative pictures on the walls, wall calendars, and a clock. These items give the room a personal feel. However, one is reminded that this is a very much a clinical facility with oxygen ports in the walls with nasal canulas hanging down from them, a defibrillator on a cart located in the center of the room, hand sanitizer dispensers and sharps containers mounted to the wall, a kiosk with informational pamphlets near the door and a reference poster for Adult Basic Life Support hanging neatly on the wall. In the center of it all, multiple pieces of exercise equipment are arranged in rows. The room is approximately 3,000 square feet. Ten treadmills line the back of the room. Ten Nu-Steps are positioned in front of them. Intermixed are eight Monark bicycles, two Ex-riders, and an arm ergometer. It is to use the equipment that participants go there; that, and for education.

Program Development and Implementation

I'm interested in primary prevention, if possible, to secondary, when I have to and just saw that diabetes is on the rise. Looked at some studies, DCCT [Diabetes Control and Complications Trial], and saw that, with exercise and weight loss, we could see a marked reduction in the onset of or the possibility of progressing to diabetes and thought it was time to do something. So we got some information on a grant up from a new group called 'Women Connected' here at [Midwest facility]. They were looking for applicants for programs to help keep the community healthy, so I applied for a grant and I got it.
(Program Director)

This series of events describes how the DSME program came about. The Department Manager and the Program Director were the ones who wrote the first grant application in 2004. They

spent much time discussing the possibility of the program prior to submitting the application. The total requested for the first grant was \$5408.40; several other grants were written for similar amounts and received in the years following through 2010. Currently, according to the Program Director, grant funds have been exhausted and funding for the program is provided through combined appeal, a fund-raising initiative through the health center.

Grant money covered expenses for the program including screening and assessments, incentives, and educational materials. Once the funds were secured, the Program Director began advertising the program to area physicians. She asked the physicians to refer patients to the program who met the criteria for pre-diabetes. Since the grant covered the cost of the program and it was at no cost to patients, physicians were eager to refer them. The program was implemented once there were at least 10 patients who chose to participate out of the referrals that were generated. The first class began in 2005. Initially, the program was designed to begin with a fixed group and to keep them in the program for six months. As additional referrals came in, those patients were put on a waiting list to begin at the end of the first group's six month period of time. Eventually, the Program Director realized that patients, who had to wait several weeks or months to begin, lost motivation and decided not to participate after all. It was then that she decided to make the program into what it is today, an open-enrollment.

Now, according to the Program Director,

There are a couple different ways people can get into the program. One is the hospital does some advertising, also health fairs, wellness programs. Different wellness programs have gotten information out so they can self-refer. They can call and say I am pre-diabetic or I think I am pre-diabetic. Can I get into the program? I will meet with them and then send something to their physician to get an okay for a release for them to

exercise, release of information, if I don't have one, to make sure they qualify for the program.

Otherwise, physicians fax a referral or call a referral in to the Program Director, and she contacts the patient to set up an orientation meeting. While scheduling the orientation, she asks the patient to record a four-day food diary of everything the patient eats and drinks and to bring it with them to the orientation meeting. The orientation meeting takes about an hour.

During the orientation, a health history is obtained from the patient including demographic information, medications taken, current diagnoses and conditions, routine checkups, nutritional assessment, weight loss history, exercise/activity assessment, and goal-setting. When talking about their medical history and risk stratification,

I find out what they have and write that down in an order for the physician asking for clearance for exercise. I put that pretty much on the physician as to whether or not they feel they are safe to start an exercise program or whether they think they need to have a stress test before they start. And we get blood pressure and heart rate and weight and height and just basic measurements, too at that time. (Program Director)

An informed consent is signed by the patient, and the patient's most recent blood test results are reviewed. The Program Director then reviews the 4-day food log. When asked how well the four-day food diary works, she replied,

If they are an accountant, it works great. I get grams of fat; I get cholesterol; I get everything. For most people, it is stuff scratched down on a piece of paper. Then we sit down together and go through it. And when they meet with me, what I do is, I go to the 'My Plate' which used to be 'My Pyramid'. Now it is 'My Plate' site and put in their age, weight, height, activity level and, normally, it says do you want to go to a healthy

weight or for your current weight. We go for a healthy weight, and print that out as an estimate of what would be a good starting plan for them, as far as how many servings of grains, how many servings of fruit and vegetables. Then when we sit and talk as they are describing to me how big the food is, because they usually don't write down any descriptions, then I estimate—this is, of course, a rough thing – but estimate how much they are having. And then we look what their average is for grains, fruits, vegetables, meat, dairy, and other. A lot of times they have an ‘other’ column about like this [uses hands to show a wide column] because it is made up of fat and sugar, junk food, pretty much. What we do is, I say, this is what they [My Plate] recommend. This is where you are. What can you do? And I don't try to get them to change everything at once because, from my experience, it doesn't usually work very well. People get frustrated after a short time and give up. But I ask them to make little steps. What is one healthy thing you can do right now? What is a healthy food you can add in? If you are not getting any vegetables, can you add a cup and a half of vegetables a day? Or, if you are eating sweets five times a day, can you cut back to three times a day? And we take it in smaller incremental steps. (Program Director)

Then, she encourages the patient to set small goals to develop a healthier eating plan. She is quick to say that a patient does not leave that day with an ideal diet in many cases, but she encourages the patient to begin changes with small steps and then work towards a healthy diet. Once the food analysis is completed and goals are written, the Program Director takes the patient on a tour of the facility. She shows the patient where to park, where to enter the building, where to go, and what to do once the patient gets there. Participants in the pre-diabetes program are not registered through the hospital like other patients because the sessions are not billed to them

through the hospital; the grant covers the expenses which includes additional lab work at three-months and at the end of the six-months and prizes/incentives. However, if participants get their lab work done at the hospital, then they are registered, but just for the lab work. When asked if this process made it easier or harder from an administrative standpoint, the Program Director responded,

I think it is probably harder. It is a little harder to track the information on them long term. All of our other patients are just kept in a different system. It would be easier to do everybody the same, probably. The information would [then] go into their permanent record. Later on, their physicians could look at the exercise information sheets once they are already out of the program, if they want the information, and that stuff would all be scanned into our system. (Program Director)

Over the years, changes were made to the way the program was implemented. One of the strategies that was used, at one point in time to discuss barriers to achievement of goals, was a group counseling session. The Program Director explains,

We used to do group meetings every month but that got to be too cumbersome and it was really hard to get them done, number one, and give everybody an opportunity to talk. And people started kind of dropping out of that. So what I try to do now is, whenever I get their lab work done, like at three months and six months, we definitely talk. And in classes, we are talking about different topics. I try to touch base with people with things that I know they were having difficulty with initially.

The Sessions

Participants are encouraged to attend two sessions per week for six months for a total of 48 sessions. However, the goals for physical activity are to incorporate 150 minutes per week,

which would be three days per week. When asked about that possibility, the Program Director responded, "You know, if we had the time frame to do three times a week, I think that would be great. In our facility right now, that just isn't an option because we do so many other programs and classes." The six-month length of time was chosen as the duration,

Because, having worked in cardiac rehab for years, I found that a lot of our clients went about three months and a lot of them I would see later and they had done really good in class and kind of then fallen off of everything. And my hope is that a longer class time, getting into the routine of taking better care of yourself for a longer period of time, might make them more likely in the long run continue with that. (Program Director)

When asked if she believed the six-month duration might be a limitation to some people joining the program she responded,

A few, but not many. Occasionally, I will get someone in. When that comes up, I will say, you can start the program and try it. If you feel like it is too long and you have gotten the benefit or you don't feel like this is a good fit, you don't have to complete it. But I would like for you to at least give it a try and see what you think. (Program Director)

An interviewee reported:

It takes a long time to change your whole lifestyle and make it your habit and that it is hard to, it is easy to get frustrated when you don't see results right away, but it really is, which 6 months, to me, is a good time period. I have always heard it takes 6 weeks to make a change happen. You have to do it for 6 weeks before it comes; but 6 months is a long enough time. I mean, it would be nice if it even went longer, but I think that is a good time to see some change. You know. You may only lose, you may not lose weight

at all, but you will physically feel better, which will give you a better mind-set too. But I think it is enough time, if you work at it 6 months, you do see a change. I saw a drop in - all my numbers went down. My weight dropped. (Connie)

Sessions are an hour long and are held in the evening on Tuesdays and Thursdays or in the morning on Wednesdays and Fridays.

As far as time of day, we do run into some issues with people who are working. That is one reason we have the later class. Used to be 4:30. We bumped it back to 4:35 because a lot of people don't get off until 4:30. I would like to bump it back a little bit later, but I have been told that I can't do that at this time. Because I am getting lots of hours. I usually have overtime. But what I tell people when they are working is, I talk to them about it. If they can't get off early, I tell them it is okay to come in late to class. I would rather have them come in late than not at all. And I do have people who come sometimes ten to fifteen minutes late, which can be a little disruptive, but I think it is really important that we can include those people in the program. I also talk to them about trying to talk to their employer and explain to them what they are doing and why and see if they can't just flex their hours a little bit and a lot of employers have been really good about that. Some of them are not at all, you know. So there are people that I have lost because they just can't get there. (Program Director).

When participants begin the program after the orientation, they walk into the facility and take their exercise record sheet out of the file beneath the large counter against the east wall. They weigh themselves on the digital scale in the hall, record their weight and the date on the exercise record sheet. Then, they have a seat in the U-shaped patient waiting area. As the previous class is finishing, staff are called in to assist the Program Director in taking baseline,

resting blood pressures and heart rates on each of the participants. Heart rates are obtained on the defibrillator machine. Participants record their resting data on the sheet.

Between eight to fifteen participants were in attendance during the observed sessions. Slightly more than half were men. Participants appeared to range in age from early 40's to late 70's. One participant claimed to be 96 years old. The classes began with all of the participants standing in a circle performing warm-up exercises. The Program Director, a student intern, or other staff member led the group. Music was played through the sound system that was mounted on the wall. The warm-up took about five minutes. During that time, the participants stepped side-to-side and did low-intensity arm exercises with hand weights. The hand weights were stacked in a rack next to the sound system. There were multiple sets of one-pound through five-pound hand weights. Most members chose one to three pounds. They did overhead press, triceps pull-ups, lateral raises, biceps curls, squats with arms held at their chest, kick-backs, and then some balance exercises. After five minutes, the participants put the hand weights away and performed static stretching – mostly of their legs. Then they chose a piece of equipment and started exercising. According to the Program Director, the participants exercise at their own comfort level. They are encouraged to exercise at a moderate intensity, but she claims anything is better than nothing. The participants exercised on one piece of equipment the entire session, or they had the option of switching equipment about every fifteen minutes until three rotations or 45 minutes were completed. Then, they slowed down for a five-minute cool-down and finished with more static stretching.

During the exercise sessions, the participants were a captive audience. It was during this time the Program Director delivered the education component of the DSME program. She used a microphone attached to a headset, loaded a presentation on the netbook, and projected it on the

screen. Then she began the presentation. It was a very informal delivery. She encouraged participants to take part in the education. Often, she began the session asking them if they had an issue they had been trying to work through.

I try to let them drive education a lot. I try to ask, you know what is it you want to talk about today? What questions do you have? A lot of times, there is silence but sometimes something will come up. And usually when it does, other people have issues with it. (Program Director)

Most of the observed presentations centered on diet. One of the participants expressed lack of knowledge in other herbs or spices to use instead of salt in her cooking. The Program Director took the opportunity to educate participants about various herbs that can be used in different types of meals. She even went so far as to talk about easy ways to grow things like basil and chives.

Another presentation centered on food choices. One participant expressed problems making appropriate food choices and volunteered to have his previous-day's intake analyzed in front of the class. As he recited his intake, the Program Director wrote it on the netbook, which was then projected onto the screen for all to see. She asked the other participants to help point out deficiencies and excesses in his diet. They looked at his carbohydrate, protein, and fat intake. They discussed alternatives for him to try instead of some of the poor choices he made. The next time the class was observed this participant announced that he tried some of their suggestions and that, while they were not his first choice, they were viable options for his diet. Another presentation topic was centered on screening one's own blood sugar. The Program Director spoke about how blood sugar levels respond to exercise and eating and serving sizes for various foods. During all of the observed sessions, participants were clearly engaged in the education,

following the Program Director with eye contact, nodding in agreement, and answering questions or commenting in general.

During one of the observed sessions, one participant claimed to be experiencing nausea. He was directed to stop exercising and to sit in the patient waiting area. An intern checked on the participant from time to time while the Program Director continued with the class. He was given something small to eat to try to get the nausea to subside and was instructed to drink water due to hypotension. Once he felt better and his blood pressure came up to an acceptable level, he was allowed to resume exercise. Another participant experienced a blood pressure measurement that was too high after exercise. He was instructed to sit for several minutes and have it reassessed. Upon reassessment, the blood pressure was within an acceptable range and he was able to leave. All of the observed sessions were conducted the same way. This was also confirmed by the Program Director and by interviewees. When asked about her first day in the program, one interviewee reported,

You are greeted and welcomed to the group. And then they weigh you and take your blood pressure and then you do warm-up exercises and that is when you get to know everybody and they introduce you and go around and introduce everybody else. And after the warm-up, then they show you the machines and get you comfortable, you know, using one. And then [Program Director] would start the lecture course or, you know, what you were going to learn that day. And then about a third of the way through or so, she stops and shows you another machine or asks somebody else to do it if she wants to keep on and that type of thing. (Barb)

Another participant reflected on first-day anxiety,

I think you feel a little intimidated by the people that have been there for a while because you see them on equipment really going at it. And if you haven't exercised for a while, you would probably think, I can't do that. But, very welcoming. A little bit of uncertainty with the equipment if you haven't used some of it, not knowing what to do. They show you everything. And they are usually always with someone, a second person there, in terms of other staff that you could ask them to show you how to use it and that usually, or [Program Director] would stop the program and just say, let me help this person and you guys keep going. And it wasn't so structured that you couldn't ask for help and receive it. (Connie)

A different participant felt very little anxiety,

Your first day in the program, well, you are welcomed and I like how they introduce you. It is really nice because you are introduced to everyone. You are introduced in a very friendly, casual way. And then when you start your workout, you are told to go at your own pace. There is no pressure whatsoever. And you are also advised if there is something you are uncomfortable with, you are welcome to withdraw. And that was nice. I never did, but I knew I could. And there were some days that I had more energy than others. And you know, we were never pushed. Nobody ever said break a sweat or made you feel like you were unworthy of being in there. Or that, I mean, the main thing was, if you are being active—I kept telling myself, if I am not doing this, I am going to sit at home in front of the television. I don't think I am the only one that feels that way. I think that is pretty common when you work full time and getting older and you are tired. So I just knew anything that I did was better than nothing. [They] introduced you to machines and kind of made suggestions. You know, don't spend the

whole entire time on one machine. It is good to be versatile and diversify most of the machines. Each machine was shown to us on how to operate it and how to, you know—I got short legs and I didn't know any of that and I was really scared about that, too. I was out of the loop with exercise machines. I know, like over at the rec center at [local University] you go in there and all those young kids are like, I am not going to look. So they made it very age appropriate. (Deb)

After participants complete three months in the program, the Program Director has their lab work re-checked to see if any changes occurred. Lab work includes cholesterol, triglyceride, and fasting glucose levels. She records the results and sends a copy to the referring physicians. The lab work is repeated again at the end of the six months for those who attend the full amount of time. Final results are also sent to the referring physician. Participants are reminded to try to maintain their weight loss and activity goals. Also, the Program Director will often refer participants to other programs within the community.

We refer sometimes to the Adult Fitness program [local, supervised fitness program]. We encourage people to do that if they live in the...area. We let them know about other exercise facilities in the area when they are completing the program where they might be able to continue. (Program Director)

Alignment with National Standards for Diabetes Self-Management Education

The *National Standards for Diabetes Self-Management Education* were developed to provide evidence-based practices for diabetes educators in order for them to deliver quality diabetes education programs. The *National Standards for Diabetes Self-Management Education* comprise ten standards that are divided into three components. Standards 1 through 4 address the structure of the DSME program, standards 5 through 8 address the process of the DSME

program, and standards 9 and 10 address outcomes. Each standard has essential elements that must be met in order for the DSME program to be considered as an effective program (Funnell et al., 2010).

Structure Standards

Standard 1: “The DSME entity will have documentation of its organizational structure, mission statement and goals and will recognize and support quality DSME as an integral component of diabetes care” (AADE, 2009, p. 1). The first essential element of this standard includes, “There is documentation that describes or depicts Diabetes Education as a distinct component within the organization’s structure and articulates the program’s mission and goals (AADE, 2009, p. 1). Documentation of the DSME program as a distinct component within the Midwest facility organization’s structure does not exist. It is a program within a department in the health care center, but not considered as a separate entity. There is no documentation of program mission or organizational goals. This is typical of the departments within this organization. The health care center, as a whole, has a mission statement, but each department does not and neither do the programs within each department. Policies and procedures specific to this program are not available; however, the department has policies and procedures, some of which are organizational policies and procedures.

The next essential element within standard 1 states, “Documentation and/or procedures that support quality education shall include at least the following: 1) job descriptions of the Program Coordinator and instructional team that are congruent with program needs, including educational needs and 2) Diabetes education process and self-management support” (AADE, 2009, p. 1). Job descriptions for all positions within the department exist, but there is only one person who is dedicated to be the main person working within the program and that is the

Program Director. Her job description is a generic description for any Registered Nurse position within the department and does not specify her role as Program Director of this DSME program. The Program Director is, however, a Certified Diabetes Educator. The Program Director recognizes quality DSME as an integral component of diabetes care and advocates for support for the DSME program. When asked why she is so passionate about self-management education being an integral part of their care she replied,

Because they are the only ones that are there every day to make the choices and decide what needs to be done and if, with anybody trying to improve their health, they have to be able to manage and take care of themselves because no one else is there 24/7 and I feel like that with every health issue that you teach with people is that they have to gain the ability to monitor and manage it themselves with the help of a physician. But the physician is there, what, every six months? (Program Director)

The DSME program does not meet any of the essential elements within standard 1 of the *National Standards for DSME*.

Standard 2: “The DSME entity shall appoint an advisory group to promote quality. This group shall include representatives from the health professions, people with diabetes, the community, and other stakeholders” (AADE, 2009, p.2). The essential elements include, “A policy that identifies the structure and process, for the program’s advisory group, will be maintained. This policy will address the advisory group’s role in promoting quality DSME/T programming (AADE, 2009, p. 2). The DSME program under study has neither an advisory group policy nor a policy addressing the advisory group function. The DSME program does not meet either of the essential elements within standard 2 of the *National Standards for DSME*.

Standard 3: “The DSME entity will determine the diabetes educational needs of the target population(s) and identify resources necessary to meet these needs (AADE, 2009, p. 3). The essential elements include, “There should be documentation of a needs assessment for the target population”, “the unique needs of the target population” should be specified, and “the availability of resources to meet these educational needs” should be documented (AADE, 2009, p. 3). An identifiable process was not used to assess the needs of the target population. The Program Director stated:

You know, we didn't do a needs assessment per se, but we did look at the rate of diabetes in the area, which is about the same as the national average and statistically looking at what percent of the population we assumed was pre-diabetic. We assumed we would have just like extrapolating that information that we have a need.

The unique needs of the target population are not specified within this program. The Program Director made anecdotal observations that the patients she worked within the cardiac rehabilitation program, many of whom also had diabetes or pre-diabetes, had very little knowledge of the disease or how to manage or prevent it. She also noticed a general rise in the rate of diabetes in the patients she was working with in other programs within the department. Allocation of resources for the program is not specified within the department other than the salary for the Program Director program is paid through the department. Funding for the program is made possible through grants. The DSME program meets one of the three essential elements described in standard 3.

The last of the standards that addresses structure is standard 4: “A coordinator will be designated to oversee the planning, implementation and evaluation of diabetes self-management education. The coordinator will have academic or experiential preparation in chronic disease

care and education in program management" (AADE, 2009, p. 4). An essential element for standard 4 requires that "A completed job application/resume of the program coordinator that identifies experience and/or education in program management and the care of individuals with chronic disease, congruent with the job description are kept on file" (AADE, 2009, p. 4). The Program Director is a Certified Diabetes Educator through the National Certification Board of Diabetes Educators and she is a member of the American Association of Diabetes Educators. Her certification and member certificate are posted on a small bulletin board above her desk. The department does not have a current resume on file for her.

The next essential element requires that "The coordinator's position description will indicate that the coordinator is responsible for oversight of the planning, implementation and evaluation of the DSME/T program" (AADE, 2009, p. 4). The Program Director does not have a job description that is specific to program oversight. It is simply an overall position description for a registered nurse within the department. Finally, "Coordinators are to follow the continuing education requirements of their professions (a minimum of 15 hours of continuing education is required annually)" (AADE, 2009, p. 4). The Program Director earned 12.25 hours of continuing education so far in this fiscal year and is in the process of earning 9 more for a total of 21.25 hours of continuing education. This is typical of a given year. These hours are documented in her file within the department. The DSME program meets two of the three essential elements for standard 4.

Process Standards

Process components are described in the standards 5 through 8. Standard 5 requires: DSME will be provided by one or more instructors. The instructors will have recent educational and experiential preparation in education and diabetes management or will be

a certified diabetes educator. The instructor(s) will obtain regular continuing education in the field of diabetes management and education. At least one of the instructors will be a registered nurse, dietitian, or pharmacist. A mechanism must be in place to ensure that the participant's needs are met if those needs are outside the instructors' scope of practice and expertise. (AADE, 2009, p. 5-6)

The Program Director's proof of registered nurse (RN) license and certification for diabetes educator are on file within the department to verify that she has obtained and maintained the required credentials. There is no record of the Program Director's resume on file. She has obtained 12.5 of the required 15 hours of continuing education so far and is in the process of earning 9 more this fiscal year. A record is kept on file in the department. The Program Director is actually the only staff person who instructs the pre-diabetes class on a regular basis. Occasionally, other department personnel assist, but generally only to help measure vitals like blood pressure and heart rate. At times, other department staff delivers the education.

A lot of the education we do is not just about nutrition and exercise, but it is about risk factor reduction and there is so much crossover between that and cardiac [rehabilitation education] that they are all very well qualified to do it. (Program Director)
There are no other members of the staff, such as a Community Health Worker, that comprise a program team; therefore, essential elements that refer to such a worker are not applicable.
However, the Program Director has a Master of Science degree in Public Health and Community Health Education from the University of Illinois. If participant needs are outside the instructor's scope of practice and expertise, the Program Director generally invites a professional to the class to address those needs or refers the participant to a professional outside of the department. Such professionals include: Exercise Physiologists within the department, Psychiatrists, Primary Care

Providers, or if necessary, the Emergency Department personnel. However, there is no documentation that describes this coordination or interaction among the other diabetes professionals. The DSME meets four of the six of the applicable elements for standard 5.

Curriculum is addressed in standard 6:

A written curriculum reflecting current evidence and practice guidelines, with criteria for evaluating outcomes, will serve as the framework for the DSME entity. Assessed needs of the individual with pre-diabetes and diabetes will determine which of the content areas listed below are to be provided: Describing the Diabetes disease process and treatment options, Incorporating nutritional management into lifestyle; Incorporating nutritional management into lifestyle; Using medication(s) safely and for maximum therapeutic effectiveness; Monitoring blood glucose and other parameters and interpreting and using the results for self-management decision making; Preventing, detecting, and treating acute complications; Preventing, detecting and treating chronic complications; Developing personal strategies to address psychosocial issues and concerns. (AADE, 2009, p. 7-8)

An essential element includes a written curriculum that reflects current evidence and practice guidelines and is tailored to meet the needs of the population. The DSME program includes education on specific content areas, but not really a defined curriculum to the extent that someone in education would consider it a curriculum. A documentation sheet titled, Step in the Right Direction Education Record (Appendix J), is kept for each participant. The Program Director, or other staff assisting, presents information on one of the content areas during each of the exercise sessions. To determine which content area will be discussed during each session, the Program Director often peruses the education records of the participants who are in the class

at the time and determines which the one suitable for most people is. Or in other words, she finds the topic that the majority of participants has not heard about and chooses to discuss that one. Alternatively, the Program Director will talk with the participants during check-in or during the warm-up to determine what issues they have been dealing with recently. From that discussion, she will sometimes generate ideas on which topic areas need to be discussed during that session.

She claims,

We kind of have a list of topics and we have developed several talks over time but a lot of what we talk about, we try to cover a broad spectrum of things on nutrition and grocery shopping and reading labels and eating healthy, sodium and fats, several different things that pertain to that. A lot of it is given on what is driven on with the clients at that time. So it really varies. So like, for example, and one of the things I like about it is, we can meet the needs of the clients in our program and not stick to something really, really specific.

Because, for example, I have a gentleman who was told he had some v-fib [heart dysrhythmia] on his 24-hour health monitor the other day and didn't understand what they were talking about. We talked about heart and heart rhythms because we check their heart rate and rhythm when they come in every day and we find things and it is important that they realize, since the risk of cardiovascular disease is twice the general population [in those at risk for diabetes], these are the kind of things to watch for.

A gentleman came in today who they said they accidentally saw some blockage in a carotid [artery] when they were looking at something else. So they were evaluating that. So, we talked about what that is and what to expect. And so it is nice to have the

flexibility to not just be, okay, we are only going to talk about nutrition and exercise and these couple of things, but to talk about their health and to meet those needs and to help them stay healthy in general. (Program Director)

Topic areas to be discussed are organized under five main categories: (1) welcome, (2) exercise, (3) food, (4) pre-diabetes, diabetes, preventing complications, and (5) making changes. Within each category are several sub-categories. The education record has a place to record that date that the topic was discussed for that particular participant. Each participant has his/her own education record. Presentations for each topic are designed by the Program Director, department staff, or undergraduate and graduate students who sometimes work with the pre-diabetes or cardiac rehabilitation programs. Often the presentations are designed as a power point. The power point is shown through a netbook which is attached to a projector and projected onto a large drop-down screen at the front of the exercise room. Presentations are informal and participants are encouraged to take part in the discussion. The curriculum is updated as new information becomes available. Information for the curriculum is generally obtained through professional organizations, like the American Diabetes Association, Centers for Disease Control and Prevention, and the National Institutes of Health.

While most of the AADE7 (self-care behaviors) are included in the curriculum, as is essential within standard 6, little time is spent on monitoring (blood glucose) because these are pre-diabetes patients. Pre-diabetes patients do not have diabetes and therefore some of the self-care behaviors are not applicable to this population. According to Funnell (2007), clear evidence is lacking to support the effectiveness of self-monitoring of blood glucose in those with diabetes; however, self-monitoring of blood glucose should be recommended in order to make appropriate modifications to food intake, exercise, and medications in those with diabetes.

Also, taking medications is not covered to the extent that is inferred through the AADE7. The self-care behavior within the AADE7 that refers to taking medications generally refers to taking medications to reduce insulin resistance or to taking exogenous insulin (Boren, 2007b). When asked about if she spends time talking with the pre-diabetes classes about diabetes medications, the Program Director states, “Not with the pre-diabetics, we don’t talk about medications a lot.” Once again, these participants do not have diabetes, but pre-diabetes, and most are not on medications for diabetes. The same goes for healthy coping (Fisher, Thorpe, DeVellis, B. & DeVellis, R., 2007) and problem solving (Hill-Briggs & Gemmell, 2007). However, the Program Director does present situations that those with pre-diabetes have to face and helps them role-play how they would respond to the situation. For example, during one of the sessions that was observed, the discussion was centered on healthy choices when eating out. The Program Director presented the class with menu options and helped them learn how to problem solve (make appropriate food choices) and then how to cope with the negative emotions dealing with such a decision. So, while problem solving and healthy coping are not individual categories within the curriculum, they are behaviors that are addressed through multiple scenarios throughout the curriculum.

Finally, an essential element within standard 6 requires the use of skill-based training methods and the use of interactive training methods. For some of the AADE7, such as healthy eating, being active, and reducing risks, the curriculum utilizes interactive methods. The Program Director often presents information and then asks participants for a specific situation they had to handle with regard to eating and exercise. During one of the observed sessions, she presented food models to the class to demonstrate appropriate serving sizes for different foods. She had one of the participants describe his food intake for the previous day and then encouraged

the class to discuss alternatives to some of the choices he made as well as to point out what decisions he made that were positive.

With regards to exercise, during one observed session, she presented ways to maximize the amount of physical activity one can accumulate in a day. She gave examples, like parking at the back of the parking lot and increasing the intensity of recreational gardening, to help participants understand how small changes in lifestyle can accumulate to more benefits in the prevention of diabetes. These are a few examples of how the curriculum is interactive and includes skill-based training methods. In summary, the DSME program meets all of the essential elements in standard 6 that are appropriate for a pre-diabetes population.

An individual education plan directs standard 7:

An individual assessment and education plan will be developed collaboratively by participant and instructor(s) to direct the selection of appropriate education, interventions and self-management support strategies. This assessment and education plan and the intervention and outcomes will be documented in the education record. (AADE, 2009, p. 9)

The DSME program does not have an individualized assessment or education plan for each participant. Education topics are listed on a sheet. They are the same for all participants. Topics include: exercise, diet, pre-diabetes, diabetes, preventing complications, and making changes. When the Program Director or other staff member discusses a topic during a session, the date the topic was discussed is documented on each participant's sheet that was present on that date. There is no written policy that describes the diabetes education process. Assessment is not done and outcomes are not evaluated. However, she claims, "We do a fasting blood sugar, we do lipids, look at blood pressure and weight and activity level are the things that we kind of

look at a three month and six month to see how they are doing" (Program Director). When asked what she does if the values are not where she would like them to be, she stated,

We discuss. Yeah, we talk about it. Usually after class, we will sit and talk for a little bit. So we do kind of counsel them, but it is not like a formal thing. And then a lot of times, we will direct education for the group towards those topics. So we will talk about, okay, if your triglycerides are going up, what are some of the things that you can do? Or if your weight hasn't been changing, why is it stuck? What are some of the problems that might be going on? We try to get a discussion going in the group somewhat, but also make sure we are adding to that and doing education with it. (Program Director)

The AADE7 self-care behaviors framework do serve as the foundation for education, however.

The DSME program meets only one of the six essential elements for standard 7.

The last of the process standards is standard 8. "A personalized follow-up plan for ongoing self-management support will be developed collaboratively by the participant and instructor(s). The patient's outcomes and goals, and the plan for on-going self-management support, will be communicated to the referring provider" (AADE, 2009, p. 11). A written policy and documentation does not exist for each participant's personalized follow-up plan. On-going self-management support is limited and mostly only happens when a participant decides to re-enroll in the program. Communication of educational services to the referring physician is not conducted; however, the Program Director does send the physician an update at 3-months and at the end of the 6-month program with lab results including total cholesterol, LDL, HDL, triglycerides, and fasting blood glucose. That being said, neither of the essential elements is completed. Therefore, standard 8 is not met through this DSME program.

Outcomes Standards

Outcomes are defined in standards 9 and 10. Standard 9: “The DSME entity will measure attainment of patient-defined goals and patient outcomes at regular intervals using appropriate measurement techniques to evaluate the effectiveness of the educational intervention” (AADE, 2009, p. 12). According to the Program Director, the main goal of the DSME program is,

Ideally to see a 5-7% weight loss and to get clients in a regular routine of exercise; ideally getting at least 2-1/2 hours per week; and the big goal is that they learn how to live a healthier lifestyle to reduce the risk of diabetes so that when they go out on their own, they have a better idea of how to do that.

Specifically, goals are for participants to achieve a 5-7% weight loss and to engage in at least 150 minutes of exercise each week. The DSME program does not document achievement of goals, *per se*. The participants weigh themselves and record the weight at each program session. They also have attendance records of the amount of sessions attended per week. However, they do not report activities that are done outside of the DSME program. Since most participants attend a maximum of two days per week for a total of 50 minutes of exercise at each session, it is not reported if they are meeting the total of 150 minutes of exercise each week. There is no policy in place for evaluation. The Program Director has the same goals for each individual and for the population as a whole, but does no formal evaluation of the attainment of those goals. Survey data and document reviews were used for this research to determine if these goals were met by the participants who graduated from the program in the last 18 months. Results of the analyses are reported in the *Impact* and *Outcomes* sections of this chapter. Additional outcomes standards are addressed in the *Alignment with AADE Standards for Outcome Measurement of*

DSME section of this chapter. Overall, the DSME program meets two of the four essential elements for standard 9.

The final outcomes standard is standard 10: “The DSME entity will measure the effectiveness of the education process and determine opportunities for improvement using a written continuous quality improvement plan that describes and documents a systematic review of the entities’ process and outcome data” (AADE, 2009, p. 13). Documentation does not exist with regard to changes that have been made to the program over the years. Recollections of what used to be done are the only evidence of some of the changes that have taken place. There is not a systematic process for continuous quality improvement. Since there is no advisory group, continuous quality improvement results are not shared with them annually. This element is not applicable. Overall, the DSME program does not meet any of the two applicable essential elements for standard 10.

Within the four structure standards, three of the twelve (25%) essential elements are being met. Nine of the eighteen (50%) essential elements within the process standards are being met. Two of the six (33%) essential elements within the outcomes standards are being met. Only one National Standard is met completely, and that is standard 6. All essential elements within standard 6 are being met through the DSME program – besides the fact that an educator in academia would not consider the education topics to be a defined curriculum. Fourteen of the thirty-six (39%) applicable essential elements are being met with this DSME program.

Interview Sample

Interviews were conducted with eleven participants. Six had completed the program while five quit before completing over 40 sessions. A pseudonym was given to interviewees to protect their identities. The DSME program graduates included three females and three males.

Their names, for the purpose of confidentiality, were assigned as Barb, Connie, Deb, Tom, Sam, and Frank. Four females and one male comprised the interviewees who quit. They were named Peggy, Betty, Cher, Joan, and Alex.

Factors Affecting Completion

From the interviews, themes emerged with regard to factors affecting completion of the entire program by participants. Coding and then analyzing transcribed interview data revealed the following themes: attitude that it is possible to overcome barriers to making desired lifestyle changes, thirst for education, and support.

Theme One: Participants who completed the program had the attitude that it is possible to overcome barriers to making desired lifestyle changes.

Participants clearly expressed a need and a desire to make lifestyle changes to prevent T2D. Lifestyle changes that were the focus for participants included losing weight, exercising and developing better eating habits. When asked what they would say to someone who said there are too many barriers to completing the program they remarked,

“You are not trying hard enough. There [are] a lot more barriers [with] having the disease that if you can prevent it with just eating right and a little bit of exercise, why not? Why wait until you have to have shots and all of the downsides of what happens with diabetes?” (Barb)

Barb was a small-framed woman with a kind, soft smile. She was very reflective before answering any questions. She was very proud of the fact that she lost 35 pounds and dropped three clothing sizes while in the program. As a result, her doctor was able to take her off one of her blood pressure medications, which resulted in a big smile when she spoke of that.

Sam remarked, “How do you know? You have to try it. There has to be a beginning. You have to want to change.” Sam was a large-built man. He seemed very outgoing and confident. He had a history of deteriorating health and had a back surgery only a couple of years ago. He learned a lot about prevention of diabetes from his wife, a physician, who told him that diet and exercise were shown to be the primary treatment options for the prevention of diabetes. “If you don’t do it, you will get T2D and you will have no-one to blame but yourself” he stated.

“You only get as much out of it as what you put into it. The harder you work and the more you increase your work - the more you work at it – the more results you see” (Connie). Connie, whose husband is diabetic, said “I didn’t want to get to that point. I see what he goes through. I just didn’t want to have to go through that myself. I think I felt like, with my weight issues, my diet habits, that I have some family history of that. My grandmother and my mother’s side and my mother and I tend to be built like them. I have their characteristics. I look like my mother. So, I felt, I would probably develop [diabetes] at some point in my life.” She was motivated by “The need to be healthier and knowing that I could possibly prevent it from getting worse.”

Frank, one of the most successful graduates from a weight-loss standpoint, said this of someone who protests that it is too hard to complete the program,

They are wrong. It took care of me. Type 2 diabetes is a lifestyle disease and my lifestyle was wrong and I changed my lifestyle. What you got to do is you have to take charge of your life. And if you want to change, you can do it. It just takes determination.
(Frank)

Tom agreed:

Any time you do something like that, there is always a challenge to finish it. My thoughts along those lines are, do the very best you can and put all you can into it and finish the program. It is very good. I wish I could go back and do it again. (Tom)

All of the participants who graduated from the DSME program remarked that they would certainly recommend the DSME program to someone who needed to make lifestyle changes. Common remarks included reflections of their own experiences, “it is excellent”, “I was very much impressed with it”, and “I would recommend it to a lot of people”.

Theme Two: Participants expressed a desire and appreciation for education. They desired knowledge of how to eat healthy, how to increase exercise, and mostly, how to prevent diabetes.

Many participants expressed how much they enjoyed the education component of the DSME program. When determining how the program helped them to prepare to be regularly physically active or to structure an appropriate diet, common replies included: “the guidelines”, “the outlined food plan [during orientation]”, “it was interesting”, or “I benefited through learning”. Barb remarked, “It changed me completely. It taught me better eating habits and ways – different ways of watching what I ate.” Deb, an educator herself, was extremely motivated to make the most of her time in the program. When she told about the time she found out she had pre-diabetes, she said,

It was a wake-up call. I felt like it was a second chance. I took it very seriously. I was absolutely shocked to find out it was pre-diabetes because it is not in my family. I had not been – I ate very healthy but I also ate a lot of junk. (Deb)

She was particularly emphatic about the benefits of the education part of the DSME program.

About the time when I would feel weak in an area, they would cover it. It was wonderful. They did a good job of covering all areas. They gave us real good examples of

how to [prepare foods] healthier. And so that was good. So everyone benefited from it. I don't know where the curriculum comes from or anything like that, but it is almost like they knew. They could feel it in the air that is what all of use in the class were needing.

(Deb)

Participants who graduated from this program commented on how the program prepared them to make the lifestyle changes necessary to help reduce their risk of developing T2D. One participant explained:

It changed me completely. It taught me better eating habits and ways, different ways, of watching what I ate that it could become a normal eating habit for me instead of just a diet. Or, you know, a short-term pattern, you know, and I have done the Weight Watchers and the different, you know, diets. Weight watchers did work. But it wasn't enough. And I think with the exercise that the [program] did, you know, it got me going in that direction, also. Plus, gave me the knowledge of what to eat and what to watch for.

(Barb)

On how the program prepared them to make the lifestyle changes necessary to help reduce their risk of developing T2D, Connie replied, "You know, it is not just the exercising. It is the education." When it came to discussing how his eating has changed, Tom commented, "I benefited a lot through learning about diets and what I could eat." Frank had this to say about how the education helped him to overcome barriers to eating healthy, "[Program Director] talked about the bad effects of these things, talked about the cholesterol and how the diabetes worked and things and how food affected it." He later made the comment, "It changed my life, like I said. I learned that diet and exercise can improve your life" (Frank).

Theme Three: Participants frequently commented on how supportive the staff was and how important it was to them to have that support.

Making significant lifestyle changes, such as eating healthier and incorporating more physical activity, can result in barriers that people with pre-diabetes need to overcome in order to reduce the risk of developing T2D. When asked how the DSME program helped her overcome a barrier to changing her diet, a participant responded:

Just through the education and looking at portion sizes. [Program Director] is real good at-- she has the cups there and the tablespoons and she shows those to us and says, this is the serving size. And she is realistic, too, with saying, you know, most people— you know, I remember talking about ice cream, a half a cup. And you know, nobody stops at that. And even though [Program Director] is small and in shape herself, she expresses that she struggles sometimes, too, and she has to work at it constantly. And, yes, it is her job, but there are times, well, just in aging herself, that she has realized that there are things she can't do as much and she puts a personal aspect in that to make you feel that she is not preaching at you and she understands where you are coming from and that you struggle. So that has helped. (Connie)

Another common barrier participants often face includes making changes to their physical

activity level in order to adopt the goal of getting at least 150 minutes per week.

One participant remarked,

She would show us exercises that we could do at home and things to do besides the cardio stuff that we would do there and that helped and you could – being able to try some stuff there, because she would have us – she would offer for you to try the things and the interns would too. Some people did. Some people didn't. And then you could

actually do it with someone showing you and see if it was something that you felt you could do on your own. That was a lot of help. (Connie)

When asked what motivated her to complete the program, one participant explained, “It is the education and the staff. They are just really - (somewhat emotional pause) –it is just not their job. They are there to help people and that really comes through and they are very encouraging and supportive” (Connie).

Factors Affecting Non-Completion

Participants who attended 40 sessions or less were considered in the non-completion category. Factors emerged through interview data as to why participants did not complete the full program. They were categorized into the following themes: personal injury, time, and feeling disconnected with others in the program.

Theme One: Participants who did not complete the program often had some type of personal injury that stood in their way of continuing. Many of them, however, expressed a desire to return to the program at some point; or a regret that they were unable to finish.

Peggy was a tall, slightly overweight woman in her mid 50's. She had a friendly disposition and seemed happy to share her experience. One of the reasons she decided to begin the program was expressed at the beginning of the interview.

As I get older, the more drugs seem to be introduced into the system. I am one that tends to like to have less and less intervention. And weight has been a problem that I have been trying to tackle for several years without success and I thought if I could tackle the weight thing and the exercising, that could cure a whole lot of things. (Peggy)

She seemed concerned when she spoke of finding out that she had pre-diabetes. "I didn't want it to progress to anything more. That was a real scare factor" (Peggy). When asked how she would reply to a pre-diabetic who was not convinced the program was right for them, she stated,

I would tell you to try it. I would say you've got a monitored exercise program with technical people there to answer your questions. You have got top-notch equipment. You have got other folks that are facing the same dilemmas. (Peggy)

Like many of those who graduated from the program, she explained:

I like the conversational presentation of the programs, the education component that they offered for me. I liked working out with something to help me review or to know. There were a few things that [Program Director] and her group did, like setting goals and then going back from month to month to review those goals. That was good to keep me on track. I think it worked for most people to the exercising and listening to what is going on versus adding another half hour of time or fifteen minutes of time to present by itself. (Peggy)

Unfortunately, Peggy's program was interrupted when she fell and broke her hip.

Joan faced the same fate when her program was halted because of an injury.

I was planning on going further into the program but I took a serious fall and pulled a tendon in my arm. So then I had to go to physical therapy every day, had to go for shots, so that kind of blew the idea of going back there for a while. (Joan)

As a janitor and housecleaner, Joan had always thought she got enough physical activity. She was concerned when she found out she had pre-diabetes and wanted to do something about it. She really enjoyed the support she got from the people in the program. "Everybody is real

friendly. They are all going through the same thing you are. Everybody that I sat next to was just so positive. It was almost like [having] a cheering coach" (Joan).

Alex believed the program was beneficial as well. He said, "I looked at it as, you know, a chance to exercise but the education part was good too." Alex claims that his back had been bothering him considerably. That was one of the factors that led to him quitting the program.

Theme Two: Participants who quit the program had issues with time. Either the time of day that the program was offered did not fit their schedules and/or they felt that their schedule was too busy to be able to continue attending the sessions.

Besides a back injury, Alex reported that the biggest reason for not completing the program was time. "It is just my schedule is so crazy, I guess. Busy schedule, busy life, trying to keep up with being there on time" (Alex). When asked about challenges that could stand in the way of others completing the program, he replied again, "Mine was time, but I would say continue when you can, I guess. Whatever those challenges are, go back and do as much as possible" (Alex). Overall, however, he was thankful for the experience he did have. In particular, he felt like he learned a lot.

I think they did a really good job there with that type of information as far as eating, you know, and frequently and frequency and all of that kind of stuff, portion size. So I am sure there is always more things I could learn, but I think they did a good job with that as far as covering most of the bases. (Alex)

Joan was asked about any challenges that stood in her way. She replied,

Well, besides making sure that I made the time to do it in my schedule. I rearranged my schedule so I could, you know, make sure I got there every day at a certain

time. And [Program Director] would always call and check on you to make sure you were okay if you didn't show up. (Joan)

Cher, was a very tall, large-built woman who was very expressive and passionate about what she believed. She worked in journalism and spoke frequently about empowerment and positive affirmation. However, she was also one who quit the program. Her comment on that regard was, "It is right after work. Never workout at that time of day. Morning does it for me." Another factor of time for her had to do with the structure of the program. She emphatically expressed her point of view that there should be a separate time for working out and a separate time for education. She did not like the education during the workout. "So that would be just a teaching aspect of it. Then on another day or an hour later, go and workout. And make those totally separate" (Cher).

Finally, Betty, who worked in an administrative office in education, said the time the sessions were offered did not fit her schedule.

Maybe the time might have been better. I was going out on my noon hour and that took, you know, my noon hour. Maybe like really early in the morning or later in the afternoon when I got off work would have been better. (Betty)

Theme Three: Participants who quit the program felt disconnected with the others in the program.

Cher expressed this more emphatically than anyone else. "Oh, god. It was terrible for me. I thought the people were really really nice. But honestly, for me, everyone in there was so much older than I was" (Cher). Going back to the issue of education during the workout, she commented,

But other people of that age, they want to [have education during the workout] because they are closer they think – psychologically, they think they are closer to death. So they want to be taught all of this and they are in a great mood by the time they leave. They love it and they feel like ‘another day, yes.’ Okay. I don’t want to feel that way 40 something years old, like, God, another day. Even though I thank God every day I am alive, I don’t want to feel like, yeah, I’m alive every day. Here I go, you know. But I really started feeling old. Just old, old, old, old, old. (Cher)

However, when it was stated that it sounded like the program did not meet her needs, she replied, ‘No. I would say that what I thought I wanted, they gave me. They just didn’t give it to me in the form that I was comfortable with’ (Cher). She was quick to add,

I thought it was extremely helpful. I thought it was extremely informative. I through it was extremely laid back, great presentation as far as making us laugh and things along those lines. I do – I just – I just felt that the location was off. I felt that the teaching, instead of letting me exercise, was off. If that had changed, I probably would have stayed with it longer. (Cher)

Betty commented,

There were a lot of older people in my program. Maybe if they had another age group that was geared to the 40’s and 50’s instead of the 70’s or 80’s. Maybe they don’t have that many people that are interested. But if they could, it would be a little bit more, you know, they talk about retirement or knee replacements. And I am thinking, okay some of us have a life. (Betty)

While Alex did not explicitly discuss the disconnect with others in the program, he made comments like, “I think I was probably more active than most everybody in there, so” and,

“Certainly for me, I believe it was adequate because I came in with an exercising background and I am not – I guess, I am not sure if they give someone without that background more attention” (Alex). Joan remarked, “And there were people that were, like, in their 80’s when we were there....most of them were even older than I was and a lot lot older.”

Although these themes emerged from the interviews as to why a participant quit the program, all of them stated how much they enjoyed various parts of the program. All of them stated that they would have liked to finish the program. And, many stated they would likely look into re-joining the program in the future.

Participant Perceptions

Completers and non-completers of the DSME program, alike, expressed positive experiences with the program. “It changed my life”, said Barb. “She changed my life”, exclaimed Frank, of the Program Director. Deb agreed, “They saved my life.” Deb remarked how she was “so excited about being able to share my feelings. I just can’t say enough positive [things] about it. I had an excellent experience and I miss it. I wish I could still come.”

Even in the midst of having reasons for quitting the program, participants collectively made comments like, “I really learned a lot”, “I feel so much better”, “I think they do a really good job”, “I changed my eating habits”. Some people perceived the program to meet their needs because of the accountability. Cher remarked, “I loved the program in the fact that it forced me to do it [physical activity].” Joan replied, “I had to be accountable.” Alex liked the program, “Because I felt it was very beneficial educationally and, for most people, equally beneficial physically with the exercise part.”

Graduates had many positive comments, many of which were similar to those stated earlier. Sam said, “I was very pleased with the program”. Tom and Connie really enjoyed it

when they were there. Frank could not say enough good things, "I was very happy with it." Barb got much self-satisfaction from the program, "I feel like I made great strides." Probably the most heartfelt response about what she wanted to share about her experience came from Deb.

Just thankfulness. I want to share my gratitude. And it is an excellent program on every level from the staff to the facility to, I mean, the curriculum. I was just extremely grateful. So, that is what I would like to express is gratitude. They saved my life. (Deb)

Impact and Outcome

Since the program is intended to be two sessions per week for six-months, participants who complete the program attend 48 sessions. For the purposes of this study, participants who completed more than 40 sessions were considered to have graduated from the DSME program. Participants who began the program but completed 40 or less were considered to have quit the program. One hundred seventeen people were oriented to the program in the last 18 months until the time of data collection. However, 26 people never began the program after the orientation session and they were not included in the evaluation. At the time of this writing, 17 participants graduated from the program. Fifty-one participants began the program but quit before finishing more than 40 sessions and 23 participants were actively enrolled in the program.

Weight loss of at least 5% is one of the main goals of this DSME program. Data were collected from surveys and document reviews to assess whether participants who were done with the program met the impact and outcome goals for weight loss. Impact evaluation also was conducted on the current participants. They were grouped as outlined above; those who were currently attending and had completed over 40 sessions were considered as graduates. There were five people that fit this category. Combining the 17 graduates of the program and the five current participants who had completed over 40 sessions, there was a total of 23 participants

considered as graduates for this study. The remaining current participants were calculated separately from those who quit.

Document reviews of initial orientation paperwork and of exercise records were conducted to obtain information on initial weight and end weight (weight at the last recorded session). Survey data provided participants' self-reported current body weight. Percent change was calculated to assess the number of participants who met the impact goal. It was calculated using participants' initial weight and end weight. Percent change was also calculated to assess the number of participants who met the outcome goal. It was calculated using participants' initial weight and self-reported current body weight.

Fifty-two percent of those who graduated, compared to 12% of those who quit, achieved the impact goal of at least 5% weight loss. The greatest loss was reported in a participant who lost 18.4% of her body weight from the initial session to the last session. Of current participants, who were not considered as graduates, 39% reported they already met the weight loss goal. Of those who graduated, none reported gaining weight during the program. Of those who quit, seven of 50, or 14%, gained weight during their time in the program. Three participants had no weight recorded for their last session attended.

Outcomes data were generated from surveys that were returned. Surveys were mailed to 94 participants, of which only 67 were eligible for evaluation due to the fact that it was determined the others did not start the program after orientation. Twenty-seven of 67 eligible participants returned surveys for a return rate of 40%. One participant who quit did not list her current weight on the survey. For those who graduated from the program and returned the survey, nine of 11, or 82%, showed at least a 5% weight loss as a long-term result. One person

gained weight. Of those who quit and returned the survey, six of 15 showed a long-term achievement and maintenance of at least 5% weight loss; or a total of 40% of those participants.

Adopting and maintaining 150 minutes of aerobic activity each week is another main goal of this DSME program. Current participants only record what they do during the exercise sessions in the program, which generally includes exercising twice a week for 60 minutes each session. This does not meet the goal of 150 minutes per week. Survey data revealed outcome achievement for physical activity. Five of 11, or 45%, of those who graduated reported achieving the exercise outcome goal. Five of 15, or 33%, of those who quit reported achieving the exercise outcome goal.

Alignment with AADE Standards for Outcome Measurement of DSME

The *AADE Standards for Outcomes Measurement of DSME* are:

1. Behavior change is the unique outcome measurement for diabetes self-management education.
2. Seven diabetes self-care behavior measures determine the effectiveness of diabetes self-management education at individual, participant, and population levels.
3. Diabetes self-care behaviors should be evaluated at baseline and then at regular intervals after the education program.
4. The continuum of outcomes, including learning, behavioral, clinical, and health status, should be assessed to demonstrate the inter-relationship between DSME and behavior change in the care of individuals with diabetes.
5. Individual patient outcomes are used to guide the intervention and improve care for that patient. Aggregate population outcomes are used to guide programmatic

services and for continuous quality improvement activities for the DSME and the population it serves. (AADE, 2003, p. 809-814)

The *AADE Standards for Outcomes Measurement of DSME* form (Appendix F) is designed to be used as a tool to measure the outcomes for each of the AADE7. Each of the AADE7 is listed and the specific knowledge, skills, and barrier resolution goals are listed. The measures and methods of measurement are listed with goals for measurement intervals. Evaluation of these goals is organized around on each of the AADE7.

Healthy eating is the first of the AADE7. Participants are expected to have knowledge of the effect of food on blood glucose, sources of carbohydrates, meal planning (what to eat, when to eat, how much to eat), and resources to assist in food choices. Skills that participants are expected to develop through a DSME program include meal planning, weighing and measuring food, carbohydrate counting, and label reading. Resolutions to overcome environmental triggers, emotional, cultural, and financial barriers are abilities that participants are expected to acquire in a DSME program (AADE, 2003). The education component of the DSME program for this study is delivered in a group setting during the exercise sessions. All of the components in the knowledge section for healthy eating is discussed during the program and is documented on the education record in the “Food” category. Participants who complete the full 48 sessions are likely to have received all of the information. Skill development for meal planning and label reading is discussed in depth; however, carbohydrate counting and weighing and measuring food is not discussed in detail. According to the Program Director, these are skills that are more applicable to someone who has diabetes, not pre-diabetes.

And basically, we are just following just like general nutrition guidelines. If they become diabetic, at that point we recommend they see a dietitian. And if they become

diabetic now – before, we would just keep them in the program and [let them] finish if they wanted to. Now, we encourage them to switch over to our Living with Diabetes program, which is specifically for people with diabetes.

Environmental triggers and emotional barriers are discussed throughout the educational sessions, but little is discussed about cultural or financial barriers.

Measures for healthy eating include types of food choices, amount of food eaten, timing of meals, effect of food on glucose, and special situations and problem solving. Methods of measurement include patient self-report, observation, food and blood glucose records, 24-hour food recall, and a food frequency questionnaire (AADE, 2003). Measurement intervals for learning are each instructional session, and measurement intervals for behavior assessment are baseline, 2 to 4 weeks, and every 3 to 6 months. Participants in this DSME program are asked to bring in a 4-day food record (patient self-report) to their orientation meeting. The Program Director evaluates the food log using the government website, My Plate, and discusses results with the participant. This is a baseline measurement. No other assessment is done; however, information about health eating is presented at many of the exercise sessions.

Being active is an AADE7 behavior that is emphasized in the program. Knowledge of this behavior includes the type, duration, and intensity of exercise as well as safety precautions and special considerations. Learning is expected to be done at each instructional session. Education is conducted at each DSME session, but it does not include learning about being active each time. Throughout various sessions, participants learn how to develop an appropriate activity plan. Skill development for being active includes the ability to develop an appropriate activity plan and balance food with medication. Many expressed feeling confident in their knowledge of and ability to construct an activity plan. However, since they have pre-diabetes,

not diabetes, it is not applicable to discuss balancing food with medication. These participants do not use insulin, which is the medication to which this skill is referring. Assessment of being active is conducted at the orientation meeting (baseline) but it is not typically discussed with each individual at 2 to 4 weeks or at 3 months. At the end of the 6 month program, discussion of a physical activity plan is conducted with the participants so they are sure of what to do after the program ends.

Monitoring, of blood glucose levels and insulin administration, comprises outcomes standard 3. Since these participants do not have diabetes, but pre-diabetes, this outcome standard does not apply because it is not standard practice for them to self-monitor glucose levels nor do they use insulin. Participants do not learn about self-monitoring blood glucose and insulin levels.

Taking medications also refers to medications for diabetes. As stated previously, these participants do not take insulin or other medications for diabetes. So, this outcomes standard does not apply for this population. However, while it is not a standard as outlined in these outcomes measures, participants reported about learning about other medications they take, such as medications for blood pressure and cholesterol.

Problem solving is an outcome that refers to knowledge of signs, symptoms, and causes of hypoglycemia (low blood sugar) and hyperglycemia (high blood sugar). Guidelines for treating and preventing hypoglycemia and hyperglycemia as well as safety considerations should be addressed in a DSME program. Discussion of these problems is limited, once again, because these participants have pre-diabetes. The Program Director explains, “Low blood sugar, we talk about sometimes, depending on if I have had some people who have had some issues with hypoglycemia. Usually, we talk about that briefly.” Measuring blood glucose, adjusting food, medication, and activity, as well as when to contact a healthcare provider is not discussed.

However, many interviewees reported having learned about problem solving to overcome other barriers, such as to exercise and eating healthy.

Yes, we talked about, you know, increasing your exercise a little bit each day.

You don't have to go overboard but – or cut back on certain foods or change what you are eating to a different, you know, combination. (Barb)

Reducing risks of the complications of diabetes is not applicable to this population.

However, many patients reported knowing about what can happen with uncontrolled diabetes. They are not educated during this program on complications like foot self-exam, aspirin therapy, or eye exams. However, when asked if the Program Director educates participants about chronic problems with diabetes, such as blindness and kidney failure, she replied, "Yes. [We talk about the] best thing to do to try to prevent those. Talk about the ABC's [A1C, blood pressure, and cholesterol] of diabetes and all that type of stuff."

Finally, participants in this population do not have to develop healthy coping skills for diabetes, as they do not have diabetes. However, many reported having gained the knowledge of benefits of treatment and self-care. "Just to be really aware of what is going on, I think," said Betty, "for so long, I had been so aware of what had been going on with my ex, I forgot about stuff that was going on with me." "It is important and essential, I would say. I would say they taught you that it was obvious," said Alex. Sam commented, "We have the choice and we are responsible for our actions."

They also acknowledged learning about goal-setting. Barb stated, "You know, set small goals. Don't look at it that I need to lose 50 pounds. Look at it that you need to lose five. Work on that five and then go for another five." Frank was very determined in his ability, "So you got

to set goals. And if you want to overcome them [barriers], you can. You can accomplish about anything you want to if you are determined to. It is a lot of work. But it is worth it.”

Outcome standards 4 and 5 are not explicitly addressed within the DSME program. An assessment of the continuum of outcomes is not conducted for individuals. Aggregate population outcomes are not clearly used to guide programmatic services. However, the Program Director addresses outcomes with individual patients. She reviews their attendance, blood pressure assessments, lab results, etc. and discusses it with the patient. This process is not described or documented anywhere.

Many of the *AADE Standards for Outcomes Measurement of DSME* do not apply to the pre-diabetes population. However, standards for outcome measurement are a significant part of a DSME program for those with diabetes. The main outcomes for this population were discussed previously. Weight loss of 5% or more and adopting and maintaining at least 150 minutes per week of physical activity have been shown to significantly reduce the development of diabetes in those at risk. Therefore, these are the outcomes standards that drive the DSME in this population.

Summary

In this chapter, results from analysis of data collected from document reviews, observations, interviews and a survey were revealed. Descriptions of program development and implementation were provided. Alignment with *National Standards for Diabetes Self-Management Education* was discussed and descriptive statistics were used to report results. Themes regarding factors that led to completion and non-completion of the entire program by participants emerged and were reported descriptively. Participants' perceptions of their experiences were described. Achievement of impact and outcome goals as calculated. Finally,

alignment with *AADE Standards for Outcome Measurement of DSME* was reported. Discussion, conclusions, and recommendations regarding these findings are presented in chapter 5.

CHAPTER FIVE

SUMMARY, MAJOR FINDINGS, CONCLUSIONS, DISCUSSION AND RECOMMENDATIONS

Summary

This qualitative case study presented an in-depth analysis of a DSME program at a Midwest health care center and to evaluate the effectiveness of the DSME program. The specific objectives of this study were: (1) to describe the program from inception to how it is currently implemented, (2) to determine if the *National Standards for Diabetes Self-Management Education* are being met, (3) to determine what factors affect completion and non-completion of the program by participants, and (4) to determine the impact and outcome of the program. Methods used included document reviews, interviews, observations, and a survey. Data were collected to provide an in-depth description of the program as well as to evaluate the program in terms of alignment with national standards and outcomes. Themes emerged from participant interviews that provided factors that led to completion or non-completion of the program by participants. Collectively, data provided overall conclusions reached in this study.

Major Findings

The following findings materialized from this research as a result of a thorough case study and evaluation of the DSME program.

1. The DSME program was initiated because the Program Director observed an anecdotal increase in the rate of diabetes in the area. She worked with her department manager and was awarded a grant to fund the program. The program was based on the same model they were using for cardiac rehabilitation as well as the AADE7. Exercise and education are the main components. The DSME program provides participants with pre-diabetes the

opportunity to exercise and receive education in order to reduce the risk of developing T2D.

2. The extent to which the program's elements align with the *National Standards for Diabetes Self-Management Education* were quantified. Within the four structure standards, three of the twelve (25%) essential elements are being met. Nine of the eighteen (50%) essential elements within the process standards are being met. Two of the six (33%) essential elements within the outcomes standards are being met. Only one National Standard is met completely, and that is standard 6. For the most part, all essential elements within standard 6 are being met through the DSME program. Fourteen of the thirty-six (39%) applicable essential elements are being met with this DSME program.
3. Factors that led to completion were categorized into three themes. Theme one: Participants who completed the program had the attitude that it is possible to overcome barriers to making desired lifestyle changes. Theme two: Participants expressed a desire and appreciation for education. They aspired for knowledge of how to eat healthy, how to increase exercise, and mostly, how to prevent diabetes. Theme three: Participants frequently commented on how supportive the staff was and how important it was to them to have that support.
4. Factors that led to non-completion were categorized into three themes. Theme one: Participants who did not complete the program often had some type of personal injury that stood in their way of continuing. Many of them, however, expressed a desire to return to the program at some point; or a regret that they were unable to finish. Theme two: Participants who quit the program had issues with time. Either the time of day that

the program was offered did not fit their schedules and/or they felt that their schedule was too busy to be able to continue attending the sessions. Theme three: Participants who quit the program felt disconnected with the others in the program.

5. Perceptions of their experience in the program by participants were very positive. Even though some of those who quit, and even some of those who graduated, offered suggestions for changes to the program, the overwhelming response was that each person felt the DSME program made a positive change in their lives. Many commented on how their diet has changed, how they feel better, how they feel like they accomplished something. Others emphatically declared that it changed their lives.
6. Impact of the program in terms of weight loss of at least 5% was achieved by those who graduated from the program. Fifty-two percent of those who graduated in the last 18 months achieved the weight loss goal; whereas, only 12% of those who quit achieved the same goal. As for the adoption of at least 150 minutes or more per week of aerobic activity, data were not sufficient to determine if those who graduated or those who quit achieved this impact goal. The only data that were reported in the documents were the exercise sessions during the program, which was not sufficient to achieve this goal. It is likely that many exercised in addition to the days in the program, but it was not recorded.
7. Eighty-two percent of those who graduated reported achieving the outcome goal of weight loss of 5% or more; while only 40% of those who quit achieved the outcome goal for weight loss. Maintaining aerobic exercise of 150 minutes or more per week was reported in 45% of graduates who returned the survey compared to 33% of those who quit.

8. Many of the *AADE Standards for Outcome Measurement of DSME* did not apply to the pre-diabetes population. Considering each of the AADE7 for which these standards apply, healthy eating and being active were the main areas of concentration in this program. However, they were not evaluated appropriately according to these standards. Monitoring, taking medications, problem solving, reducing risks, and health coping were all mentioned during the education in various forms, but not assessed.

Conclusions

1. The DSME program under study was the idea of a committed individual who has a passion for prevention of chronic diseases, specifically diabetes. She saw a need in the area, worked to ensure sufficient funding, and developed the program based on the cardiac rehabilitation model they used within the department. She developed the program from the ground up and has successfully helped many participants achieve weight loss and physical activity goals.
2. Participants in the DSME program, whether or not they graduated, were highly satisfied, for the most part, with what they attained from the program. They enjoyed the DSME staff, especially the Program Director, the education they received, and the opportunity to exercise and to get support in their mission to prevent T2D.
3. Many participants declared that they valued the support of others during the program. The support they received was motivational for them to work towards their goals.
4. Greater results were obtained by those who completed the program versus those who did not complete the program. Short-term and long-term results for weight loss of at least 5% were substantially better in those who completed the program. Maintenance of physical

activity was higher in those who graduated as well. This reveals the importance of adherence to the DSME program.

5. A surprisingly high rate of attrition was discovered in this research. Of those who began the program in the last 18 months, only 25% completed the program while 56% quit the program (25% were still actively enrolled). Of those interviewed, most of them had a physical injury that prohibited them from continuing with the program. However, others cited various other reasons including time issues and feeling disconnected with others in the program. Reasons for attrition should be explored further.
6. Anecdotally, there was a higher rate of people who began the program after referral once it was changed to an open enrollment versus the previous closed enrollment process. People who were referred, and then had to wait to begin when the program had a closed enrollment, lost interest in joining. So the open enrollment process has a higher efficacy than the closed enrollment process.
7. This DSME program does not currently meet the criteria to achieve accreditation from AADE. Most of the *National Standards for Diabetes Self-Management Education* as well as the *AADE Standards for Outcome Measurement of DSME* are not being met.

Discussion

The DSME program under study has been established since 2005. It is the product of an idea from one individual who has a passion for prevention. She saw a need and worked to fill the need. The diversity and level of expertise of the Program Director is outstanding. She is a Registered Nurse, has a Masters in Public Health in Community Health from the University of Illinois, and is a Certified Diabetes Educator. She envisioned the program, applied for grants to obtain appropriate funding, and developed the program from the ground up. Her passion and

determination to make the program successful is remarkable. She is fully committed to the participants and works very hard to give the participants an excellent experience. This is evident in their perception of their experiences. A declaration that the Program Director and/or the DSME program itself changed their lives was a common occurrence during the interviews.

Although participants perceived their experiences positively, there was a high rate of attrition. That being said, positive results were seen in those who completed the program with regard to obtaining and maintaining the main goals of the DSME program. “A central purpose of DSME is to help patients make informed decisions and to facilitate their self-care behavior” (Mulcahy et al., 2003a, p. 774). Participants who completed the program facilitate their self-care behavior by maintaining weight loss and engaging in physical activity. They reported feeling informed and empowered to make appropriate decisions with regard to healthy eating and being active. Participants valued support from the program participants and Program Director and staff. Studies have shown that support can be a predictor of dietary self-care and diabetes control. One such study was conducted and published in 2011. The researchers examined predictors that motivated people with diabetes to improve dietary self-care. The study, titled Longitudinal Motivational Predictors of Dietary Self-Care and Diabetes Control in Adults With Newly Diagnosed Type 2 Diabetes Mellitus, showed that autonomy support was one of the main predictors for improved dietary self-care. It was stated that,

Self-determination theory proposes that autonomous motivation and competence [other predictors] is determined by the level of autonomy support health care professionals provide through acknowledgment of the patients’ perspectives, support of their initiatives, and offering choices for treatment options while minimizing pressure and control. (Nouwen, Balan, Ruggiero, Ford, Twisk, & White, 2011)

The DSME program under study is unique in that it does not resemble a traditional model, which involves a patient meeting individually with multiple DSME professionals for information, but instead includes a supervised group exercise component during which education is provided. Over the years, several changes have been made to the way the program was being implemented to increase the quality of the DSME program. One such change included moving from a closed enrollment, in which a group of people would start at the same time, to an open enrollment, in which participants would begin the program as they were referred. This has advantages as well as disadvantages. An advantage to open enrollment includes being able to accommodate participants when they are motivated to begin. The Program Director reported that many people decided not to attend when they had to wait to begin during the closed enrollment period after being referred to the program. Therefore, by changing to an open enrollment, she can accept participants into the program as soon as they are referred and motivated to begin. A disadvantage to this system, however, is the difficulty in making sure all participants get the same education on the same topics throughout each of their six-month programs. Even with careful documentation, some participants may get more or less education on a particular topic than others. Some may miss certain topics altogether.

With regard to education, a written curriculum with criteria for evaluating outcomes is a central part of standard 6 of the *National Standards for Diabetes Self-Management Education*. Standard 6 was the only standard that was considered to have the all of the essential elements completely met; however, as described in chapter 4, it likely does not meet an academic's definition of a defined, written curriculum. That being said, there are improvements that can be made so that it meets a more academic definition of a written curriculum. It should be individualized according to the participants' needs. It should include skill-based training and

adopt the principles of AADE7 (AADE, 2009). Although participant perceptions of their experiences were very good and although many participants reported how much they enjoyed the educational component, this is a major area of need within the program. The DSME program under study needs to include a written curriculum to ensure all participants are getting the education and skills they need to be as successful as possible in their self-care.

Contrary, there is an advantage to not having a strict written curriculum. As described previously in chapter 4, the Program Director and participants reported that, during many sessions, the topic of education for the day was based on what issue(s) the participants were dealing with at the time. The Program Director would ask the group if they had anything specific in mind that they wanted to discuss and they would determine the topic for the day. This is an advantage because the education can be tailored to the participants' issue at the present time. During the observed sessions a variety of topics surfaced due to participant request to discuss certain issues. While the exact presentation may not have been given to other pre-diabetes classes, the general message was conveyed. For example, the circumstance mentioned in chapter 4 was about a participant who wanted help evaluating his diet. This same diet may not have been evaluated in the other classes, but the general message about choosing and refraining from certain foods was delivered on several occasions throughout the various classes.

The DSME program under study is non-traditional in that it includes a group exercise component and an expectation that participants will complete six months, or 48 sessions, within the program. Although the Program Director did not see the time frame as a possible deterrent, the attrition rate was high and that may be one possible reason. Consideration as to whether this was a common rate of attrition, or not, led to further research by this researcher. Upon investigation of typical attrition rates in DSME programs, very few studies were found.

Gucciardi, DeMelo, Offenheim, & Stewart (2008) conducted a study to determine factors that may lead to attrition in DSME programs. They reported an attrition rate of 44% in their study.

Results of their study included reasons given by participants for attrition from the program.

Contributing factors were, "Working full and part-time, being over 65 years of age, having a regular primary care physician or fewer diabetes symptoms" and the most common reasons included, "Conflict between their work schedules and the centre's hours of operation, patients' confidence in their own knowledge and ability when managing their diabetes, apathy towards diabetes education, distance to the centre, forgetfulness, regular physician consultation, low perceived seriousness of diabetes, and lack of familiarity with the centre and its services"

(Gucciardi et al., 2008, p. 1). AADE did not report a common rate of attrition, but did recommend that program attrition as one of the areas of focus for a continuous quality improvement project within standard 10 (AADE, 2009).

Recommendations for the DSME Program

The Program Director has expressed a desire to continue improving and growing the program. The following recommendations are made to align the program with national standards. With that in mind, the recommendations should not be viewed as a failure of the program because the evidence described above demonstrates overwhelmingly that the DSME program is effective in helping people with pre-diabetes. However, in the spirit of offering ways to improve the program, these are the primary recommendations:

1. Solidify the program as a major service within the health care center. A mission statement and documented goals for the DSME program, separate from those for the health care center, should be developed. It should have a designated staff beyond the

- Program Director. The staff should have specific responsibilities to the program to enhance consistency and reliability of available personnel.
2. Hire or train others to function as Certified Diabetes Educators. This will ensure sustainability of the program should the current Program Director be unable to fulfill her duties for any reason.
 3. Appoint an advisory group. According to the *National Standards, Essential Elements, and Interpretive Guidance*, this advisory group should “include a primary care provider, educator, community member with diabetes, etc.” (AADE, 2009, p. 2). The group would review evaluations conducted on the program and the participants and make recommendations to improve the effectiveness of the program.
 4. Provide a consistent written curriculum with criteria for evaluating outcomes.

Although participants seem very pleased with what they learn in the program, there is no evaluation of what has been learned. Therefore, it is unclear as to the extent that the participants have learned the material.
 5. Develop an assessment plan for each individual. Select education, interventions, and support necessary for that individual to meet the goals within the plan. Evaluate and document the outcomes at various times throughout the program. Communicate the results to the referring physician to promote high quality patient care and optimal health outcomes.
 6. Create an exit interview with each participant as well as a personalized annual follow-up plan. Include instructions for the participant on what to do to maintain goals. Communicate results to the referring physician.

7. Determine opportunities for improvement using a written continuous quality improvement plan. Use assessment data to drive the plan.
8. Designate other times for the exercise sessions that are satisfactory for participants who work during regular business hours. Consider the feasibility of lumping participants together who are similar in some way, such as by age, so they feel connected to the group.
9. Continue the commitment of passionate, caring personnel who make every effort to make a difference in participants' lives.

Recommendations for Future Research

Most of the *National Standards for Diabetes Self-Management Education* focus on participants meeting individually with a DSME staff member. No mention was made within the standards to suggest that a supervised exercise program should be part of a DSME. While that model serves many of the standards well, this research has determined that participants in the DSME program under study valued the group exercise component of the program. Participants spoke of developing relationships with other participants and of how they valued support from others in the program. Not surprisingly, one of the main themes that emerged as a factor affecting completion of the program included support of those around them. Incidentally, one of the main themes that emerged from those who quit the program included feeling disconnected from others in the program. This suggests that feeling connected with others in the program might have increased their satisfaction with the program. Therefore, they may have continued with the DSME program.

1. Conduct research to determine whether or not a group exercise component significantly increases attainment of goals or prevention of T2D versus the traditional model.

2. Conduct research to determine the ideal number of DSME program sessions to obtain maximum benefit. Once again, this strays from the traditional model of DSME; however, this research has shown benefits from a group exercise component. Large differences were noted in those who completed the program versus those who quit. However, the ideal number of sessions to obtain benefit is unknown and needs further exploration.
3. Conduct research to determine effective strategies to decrease attrition in DSME programs. Reasons for attrition were documented in this study as well as few other published studies. However, current research does demonstrate whether or not specific changes to the DSME program will actually decrease attrition.

Recommendations for Health Education/ Health Educators

1. Research the feasibility to offer CDE certification in the undergraduate or graduate curriculum. Since Health Educators are typically very prevention oriented this aligns with that way of thinking. Also, obtaining this certification during one's degree program would effectively give them an extra advantage over someone interested in establishing or working with a DSME program.
2. Promote DSME within the community and within medical centers. Work with clinicians and participants to establish effective programs.
3. Conduct evaluations on recognized DSME programs and provide recommendations or opportunities for improvement.

Closing Reflection

Reasons for not meeting standards could be numerous. First, this is a pre-diabetes program, not a program for people with diabetes. Therefore, some of the standards and outcomes measures do not apply to this population. Actually, some of the standards described may be

contraindicated in this population, such as self-monitoring of blood glucose levels. Since the Program Director is basically the only full-time staff member appointed to this program, it appears there is little time for her to devote to anything but getting participants started in the program and conducting the actual program sessions. Designated staff is essential to help move this program forward. Planning, implementing, and evaluating are enormous tasks for one person to tackle by herself.

From an administrative point of view, it may be disenchanting to discover that some of the national standards and outcomes are not met with this DSME program. Impact and outcome data, however, show that the goals of the program itself are being met largely by those who complete the full six months. However, as one reads through the interview data, in particular, it is apparent that participants really value the program and speak very highly of the Program Director and other staff. All of the interviewees expressed how much of a difference the experience has made in their lives. To this researcher, that speaks volumes as to the effectiveness of this program.

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APPENDICES

Diabetes Education Accreditation Program



APPENDIX A

NATIONAL STANDARDS, ESSENTIAL ELEMENTS AND INTERPRETIVE GUIDANCE

NSDSMEP	Essential Elements	Essential Elements Checklist	Interpretive Guidance (See Glossary for more information)
<p>Standard 1. Organizational Structure The DSME entity will have documentation of its organizational structure, mission statement & goals and will recognize and support quality DSME as an integral component of diabetes care</p>	<p>A) There is documentation that describes or depicts Diabetes Education as a distinct component within the organization's structure and articulates the program's mission and goals.</p> <p>B) Documentation and/or procedures that support quality education shall include at least the following:</p> <ul style="list-style-type: none"> i) Job descriptions of the Program Coordinator and instructional team that are congruent with program needs, including educational needs of target population. ii) Diabetes education process and self-management support 	<p>Documentation of org chart of DSME/T Program:</p> <p>YES <input type="checkbox"/></p> <p>NO <input type="checkbox"/></p> <p>Documentation of program mission and goals:</p> <p>YES <input type="checkbox"/></p> <p>NO <input type="checkbox"/></p> <p>Policies and procedures are available:</p> <p>YES <input type="checkbox"/></p> <p>NO <input type="checkbox"/></p> <p>Job Descriptions for all positions relating to the DSME/T Program:</p> <p>YES <input type="checkbox"/></p> <p>NO <input type="checkbox"/></p>	<p>Policies and procedures are an integral part of any quality process and should be developed for applicable program components. (Policy = directive or statement that must be adhered to; Procedure = guidelines for implementation of policy.)</p> <p>The mission can be described as a brief description of the program's fundamental purpose. It answers the question, "why do we exist?" Documentation should broadly describe the program's present capabilities, customer focus, and activities. The targeted audience is typically identified in the mission statement.</p> <p>If diabetes education experience is used as the instructor qualification criteria instead of continuing education, the amount of previous diabetes education experience needed for the instructor who is not credentialed as a diabetes education and/or diabetes clinical management specialist shall be included in the instructor's job description.</p>

NATIONAL STANDARDS, ESSENTIAL ELEMENTS AND INTERPRETIVE GUIDANCE

NSDSMEP	Essential Elements	Essential Elements Checklist	Interpretive Guidance (See Glossary for more information)
<p>Standard 2. The DSME entity shall appoint an advisory group to promote quality. This group shall include representatives from the health professions, people with diabetes, the community, and other stakeholders.</p>	<p>A) A policy that identifies the structure and process, for the program's advisory group, will be maintained.</p> <p>i) This policy will address the advisory group's role in promoting quality DSME/T programming.</p>	<p>Advisory Group Policy:</p> <p>YES <input type="checkbox"/></p> <p>NO <input type="checkbox"/></p> <p>Advisory Group Function:</p> <p>YES <input type="checkbox"/></p> <p>NO <input type="checkbox"/></p>	<p>The advisory group for each DSME/T program will vary according to program size, location and scope and complexity of services provided.</p> <p>AADE suggests the advisory group includes a primary care provider, educator, community member with diabetes, etc. The group actively reviews and makes recommendations on the DSME/T annual program plan and evaluation.</p>

NATIONAL STANDARDS, ESSENTIAL ELEMENTS AND INTERPRETIVE GUIDANCE

NSDSMEP	Essential Elements	Essential Elements Checklist	Interpretive Guidance (See Glossary for more information)
<p>Standard 3. The DSME entity will determine the diabetes educational needs of the target population(s) and identify resources necessary to meet these needs.</p>	<p>A) There shall be documentation of:</p> <ul style="list-style-type: none"> i) a needs assessment for the target population. ii) the availability of resources to meet these educational needs 	<p>An identifiable process was used to assess the needs of the target population:</p> <p>YES <input type="checkbox"/> NO <input type="checkbox"/></p> <p>Unique needs of target population specified:</p> <p>YES <input type="checkbox"/> NO <input type="checkbox"/></p> <p>Allocation of resources specified:</p> <p>YES <input type="checkbox"/> NO <input type="checkbox"/></p>	<p>The development of a DSME/T program must include identifying who it intends to provide services to (the target population/audience). The decision about who to provide services to should relate to the organization's mission. Additional decisions and assessment about the target population are needed, and include the following:</p> <ol style="list-style-type: none"> 1) The volume of people who will be in need of service on an ongoing basis 2) The type of diabetes that most potential participants have 3) Where they live 4) Unique characteristics of large segment(s) of the target population that are relatively homogenous. <p>Allocation of resources should be based on assessment of the target population.</p>

NATIONAL STANDARDS, ESSENTIAL ELEMENTS AND INTERPRETIVE GUIDANCE

NSDSMEP	Essential Elements	Essential Elements Checklist	Interpretive Guidance (See Glossary for more information)
<p>Standard 4. A coordinator will be designated to oversee the planning, implementation and evaluation of diabetes self-management education. The coordinator will have academic or experiential preparation in chronic disease care and education and in program management.</p>	<p>A) A completed job application/resume of the program coordinator that identifies experience and/or education in program management and the care of individuals with chronic disease, congruent with the job description, is kept on file.</p> <p>B) The coordinator's position description will indicate that the coordinator is responsible for oversight of the planning, implementation and evaluation of the DSME/T program. (See Standard 1)</p> <p>C) Coordinators are to follow the continuing education requirements of their professions (a minimum of 15 hours continuing education is required annually)</p>	<p>Coordinator's resume (reflects academic, continuing education, and/or experiential preparation):</p> <p>YES <input type="checkbox"/></p> <p>NO <input type="checkbox"/></p> <p>Position description describes program oversight by Coordinator:</p> <p>YES <input type="checkbox"/></p> <p>NO <input type="checkbox"/></p>	<p>The breadth and depth of responsibilities of the program coordinator will vary with the program size and complexity, but, at a minimum, the coordinator must have the ability to be responsible for planning, implementation and evaluation of services. The job description of coordinator should be congruent with the size and complexity of the program.</p> <p>(See Standard 1)</p>

NATIONAL STANDARDS, ESSENTIAL ELEMENTS AND INTERPRETIVE GUIDANCE

NSDSMEP	Essential Elements	Essential Elements Checklist	Interpretive Guidance (See Glossary for more information)
<p>Standard 5. DSME will be provided by one or more instructors. The instructors will have recent educational and experiential preparation in education and diabetes management or will be a certified diabetes educator. The instructor(s) will obtain regular continuing education in the field of diabetes management and education. At least one of the instructors will be a registered nurse, dietitian, or pharmacist. A mechanism must be in place to ensure that the participant's</p>	<p>A) Resumes and proof of licenses, registration and/or certification shall be maintained to verify that program staff is comprised of instructor(s) who have obtained and maintained the required credentials.</p> <p>B) If Community Health Workers (CHW) are part of the DSME/T program team, there is documentation of successful completion of a standardized training program for CHWs and additional and ongoing training related to diabetes self-management.</p> <p>i) Training includes scope of practice relative to role in DSME/T</p> <p>C) If CHWs are part of the DSME/T program's team, there shall be documentation that they are directly supervised by, the named diabetes educator(s) in the program.</p> <p>D) Proof of continuing education will be maintained to provide evidence that each instructor maintain their qualifications according to the specific criteria</p>	<p>Instructor's current credentials: <input type="checkbox"/> YES <input type="checkbox"/> NO</p> <p>Instructor's current resume: <input type="checkbox"/> YES <input type="checkbox"/> NO</p> <p>15 hours annual continuing education for all individuals: <input type="checkbox"/> YES <input type="checkbox"/> NO</p> <p>At least one of the instructors is an RN, RD or Pharmacist: <input type="checkbox"/> YES <input type="checkbox"/> NO</p> <p>CHW training, continuing education and name of supervisor, if applicable: <input type="checkbox"/> YES <input type="checkbox"/> NO</p>	<p>There is evidence that DSME/T is most effective when delivered by a multidisciplinary team that is comprised of members with varying types and levels of expertise (both professional and CHWs) who collaboratively plan and implement a comprehensive plan of care. The concept of "team approach" should be implemented through collaboration and linkages with other health care providers of various disciplines, outside of the program, particularly where a participants needs cannot be met by the program staff.</p> <p>Continuing education for instructional staff is specified as being diabetes specific, diabetes-related, and behavior change self- management education strategies (e.g., AADE7 self-care behaviors)</p> <p>CHWs will have non-technical and nonclinical instructional responsibilities; they will receive on-going informal training and</p>

<p>needs are met if those needs are outside the instructors' scope of practice and expertise.</p> <p>Standard 5, cont.</p>	<p>below and consistent with their job description:</p> <p>i) Instructors:</p> <ul style="list-style-type: none"> a) 15 hours of continuing education annually for all instructors. b) These hours must be from a nationally recognized accrediting body. <p>E) For programs, particularly those that have solo instructors, there shall be a policy that identifies a mechanism for ensuring participant needs are met if needs are outside of instructor's scope of practice and expertise.</p> <p>F) There shall be documentation that:</p> <ul style="list-style-type: none"> i. describes a process for ensuring that appropriate care coordination among the diabetes care team occurs. ii. Of team coordination/interaction. 	<p>Mechanisms for ensuring participants' needs are met.</p> <p>YES <input type="checkbox"/></p> <p>NO <input type="checkbox"/></p> <p>Team coordination/interaction is documented:</p> <p>YES <input type="checkbox"/></p> <p>NO <input type="checkbox"/></p>	<p>formal training as appropriate.</p> <p>Mechanisms for meeting needs outside of scope of practice include:</p> <ol style="list-style-type: none"> 1. Referral to other practitioner 2. Partnering with a professional with additional expertise (e.g., exercise physiologist or behavioral specialist) <p>Quality care is more likely when the multidisciplinary team meets on an as needed basis; this should be documented. The Documentation can rely on a checklist or some other vehicle. The purpose is to make certain that care and changes in care are known by all team members.</p>
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NATIONAL STANDARDS, ESSENTIAL ELEMENTS AND INTERPRETIVE GUIDANCE

NSDSMEP	Essential Elements	Essential Elements Checklist	Interpretive Guidance (See Glossary for more information)
<p>Standard 6. A written curriculum reflecting current evidence and practice guidelines, with criteria for evaluating outcomes, will serve as the framework for the DSME entity. Assessed needs of the individual with pre-diabetes and diabetes will determine which of the content areas listed below are to be provided:</p> <ul style="list-style-type: none"> o Describing the Diabetes disease process & treatment options. o Incorporating nutritional management into lifestyle. o Incorporating Physical activity into lifestyle. 	<p>A) A written curriculum that meets the patients' needs will be maintained and updated as needed to reflect current evidence and practice guidelines.</p> <p>B) The curriculum:</p> <ul style="list-style-type: none"> i) Uses principles and concepts of the AADE7self-care behavior framework (self-care behaviors): <ul style="list-style-type: none"> a) Healthy Eating. b) Being Active. c) Monitoring. d) Taking medications. e) Healthy coping. f) Problem solving. g) Reducing risks. ii) Includes content about the diabetes disease process/pathophysiology. iii) Is tailored for the target population. iv) Uses primarily interactive, collaborative, skill-based training methods and maximizes the use of interactive training methods. 	<p>A written curriculum tailored to meet the needs of the target population:</p> <p>YES <input type="checkbox"/> NO <input type="checkbox"/></p> <p>Adopts principles of AADE7 and includes disease content:</p> <p>YES <input type="checkbox"/> NO <input type="checkbox"/></p> <p>Curriculum is kept updated, reflecting current evidence, practice guidelines and is culturally appropriate:</p> <p>YES <input type="checkbox"/> NO <input type="checkbox"/></p> <p>Curriculum maximizes use of interactive training methods:</p> <p>YES <input type="checkbox"/> NO <input type="checkbox"/></p>	<p>Medicare requires DSMT programs to have a written curriculum that includes specified content areas relating to the patient's understanding of self-management skills, knowledge and behavior change. The educational plan and comprehensive curriculum are based on the AADE7 and typically include a needs assessment, teaching techniques/tools, collaborative goal setting with implementation and criteria for assessing behavior change and goal achievement, and appropriate documentation.</p> <p>The curriculum and accompanying training materials are most effective if they are at the appropriate level of literacy and numeracy of the population being served and based upon evidenced-based principles of education and healthcare. Additionally, a curriculum that takes into account cultural beliefs, attitudes and practices held by a majority of the</p>

<ul style="list-style-type: none"> o Using medication(s) safely and for maximum therapeutic effectiveness. <p>Standard 6, cont</p> <ul style="list-style-type: none"> o Monitoring blood glucose and other parameters and interpreting and using the results for self management decision making. o Preventing, detecting, and treating acute complications. o Preventing, detecting and treating chronic complications. o Developing personal strategies to address psychosocial issues and concerns. 			<p>population targeted will help ensure successful DSME/T.</p> <p>Using principles and concepts of the AADE7 self-care behavior framework for curriculum development or adaptation of standardized DSME/T curriculums will provide continuity throughout the DSME/T process (assessment through evaluation) and will center the focus of DSME/T on behavior change, the primary purpose of diabetes education. Uses primarily interactive, collaborative, skill-based training methods and maximizes the use of interactive training methods.</p> <p>Criteria for evaluating immediate outcomes (learning and barrier resolution) and, as applicable, intermediate outcomes (behavior change goal achievement), using the AADE7 self-care behavior framework, (continuum of outcome measures) should be part of the written curriculum.</p>
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NATIONAL STANDARDS, ESSENTIAL ELEMENTS AND INTERPRETIVE GUIDANCE

NSDSMEP	Essential Elements	Essential Elements Checklist	Interpretive Guidance (See Glossary for more information)
<p>Standard 7. An individual assessment and education plan will be developed collaboratively by participant and instructor(s) to direct the selection of appropriate education, interventions and self-management support strategies. This assessment and education plan and the intervention and outcomes will be documented in the education record.</p>	<p>A) There will be documentation to identify that pertinent assessment data was obtained in a collaborative, ongoing manner between the participant and instructor.</p> <p>B) The AADE7 self-care behavior framework will serve as the foundation for the assessment and include the following elements:</p> <ul style="list-style-type: none"> i) Relevant medical history. ii) Present health status, health service or resource utilization. iii) Risk factors. iv) Diabetes knowledge and skills. v) Cultural influences. vi) Health beliefs and attitudes. vii) Health behaviors and goals. viii) Support systems ix) Barriers to learning. x) Socioeconomic factors <p>C) There will be a written policy that describes the diabetes education process (assessment, planning, intervention and evaluation) and there will be documentation of the</p>	<p>Collaborative participant assessment: <input type="checkbox"/> YES <input type="checkbox"/> NO</p> <p>Education Process Policy: <input type="checkbox"/> YES <input type="checkbox"/> NO</p> <p>Plan of care based on assessment and meets the individual's needs: <input type="checkbox"/> YES <input type="checkbox"/> NO</p> <p>Integration of AADE7: <input type="checkbox"/> YES <input type="checkbox"/> NO</p> <p>Intervention per plan provided and outcomes evaluated: <input type="checkbox"/> YES <input type="checkbox"/> NO</p>	<p>The Diabetes Educational Process is comprised of an individualized assessment, goal setting, development of an educational plan, implementation of the educational plan and evaluation of the effectiveness of the DSME/T interventions. The process is collaborative between/among the participant and instructor/s. An integral part of the process includes documentation in the education/medical/clinical record which promotes continuity of care.</p> <p>Also see Standard 6.</p> <p>Communication back to the referring physician and other members of the diabetes care team is essential to high quality patient care and optimal health outcomes.</p>

Standard 7, cont.	<p>following for each patient:</p> <ul style="list-style-type: none">i) Educational planii) Educational interventions provided. <p>a) If interventions not provided according to the plan, there shall be documentation about plan revision.</p> <p>iii) Achievement of learning objectives</p> <p>D) Staff providing service will be identifiable in a way that can be authenticated.</p> <p>E) There shall be documentation to identify that an educational goal/s, and learning objectives and the plan for educational content and method/s were collaboratively developed between the participant and instructor(s).</p>	<p>Collaborative development of education goal, objectives and plan:</p> <p>YES <input type="checkbox"/></p> <p>NO <input type="checkbox"/></p>	
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NATIONAL STANDARDS, ESSENTIAL ELEMENTS AND INTERPRETIVE GUIDANCE

NSDSMEP	Essential Elements	Essential Elements Checklist	Interpretive Guidance (See Glossary for more information)
<p>Standard 8. Process A Personalized follow-up plan for on-going self-management support will be developed collaboratively by the participant and instructor(s). The patient's outcomes and goals, and the plan for on-going self-management support will be communicated to the referring provider.</p>	<p>A) There will be a written policy and documentation that identifies that a personalized follow-up plan to ensure on-going self-management support (DSMS) was developed in collaboration with the participant.</p> <p>B) There shall be documentation that identifies that the patient's outcomes and goals, and the plan for DSMS are communicated to the referring physician (or qualified non-physician practitioner).</p>	<p>Communication of educational services to physician/ qualified non-physician practitioner:</p> <p>YES <input type="checkbox"/></p> <p>NO <input type="checkbox"/></p> <p>Policy for personalized process and on-going self-management support strategies:</p> <p>YES <input type="checkbox"/></p> <p>NO <input type="checkbox"/></p>	<p>Achieving and maintaining behavior change goals that are necessary for successful diabetes self-management usually requires ongoing support upon completion of a diabetes education program/course. Diabetes self-management support (DSMS) can be provided by a variety of different people including health care professionals, community health workers, peer support and family; using a variety of different methods (telephone, web and e-mail, meetings, etc.). It is important to have an individualized plan for ensuring the provision of DSMS for most DSME/T participants to help people continue to keep focused on diabetes.</p> <p>Communication back to the referring physician and other members of the diabetes care team is essential to high quality patient care and optimal health outcomes.</p>

NATIONAL STANDARDS, ESSENTIAL ELEMENTS AND INTERPRETIVE GUIDANCE

NSDSMEP	Essential Elements	Essential Elements Checklist	Interpretive Guidance (See Glossary for more information)
<p>Standard 9. The DSME entity will measure attainment of patient-defined goals and patient outcomes at regular intervals using appropriate measurement techniques to evaluate the effectiveness of the educational intervention.</p>	<p>A) The evaluation policy shall use the AADE7 self-care behavior framework (or equivalent), core outcomes measures, behavioral and clinical outcomes for each patient individually and in aggregate. Outcomes will be compared to quality indicators to assess the effectiveness of the patients' care plan and the education intervention.</p> <p>i) Individualized and aggregate outcomes data includes at a minimum, attainment of participant-defined behavior change goal(s) (intermediate outcomes) and at least one post-intermediate or long term health outcome measure.</p> <p>ii) There shall be evidence that there was a critical analysis that determined the choice for the post-intermediate (clinical improvement) or long term (health status improvement) outcome measure that will be or was tracked.</p>	<p>Individual and aggregate achievement of behavior change goal(s):</p> <p>YES <input type="checkbox"/></p> <p>NO <input type="checkbox"/></p> <p>Policy required that outcomes data include appropriate measures:</p> <p>YES <input type="checkbox"/></p> <p>NO <input type="checkbox"/></p> <p>Reason for choice of outcome measures:</p> <p>YES <input type="checkbox"/></p> <p>NO <input type="checkbox"/></p> <p>Effectiveness of intervention is based on data:</p> <p>YES <input type="checkbox"/></p> <p>NO <input type="checkbox"/></p>	<p>Individual patient outcome measures are used to guide the intervention and improve care for that participant.</p> <p>Aggregate population outcome measures (program outcome measures) are used to guide programmatic services and CQI activities for the DSME/T and the population it serves.</p> <p>AADE electronic data collection tools could be used for data collection and analysis; other data collection tools are also applicable.</p> <p>Communication to the instructional team and members of the diabetes care team is essential to high quality patient care and optimal health outcomes.</p> <p>See the AADE "technical review" paper for additional guidance: Diabetes Self-Management Education Core Outcomes Measures</p>

NATIONAL STANDARDS, ESSENTIAL ELEMENTS AND INTERPRETIVE GUIDANCE

NSDSMEP	Essential Elements	Essential Elements Checklist	Interpretive Guidance (See Glossary for more information)
<p>Standard 10. Outcomes The DSME entity will measure the effectiveness of the education process and determine opportunities for improvement using a written continuous quality improvement plan that describes and documents a systematic review of the entities' process and outcome data.</p>	<p>A) There is documentation that:</p> <ul style="list-style-type: none"> i) identifies opportunities for improvement, as indicated by data tracked, were identified; and ii) a process for improvement implemented if feasible (or an explanation for why it was not). iii) a continuous quality improvement (CQI) improvement activity shall be undertaken annually. 	<p>Systematic process for implementing a CQI process/plan:</p> <p>YES <input type="checkbox"/></p> <p>NO <input type="checkbox"/></p> <p>Program improvement, if applicable, is based on data deficiencies that have been analyzed:</p> <p>YES <input type="checkbox"/></p> <p>NO <input type="checkbox"/></p> <p>CQI results shared with the Advisory Group annually:</p> <p>YES <input type="checkbox"/></p> <p>NO <input type="checkbox"/></p>	<p>Program operation elements, e.g., wait times and program attrition are options for CQI projects. Data tracked and used for CQI purposes could also include other program quality indicators (data related to program operations/structure, process issues) such as wait time for educational services; reimbursement issues; number of referrals, etc.</p> <p>AADE suggests that the CQI plan be in place that is consistent with the organization's mission and strategic plans, and evaluates the DSMT education process and program outcomes. We also suggest that the components in the CQI plan should be in the CQI results. The CQI plan and reports should be shared with the advisory group.</p> <p>AADE electronic data collection tools could be used for CQI; other data collection tools are also applicable.</p>

APPENDIX B

Interview Questions for DSME Program Director

STRUCTURE

Standard 1:

1. Do you have documentation of...?
 - a. The organizational structure of the program?
 - b. The mission statement?
 - c. The goals?
 - d. How were these developed?

*** looking for managerial support; policies, procedures, and guidelines; institutional commitment to the educational entity

2. Describe how you recognize DSME as an integral component of diabetes care.

Standard 2:

3. Have you appointed an advisory group to promote quality – including representatives from the health professions, people with diabetes, the community, and other stakeholders?
 - a. How did you identify these people?

Standard 3:

4. Have you/ How have you determined the diabetes educational needs of the target population(s) and identified resources necessary to meet those needs?
 - a. Identify access issues
 - b. Identify demographic variables – ethnic background, age, formal educational level, reading ability, and barriers to participate in education

Standard 4:

5. Who has been designated to oversee the planning, implementation, and evaluation of DSME (coordinator)? How was this person chosen?
6. What academic or experiential preparation in chronic disease care and education and in program management does this coordinator have?

PROCESS

Standard 5:

7. Who are the instructors of DSME?
8. Do each of the instructors have recent educational and experiential preparation in education and diabetes management? If yes, from where? What type?
9. Are they certified diabetes educators?
10. Do the instructors obtain regular continuing education in the field of diabetes management and education?
11. Is at least one of the instructors a registered nurse, dietitian, or pharmacist?

12. Do you utilize the services of other health professionals (e.g., a physician, behaviorist, exercise physiologist, ophthalmologist, optometrist, podiatrist)? To what extent?
13. Do you utilize the services of lay health and community workers and peers?
14. Do the health professionals working with DSME have certification through the National Certification Board for Diabetes Educators (NCBDE)? Through board certification in advanced Diabetes Management (BC-ADM) offered by the American Nurses Credentialing Center (ANCC)?
15. Does the team have a collective combination of expertise in the clinical care of diabetes, medical nutrition therapy, educational methodologies, teaching strategies, and the psychosocial and behavioral aspects of diabetes self-management?

Standard 6:

16. Do you have a written curriculum reflecting current evidence and practice guidelines, with criteria for evaluating outcomes to serve as the framework for the DSME entity?
 - a. How was this developed?
17. Do you conducted an assessment of needs of the individual with pre-diabetes and diabetes to determine which content is to be provided?
 - a. Content areas:
 - Describing the *diabetes disease process* and *treatment options*
 - Incorporating *nutritional management* into lifestyle
 - Incorporating *physical activity* into lifestyle
 - Using *medication(s)* safely and for maximum therapeutic effectiveness
 - *Monitoring blood glucose* and other parameters and interpreting and using the results for self-management decision making
 - Preventing, detecting, and treating *acute complications*
 - Preventing detecting, and treating *chronic complications*
 - Developing personal strategies to address psychosocial issues and concerns
 - Developing personal strategies to promote health and behavior change
18. Does the curriculum emphasize:
 - a. Practical, problem-solving skills?
 - b. Collaborative care?
 - c. Psychosocial issues?
 - d. Behavior change?
 - e. Strategies to sustain self-management efforts?

Standard 7:

19. Do the instructor(s) and the participant develop collaboratively an individual assessment and education plan?
 - a. Does the assessment include: relevant medical history, age, cultural influences, health beliefs and attitudes, diabetes knowledge, self-management skills and behaviors, readiness to learn, health literacy level, physical limitations, family support, and financial status?
 - b. Patient's personal self-management goals

20. If so, is this plan documented in the education record?
21. Is a periodic reassessment conducted?
22. Is the assessment and educational plan shared among the DSME team?

General Questions

23. How is the program currently being implemented?
24. What additional data do you collect?

Standard 8:

25. Has a personalized follow-up plan been developed for ongoing self management support?
26. Are the patient's outcomes and goals and the plan for ongoing self management support communicated to the referring provider?

OUTCOMES

Standard 9:

27. Do you measure attainment of patient-defined goals and patient outcomes at regular intervals using appropriate measurement techniques to evaluate the effectiveness of the educational intervention?
28. Is a plan in place to communicate personal goals and progress to other team members?

Standard 10:

29. Is a written continuous quality improvement (CQI) plan used to measure the effectiveness of the education process and to determine opportunities for improvement?
30. Are timelines and important milestones, including data collection, analysis, and presentation of results, incorporated in the plan once improvement projects are identified and selected?

Misc:

31. Tell me about the history of this program – from inception to how it has emerged to what it is today.
32. What process was used to make decisions on changes in the program?

APPENDIX C

Interview Questions for Participants

1. How did you find out about the DSME program?
2. What motivated you to participate? OR What factors led you to drop out of the program before completing it?
3. Suppose I was trying to decide whether or not to participate in the program, what would you say to me?
4. What would the ideal program look like?
5. Some people would say there are challenges that stand in the way of completing the program. What would you tell them?
6. Would you say the program was different than what you expected? Why or why not?
7. Suppose it was my first day in this program. What would it be like?
8. Some people would say that this program is not adequate to meet the needs of those who are trying to prevent diabetes. What would you tell them?
9. What kinds of things have you changed in your life because of what you experienced in this program?
10. Tell me about your level of physical activity now compared to before participating in this program.
 - a. In what types of activities do you participate now?
 - b. How has the DSME program helped you to prepare to be regularly physical active? How did you decide what to do?
 - c. How has the DSME program helped you to develop an appropriate activity plan?

- d. Tell me about any barriers/challenges you had to overcome. How has the DSME program helped you to overcome barriers?
 - e. Is there something more you would have liked to gain from your experience in the DSME program with regards to being physically active?
11. Tell me about your diet before you started this program.
- a. How has the DSME program helped you to structure your diet appropriately?
 - b. How do you go about planning meals? How is this different than before you participated in the program?
 - c. Have you experienced any challenges or barriers to changing your diet? If so, what were they? How did the DSME program help you overcome these challenges?
 - d. Is there something more you would have liked to gain from your experience in the program with regards to following an appropriate diet?
12. What did you learn from this program about taking medications?
- a. What has your experience in the DSME program taught you about the medications you take?
 - b. Tell me about a time when you missed a dose before you were in this program. What did you do? How would you handle it now?
 - c. How did you learn about the side affects you may experience from your medications?
 - d. Tell me about a time when you experienced low blood sugar. How did you recognize it was low? What did you do? In what way was this different than how you handled it before the program?

- e. Is there something more you would have liked to gain from your experience in the program with regards to taking medications?
13. How has the DSME prepared you to monitor your blood glucose? How is this different than how you did it before the program?
- a. Is there something more you would have liked to gain from your experience with regards to monitoring your blood glucose?
14. Tell me what you learned from this program about recognizing high and low levels of blood glucose.
- a. How do you identify the causes, treatment, and prevention strategies for hypoglycemia?
 - b. Suppose I felt like my blood sugar was low, what would you tell me to do? How is this different than the advice you would have given me before the program?
 - c. Suppose I felt like my blood sugar was high, what would you tell me to do? How is this different than the advice you would have given me before the program?
 - d. Is there something more you would have liked to gain from your experience in the program with regards to problem solving especially for blood glucose?
15. What complications of diabetes have you learned about in this program?
- a. If I was experiencing diabetes complications, what would you tell me to do?
 - b. What did this program teach you about how to decrease risks of diabetes complications?
 - c. How did the program prepare you to overcome barriers to reducing risks of diabetes complications?

- d. Is there something more you would have liked to gain from your experience in the program with regards to reducing risks of diabetes complications?
- 16. How has the DSME prepared you to adapt to living with diabetes if you were to be diagnosed with it?
 - a. What did you learn about the benefits of treatment and self-care in this program?
 - b. What has the program taught you about setting goals, problem-solving, and coping with diabetes?
 - c. Suppose I experience barriers to adapting to living with diabetes? How would you suggest I go about overcoming those barriers?
- 17. Is there something more you would have liked to gain from your experience in the program with regards to living with diabetes, should you have to?
- 18. What else would you like to share about your experience in this program?

APPENDIX D
Survey

Name: _____

Age: _____

Gender: Male Female

Current body weight in pounds: _____

Date you completed the Step in the Right Direction program? _____ (month and year)

Current aerobic exercise program

Type (walking, cycling, jogging, etc.) _____

Average number of days per week: 0 1 2 3 4 5 6 7

Average minutes per week: 0 - 149 150 - 300 300+

Average intensity:	1	2	3	4	5	6	7	8	9	10
	Easiest					Hardest				

Current anaerobic exercise program (resistance training)

Average number of days per week: 0 1 2 3 4 5 6 7

Average minutes per week: 0 - 149 150 - 300 300+

Average intensity:	0	1	2	3	4	5	6	7	8	9	10
	Easiest					Hardest					

Have you been diagnosed with type 2 diabetes (not pre-diabetes)? Yes No
If so, when? _____ (month and year)

Please place your completed survey in the enclosed envelope and place it in the mail. Thank you!

Would you be willing to participate in an interview with the researcher to describe your experience in the Step in the Right Direction Program? If so, please fill out the enclosed interview request.

APPENDIX E

Interview Request Sheet

To provide the best possible program that meets the needs of the participants, it is important to obtain your perspectives on the program. If you are willing to participate in an interview with the researcher to discuss your experience in the program, please complete the information below. Mail it in the enclosed stamped, addressed envelope with your survey. The researcher will contact you to schedule a time for the interview upon receipt of this sheet. Your feedback is very important and will be used to improve the program.

Thank you for your participation!

Name:

Email:

Phone number:

APPENDIX F

AADE Standards for Outcomes Measurement of DSME Checklist

AADE 7	Knowledge, skills, barrier resolution	Measures and methods of measurement	Measurement intervals	DSME Assessment
Healthy Eating	<p>Knowledge</p> <ul style="list-style-type: none"> • Effect of food on blood glucose • Sources of carbohydrates • Meal plan (what to eat, when to eat, how much to eat) • Resources to assist in food choices <p>Skill</p> <ul style="list-style-type: none"> • Meal planning • Weighing and measuring food • Carb counting • Label reading <p>Barrier Resolution</p> <ul style="list-style-type: none"> • Environmental triggers • Emotional • Cultural • financial 	<p>Measures</p> <ul style="list-style-type: none"> • type of food choices • Amount of food eaten • Timing of meals • Effect of food on glucose • Special situations and problem solving <p>Methods</p> <ul style="list-style-type: none"> • Patient self-report • Observation • Food and blood glucose records • 24-hour food recall • food frequency questionnaire 	<p>Learning</p> <ul style="list-style-type: none"> • each instructional session <p>Behavioral</p> <ul style="list-style-type: none"> • Baseline • 2 to 4 weeks • Every 3 to 6 months 	
Being Active	<p>Knowledge</p> <ul style="list-style-type: none"> • type • Duration • Intensity • Safety precautions, special considerations 	<p>Measures</p> <ul style="list-style-type: none"> • type • Frequency • Duration • Intensity <p>Methods</p>	<p>Learning</p> <ul style="list-style-type: none"> • each instructional session <p>Behavioral</p> <ul style="list-style-type: none"> • Baseline • 2 to 4 weeks 	

	<p>Skill</p> <ul style="list-style-type: none"> • develops appropriate activity plan • Balance with food, medication <p>Barriers</p> <ul style="list-style-type: none"> • Physical limitations • Time • Environment • fear 	<ul style="list-style-type: none"> • Self-report • Observation • pedometer 	<ul style="list-style-type: none"> • Every 3 to 6 months 	
Monitoring	<p>Knowledge</p> <ul style="list-style-type: none"> • Testing schedule • Target values • Proper disposal of sharps • Interpretation , use of results <p>Skill</p> <ul style="list-style-type: none"> • SMBG technique • Recording BG values • Equipment use, care <p>Barriers</p> <ul style="list-style-type: none"> • Physical • Financial • Cognitive • Time • Inconvenient • Emotional 	<p>Measures</p> <ul style="list-style-type: none"> • Frequency of missed tests • Frequency and schedule of monitoring (e.g., times/day, days/wk) • Planned, unplanned testing • Review of pharmacy refill record <p>Methods</p> <ul style="list-style-type: none"> • Review of log book • Meter memory review or printout • Self-report • Demonstration of technique 	<p>Learning</p> <ul style="list-style-type: none"> • each instructional session <p>Behavioral</p> <ul style="list-style-type: none"> • Baseline • 2 to 4 weeks <p>Every 3 to 6 months</p>	
Taking Medication	<p>Knowledge</p> <ul style="list-style-type: none"> • Name, dose, frequency 	<p>Measures</p> <ul style="list-style-type: none"> • Adherence to medication 	<p>Learning</p> <ul style="list-style-type: none"> • each instructional session 	

	<ul style="list-style-type: none"> Medication action Actions for missed dose Side effects, toxicity Action for side effect Storage, travel, safety Recognition of efficacy <p>Skill</p> <ul style="list-style-type: none"> Preparation, technique, administration Safe handling, disposal of equipment Dose adjustment Recognition, treatment, prevention of low BG <p>Barriers</p> <ul style="list-style-type: none"> Vision or dexterity Financial Fear of needles Cognitive, math skills Embarrassment 	<p>regimen</p> <ul style="list-style-type: none"> Dose accuracy <p>Methods</p> <ul style="list-style-type: none"> Pill count Review of pharmacy refill record Demonstration Self-report BG and med records Observation, role playing 	<p>Behavioral</p> <ul style="list-style-type: none"> Baseline 2 to 4 weeks, or earlier if warranted Every 3 to 6 months, or if medication concerns are suspected 	
Problem Solving	<p>Knowledge</p> <ul style="list-style-type: none"> Signs, symptoms, causes Treatment, guidelines, prevention strategies 	<p>Measures</p> <ul style="list-style-type: none"> BG testing Adjusting food, medication, activity Contact with healthcare 	<p>Learning:</p> <ul style="list-style-type: none"> Each instructional session <p>Behavioral:</p> <ul style="list-style-type: none"> Baseline 2 to 4 weeks 	

	<ul style="list-style-type: none"> • Sick-day rules • Safety concerns (e.g., driving, operating equipment) <p>Skill</p> <ul style="list-style-type: none"> • Hypoglycemia treatment • Glucagon administration (if applicable) • Use of BG data to determine appropriate actions related to food, exercise, medication <p>Barriers</p> <ul style="list-style-type: none"> • Cognitive • Financial • Coping strategies • Emotional • Physical 	<p>provider for problem resolution</p> <ul style="list-style-type: none"> • Checking meter and strips for function • Number of BG tests/month that require assistance • Number of times that ketones are tested (when appropriate) • Missed days from work, school, or related activities <p>Methods</p> <ul style="list-style-type: none"> • Patient self-report • Review of log book (unreliable) • Meter memory review or printout • Medical chart review • Frequency of medication adjustment 	<ul style="list-style-type: none"> • Every 3 to 6 months 	
Reducing Risks	<p>Knowledge</p> <ul style="list-style-type: none"> • Standards of care • Therapeutic goals • How to decrease risks (through preventive care services) <p>Skill</p> <ul style="list-style-type: none"> • Foot exam • BP (self) • SMBG 	<p>Measures (per Standards of Care)</p> <ul style="list-style-type: none"> • Smoking status • Frequency of foot self-exam • Aspirin therapy • Eye exam • MD visit • Diabetes educator visit • RD visit • Lipids checked 	<p>Learning:</p> <ul style="list-style-type: none"> • Each instructional session <p>Behavioral:</p> <ul style="list-style-type: none"> • Baseline • 2 to 4 weeks <p>Every 3 to 6 months</p>	

	<ul style="list-style-type: none"> Maintaining personal care record <p>Barriers</p> <ul style="list-style-type: none"> Financial Time Unaware of disease process or seriousness Lacking rapport with provider Travel Physical disabilities 	<ul style="list-style-type: none"> BP checked Flu vaccine, pneumonia vaccine Urine check for protein Pre-pregnancy counseling <p>Methods</p> <ul style="list-style-type: none"> Self-report Chart or exam code audit demonstration of self-care activities 		
Healthy Coping	<p>Knowledge</p> <ul style="list-style-type: none"> Recognizing that everyone has problems Benefits of treatment and self-care Motivation is internal function <p>Skill</p> <ul style="list-style-type: none"> Goal setting Problem solving Coping strategies Self-efficacy <p>Barriers</p> <ul style="list-style-type: none"> Lack of awareness Financial Lack of support Physical Psychosocial distress 	<p>Measures</p> <ul style="list-style-type: none"> Depression score Stress Quality of life Functional measurement Treatment self-efficacy Patient empowerment Self-report <p>Methods (recommended validated instruments)</p> <ul style="list-style-type: none"> SF-36/SF-12 P.A.I.D. Zung/Beck Depression Scale D-SMART 	<p>Learning:</p> <ul style="list-style-type: none"> Each instructional session <p>Behavioral:</p> <ul style="list-style-type: none"> Baseline 2 to 4 weeks <p>Every 3 to 6 months</p>	

APPENDIX G

Script to Recruit Subjects Prior to Involvement in Study

Hello –

My name is Stacey Ruholl and I am a Doctoral Candidate in the Department of Health Education and Recreation at Southern Illinois University Carbondale and I am an Associate Professor at Eastern Illinois University.

I would like to request your participation in a research study to evaluate the effectiveness of the Step in the Right Direction Program through the METS department at Sarah Bush Lincoln Health Center. You have been selected to participate in this study because you participated in the Step in the Right Direction Program.

There are two parts in which you can choose to participate. One is a survey that will take approximately 15 minutes to complete. The other is an interview that will take approximately one hour. You may choose to participate in either one or in both. Participation in this study is voluntary.

Your input is very valuable to this research. Are you willing to participate? If so, I would like to schedule an appointment with you.

Thank you very much!

Stacey Ruholl

APPENDIX H

Cover Letter

Dear Participant,

I am a doctoral candidate in the Health Education and Recreation Department at Southern Illinois University Carbondale and I currently teach at Eastern Illinois University in the Kinesiology and Sports Studies Department. I am conducting a research study to evaluate the Step in the Right Direction Program through Sarah Bush Lincoln Health Center. You were selected to be a potential subject in this study because you participated the Step in the Right Direction Program.

I would appreciate it if you would assist me in my research by completing a survey. It will take approximately 15 minutes to complete the survey. Completion and return of the survey indicates voluntary consent to participate in this study. All surveys are completely anonymous.

I am also interested in learning about your experiences as a participant in this program. Included with the survey is a card you can mail back indicating your willingness to participate in an interview. Participation in the interview is voluntary and is not required even if you choose to complete the survey. If you choose to participate, it will take approximately 60 minutes of your time. You will be audio taped during the interview.

If you have any questions about this research, you may contact me or my committee chair, Dr. Roberta Ogletree. Our contact information is listed below:

Stacey L. Ruholl
Kinesiology and Sports Studies
2511 Lantz Arena
Charleston IL 61920
(217) 581- 3510
slruholl@ciu.edu

Dr. Roberta Ogletree
Health Education and Recreation
Pulliam Hall
Carbondale IL 62901
(618) 453-2777
bobbie@siu.edu

Thank you for your participation!

Sincerely,

Stacey L. Ruholl

This project has been reviewed and approved by the SIUC Human Subjects Committee. Questions concerning your rights as a participant in this research may be addressed to the Committee Chairperson, Office of Research Development and Administration, SIUC, Carbondale, IL 62901-4709. Phone (618) 453-4533. E-mail: siuhsc@siu.edu

APPENDIX I

Informed Consent Form for Interviewees

Introduction

My name is Stacey Ruholl and I am a Doctoral Candidate in the Department of Health Education and Recreation at Southern Illinois University Carbondale. I am currently conducting research regarding the effectiveness of the Step in the Right Direction program through METS at Sarah Bush Lincoln Health Center.

You have been selected to participate in an interview for this study because you participated in the Step in the Right Direction program. Participation in this study is voluntary. You may discontinue your participation in the interview at any time.

Benefits

There may or may not be any direct benefit to you from participation in this study. However, the investigator may learn more about the effectiveness of the Step in the Right Direction Program. By having a better understanding of the effectiveness of the program, changes may be made to the program to improve it.

Procedures

If you agree to contribute to this study, you will be asked to participate in an interview that will last approximately one hour. Moreover, you also agree to allow the researcher to quote statements in the written report with the understanding that no names will be attached to maintain confidentiality.

Voluntary Nature

Participation in this research is entirely voluntary. You may refuse to participate or withdraw at any time without consequences.

Confidentiality

The results of this study will be kept completely confidential. The interviews will be audio taped to assist the researcher in writing the report. The tapes will be erased after the information has been obtained and names will be eliminated in the written report to maintain confidentiality. Research records will be kept confidential, consistent with federal and state regulations. Only the investigator will have access to the data which will be kept for three months and then destroyed.

Investigator Statement

"I certify that the research study has been explained to the individual, by me and that the individual understands the nature and purpose, the possible risks and benefits associated with taking part in this research study. In addition the participant has been made aware that they are being audio recorded throughout the interview discussion and is giving the investigator permission to directly quote their comments knowing that names will not be attached to the comments to ensure confidentiality."

Signature of PI

Stacey Ruholl, M.S.

Principal Investigator

(217) 581-3510

Email: sruholl@eiu.edu

Copy of Consent

I have been given two copies of this Informed Consent. I will sign both copies and retain one copy for my files. By signing below I agree to participate.

Signature of Participant

By signing below I agree to allow the researcher to audio-tape/digitally record our interview for the purpose of this research study.

Signature of Participant

IRB Approval

This project has been reviewed and approved by the SIUC Human Subjects Committee. Questions concerning your rights as a participant in this research may be addressed to the Committee Chairperson, Office of Research Development and Administration, Southern Illinois University, Carbondale, IL 62901-4709. Phone (618) 453-4533. E-mail siuhsc@siu.edu

If you have any questions, comments or concerns about this project you may contact me, Stacey Ruholl, at 217-581-3510 or my doctoral dissertation advisor Dr. Roberta Ogletree at 618-453-2777.

APPENDIX J

**Step in the Right Direction Education Record**

TOPICS	DATE	DATE
1) WELCOME		
a) Welcome to Step in the Right Direction		
2) EXERCISE		
a) Introduction to Safe Exercise		
b) The Many Benefits of Exercise		
c) Exercise Intensity –Am I doing Enough or TOO Much		
d) Overcoming roadblocks to exercise		
3) FOOD		
a) Carbohydrates		
b) Dietary Fats		
c) Keeping a food diary		
d) Counting Calories		
e) Dietary sodium		
f) Choosing Healthier Meats to Eat		
g) Whole Grains		
h) Recipe conversions		
i) Vegetables		
j) Evaluate and fine tune your eating		
k) Label trickery		
l) Fiber		
m) Fast food and nutrition		
4) PRE-DIABETES, DIABETES, PREVENTING COMPLICATIONS		
a) What are Pre-Diabetes and Diabetes?		
b) Blood Pressure and Hypertension		
c) Cholesterol		
d) Stress		
e) Complications of Diabetes		
f) Diabetic Retinopathy		
g) Oral Hygiene and Your Health		
h) Foot Care		
5) MAKING CHANGES		
a) Setting smart Goals		
b) Behavior Modification		

VITA

Graduate School
Southern Illinois University

Stacey L. Ruholl

ruholl4@frontiernet.net

University of Evansville
Bachelor of Science, Exercise Science, 1996

Eastern Illinois University
Master of Science in Physical Education, Exercise Science Concentration, 1997

Dissertation Title:

CASE STUDY AND EVALUATION OF A PRE-DIABETES SELF-MANAGEMENT EDUCATION PROGRAM

Major Professor: Dr. Roberta Ogletree

Publications:

Ruholl, S. & Oliver, J.A. (2011). Diabetes in school-age children: It's not limited to Type 1 anymore. *Illinois Journal*, 67, 46-48.

Oliver, J.A. & Ruholl, S. (2008). Vending machines in Illinois high schools. *Illinois Journal*, 61, 47-53.

Ruholl, S. (2006). Children and adolescents with diabetes: A physical educator's guide. *Illinois Journal*, 57, 41-44.

HUMAN SUBJECTS APPROVAL

SIUC HSC FORM A

REQUEST FOR APPROVAL TO CONDUCT RESEARCH ACTIVITIES
INVOLVING HUMAN SUBJECTS

CERTIFICATION STATEMENT

By making this application, I certify that I have read and understand the University's policies and procedures governing research activities involving human subjects. I agree to comply with the letter and spirit of those policies. I acknowledge my obligation to:

1. Accept responsibility for the research described, including work by students under my direction.
2. Obtain written approval from the Human Subjects Committee of any changes from the originally approved protocol BEFORE implementing those changes.
3. Retain signed consent forms in a secure location separate from the data for at least three years after the completion of the research.
4. Immediately report any adverse effects of the study on the subjects to the Chairperson of the Human Subjects Committee, SIUC, Carbondale, Illinois - 618-453-4533 and to the Director of the Office of Research Development and Administration, SIUC. Phone 618-453-4531. E-mail: suhsc@siu.edu

Project Title

Case Study and Evaluation of a Pre-Diabetic Self-Management Education Program

RESEARCH ADVISOR'S ASSURANCE: My signature on this application certifies that the student is knowledgeable about the regulations and policies governing research with human subjects. I am aware of my obligations stated on Form A and will be available to supervise the research. When on sabbatical leave or vacation, I will arrange for an alternate faculty sponsor to assume responsibility during my absence. I will advise the Human Subjects Committee by letter of such arrangements.

Researcher(s) or Project Director(s)
Please print or type name below signature.

Sherry L. Ruholl

Sherry L. Ruholl

10/10/11

Date

Researcher's Advisor (required for all student projects) Dr. Robert Oglebee
Please print or type name below signature.

*Robert Oglebee**10/10/11*

Date

The request submitted by the above-named researcher(s) was approved by the SIUC Human Subjects Committee.

This approval is valid for one year from the review date. Researchers must request an extension to continue the research after that date. This approval form must be included in all Master's theses/research papers and Doctoral dissertations involving human subjects that are submitted to the Graduate School.

Chairperson, Southern Illinois University Human Subjects Committee

11-30-11

Date





January 19, 2012

Ms. Stacey Ruholl
Kinesiology and Sports Studies
Eastern Illinois University
2511 Lantz
Charleston, IL 61920

Project: Case Study and Evaluation of a Pre-Diabetes Self-Management education Program

Dear Ms. Ruholl,

Thank you for presenting your IRB application for the Case Study and Evaluation of a Pre-Diabetes Self-Management Education Program to the Medical Ethics/IRB meeting on January 19, 2012. After a full review of your application, the Sarah Bush Lincoln Health Center IRB has approved your application. The Committee requests that you present your findings to the Sarah Bush Lincoln Health Center Medical Ethics/IRB Committee at the end of the project in January 2013.

Sincerely,

A handwritten signature in black ink that appears to read "Edward C. Huppert, MD".

Edward C. Huppert, MD
Vice President, Medical Affairs
Medical Ethics/IRB Committee

BCII/cw



February 3, 2012

Stacey Ruholl
Kinesiology and Sports Studies

Thank you for submitting the research protocol titled, “Case Study and Evaluation of a Pre-Diabetes Self-Management Education Program” for review by the Eastern Illinois University Institutional Review Board (IRB). The IRB has approved this research protocol following an expedited review procedure. IRB review has determined that the protocol involves no more than minimal risk to subjects and satisfies all of the criteria for approval of research.

This protocol has been given the IRB number 12-013. You may proceed with this study from [2/3/2012](#) to [2/2/2013](#). You must submit Form E, Continuation Request, to the IRB by [1/2/2012](#) if you wish to continue the project beyond the approval expiration date.

This approval is valid only for the research activities, timeline, and subjects described in the above named protocol. IRB policy requires that any changes to this protocol be reported to, and approved by, the IRB before being implemented. You are also required to inform the IRB immediately of any problems encountered that could adversely affect the health or welfare of the subjects in this study. Please contact me, or the Compliance Coordinator at [581-8576](#), in the event of an emergency. All correspondence should be sent to:

Institutional Review Board
c/o Office of Research and Sponsored Programs
Telephone: [581-8576](#)
Fax: [217-581-7181](#)
Email: eiuirb@www.eiu.edu

Upon completion of your research project, please submit Form G, Completion of Research Activities, to the IRB, c/o the Office of Research and Sponsored Programs.

Thank you for your assistance, and the best of success with your research.

Richard Cavanaugh, Chairperson
Institutional Review Board
Telephone: [581-6205](#)
Email: recavanaugh@eiu.edu