

EDUCATIONAL INTERVENTIONS AND PREDICTORS OF HEALTH RELATED
QUALITY OF LIFE AMONG ADOLESCENTS WITH TYPE 1 DIABETES

by

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DEDICATION

I dedicate this dissertation to my parents, Adnan and Fatima, the two most important people in my life. Without your love, support, and prayers I could not have made it this far. I will always love you for making me the person I am.

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I would like to express my sincere appreciation to members of my committee. Dr. Milligan, the chair of the committee, provided continuous guidance and advice throughout the dissertation process. Her research expertise, leadership, insightful advice, and consistent encouragement made this dissertation possible. Dr. Milligan always treated me with care and compassion and was always eager to offer support and encouragement. Dr. Jacobsen's expertise in systematic reviews made me sharpen the focus of my research. Her expeditious responses to my continuous inquiries and detailed comments on my research have contributed to my expanded understating of research. Dr. Jacobsen was always prompt in suggesting various research options whenever I was stuck. Her mentoring and encouragement made it possible for me to submit my papers for publication. Dr. Rodan's knowledge on interventional studies was invaluable during the systematic review phase of my dissertation. Her command of statistics and interventions among adolescents helped me to look at my topic with deeper understanding. Dr. Conn, an expert in field of systematic reviews and meta-analysis, taught me how to conduct a systematic review. The summer course I took with her in 2012 was instrumental in this dissertation. Her support and willingness to be a consultant on my committee is highly appreciated.

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LIST OF ABBREVIATIONS AND SYMBOLS

American Diabetes Association	ADA
Adjusted Odds Ratio	aOR
Centers for Disease Control	CDC
Child Health Questionnaire Child Form	CHQ-CF87
Coping Skill Training	CST
Cumulative Index to Nursing and Allied Health Literature.....	CINAHL
Diabetes Control and Complication Trial	DCCT
Diabetes Self-Management Education.....	DSME
Diabetes Quality of Life.....	DQOL
Diabetes Quality of Life for youth.....	DQOL-Y
Diabetes Quality of Life for youth short form	DQOLY-SF
Effective Public Health Practice Project.....	EPHPP
Epidemiology of Diabetes Interventions and Complications Quality of Life Questionnaire	EDIC-QOL
George Mason University	GMU
Glycosylated Hemoglobin	HbA1c
Health Related Quality of Life.....	HRQoL
Human Subjects Review Board	HSRB
International Diabetes Federation	IDF
International Society of Pediatric and adolescent Diabetes	ISPAD
Medical Literature Analysis and Retrieval System Online.....	MEDLIN
Odds Ratio	OR
Pediatric Quality of Life Inventory TM.....	PedsQL
Pediatric Quality of Life Inventory DM: Diabetes Module.....	PedsQL-DM
Low Self Rated Health- Poor or Fair	P/F
Preferred Reporting Items for Systematic Reviews and Meta-analysis.....	PRISMA
Quality of Life.....	QoL
Quality Assessment Tool for Quantitative Studies	QATQS
Randomized Control Trial	RCT
Self-Rated Health.....	SRH
State Children's Health Insurance Program	SCHIP
Structured Diabetes Education.....	SDE
Systematic Review.....	SR
Type 1 Diabetes	T1D
High Self Rated Health- Very Good or Excellent	VG/E
World Health Organization.....	WH

ABSTRACT

EDUCATIONAL INTERVENTIONS AND PREDICTORS OF HEALTH RELATED QUALITY OF LIFE AMONG ADOLESCENTS WITH TYPE 1 DIABETES

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George Mason University, 2016

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This dissertation had two objectives: A) determine the optimum diabetes self-management educational (DSME) interventions in improving health-related quality of life (HRQoL) among adolescents with type 1 diabetes (T1D) and describe its characteristics, and B) assess the HRQoL of adolescents with T1D using one self-rated health (SRH) question and identify the most significant factors contributing to lower HRQoL. To address objective (A), a systematic review (SR) of 14 eligible studies was conducted using the Preferred Reporting Items for Systematic Reviews and Meta-analysis (PRISMA) guidelines. Results showed that the successful interventions provided a combination of direct and indirect behavioral skills or, at the very least, indirect behavioral skills such as stress reduction and coping strategies lasting at least two months. To address objective (B), a sample of adolescents with T1D ($n=5,799$) from the T1D Exchange Clinic Registry was analyzed. Descriptive statistics showed that those with lower HRQoL whose SRH was “fair” or “poor” ($n=600$), 62% were female, 59%

were aged 16-18 years, 66% had public or no insurance, and 93% had high HbA1c.

Logistic regression results showed that the most significant factor associated with lower HRQoL (SRH) among adolescents with T1D is stress. Both the systematic review and secondary data analysis identified stress as important factor in contributing to lowering HRQoL among T1D adolescents. Health care providers and researchers should design optimal DSME interventions that target stress as one of the most important factors associated with lower HRQoL among adolescents with T1D.

CHAPTER ONE: INTRODUCTION

Background of the Study

Type one diabetes (T1D) is the most common type of diabetes in adolescents, and accounts for 90% of all new cases among adolescents in industrialized countries (Cameron, Amin, de Beaufort, Codner, & Acerini, 2014). According to the International Diabetes Federation (IDF), globally it is estimated that 80,000 of those under the age of 15 years develop T1D annually and about 500,000 live with T1D (IDF, 2015). These numbers are expected to double in the next 15 to 20 years (Harjutsalo, Sjoberg, & Tuomilehto, 2008; Peters & Laffel, 2011). The seven countries with the highest incidence of T1D between birth and 14 years of age are Finland, Sardinia, Canada, Sweden, Norway, United Kingdom, and Saudi Arabia (IDF, 2015). Adolescents with T1D report lower health-related quality of life (HRQoL) than peers without diabetes (Kalyva et al. 2011; Nardi et al., 2008; Samardzic et al., 2016).

Type 1 diabetes leads to many complications that include neuropathy, nephropathy, and retinopathy, known as microvascular complications (ADA, 2016). These complications occur when small blood vessels supplying the nerves, kidney, and eyes are damaged, leading to loss of sensation in peripherals, kidney failure and blindness. Macrovascular complications affect large blood vessels mainly in the heart,

increasing the risk for cardiovascular disease (CVD) in adolescents who develop diabetes before puberty, compared to those who develop the disease in later years. Most of the symptoms of these complications begin to develop during adolescent years but show up in adulthood. Furthermore, research shows that developing diabetes during adolescence and living with the disease for a long time is associated with increased risk for diabetes complications (ADA, 2016; Danne et al., 1994). The estimated global cost for treating diabetes and preventing complications in 2011 was about \$465 billion. By 2030, this number is expected to be more than \$595 billion (World Health Organization [WHO], 2016).

Self-managing T1D among adolescents is an important issue not only because of the health complications related to the disease, but also because most adolescents that have T1D face treatment, psychological, and environmental challenges that can influence their diabetes self-management (Bulaclac, 2011). Because of these challenges, many adolescents are unable to control their HbA1c levels and experience lower HRQoL. Identifying these challenges that affect adolescents' HRQoL is essential to developing optimum diabetes self-management interventions to improve HRQOL among adolescents with T1D.

Managing T1D and delaying related complications by implementing diabetes self-management interventions among adolescents is essential to their HRQoL. Health related quality of life refers to adolescents' sense of wellbeing after considering the impact of an illness or treatment on their physical, psychological, emotional, and social functioning (Abualula, Jacobsen, Milligan, Rodan, & Conn, 2016; Lin, Lin, & Fan, 2013). Improved

quality of life has been recognized by the U.S. Centers for Disease Control (CDC)'s *Healthy People 2020* as one of the best correlates of diabetes management improvement among adolescents and other populations with diabetes (Abualula et al., 2016; Koh, 2010). Thus, the goal of improving HRQoL among adolescents with T1D can be considered as important as improving control of glycemic levels (Glycosylated Hemoglobin HbA1c) in this population (American Diabetes Association [ADA], 2016; Cameron et al., 2014). Currently, adolescents with T1D report lower HRQoL compared to other age groups and their peers without diabetes (Kalyva et al. 2011; Nardi et al., 2008; Samardzic et al., 2016).

Assessing HRQoL of adolescents with T1D and examining factors that affect their ratings are the first steps in recognizing the best interventions for improving HRQoL. Many measures are available to assess the HRQoL of adolescents, either by assessing several domains and components of health; for example, the diabetes quality of life for youth (DQoLY) or by using a single question to assess the global perception of health such as self-rated health (SRH) (Erickson, Undén, & Elofsson 2001; Huang et al., 2004; Ismail, 2011; Jonsson, Nystrom, Sterky, & Wall, 2001; Jylha, 2009; Shadbolt, 1997; Tsai, Ford, Li, Zhao, & Balluz, 2010).

Because so many adolescents are affected by T1D and that number is growing, it is important to identify factors that affect adolescents' HRQoL ratings and interventions that are effective for improving HRQoL in this population. The International Society of Pediatric and Adolescent Diabetes (ISPAD) clinical practice consensus guidelines (2015) and the most recent standard of medical care for diabetes published in the United States

(2016) indicate the need to routinely monitor glycosylated hemoglobin (HbA1c) and HRQoL as part of adolescents' diabetes care (ADA, 2016; Cameron et al., 2014). However, most interventions focus on improving HbA1c and only a few emphasize HRQoL.

Interventions implemented among adolescents with T1D with the objective of improving HRQoL have differed in their purposes, target populations, types of interventions explored, and the outcomes synthesized (Abualula et al., 2016). However, existing interventions, in particular, diabetes self-management education (DSME) interventions targeting HRQoL among adolescents, lack the identification of the most effective DSME intervention. Moreover, given a variety of factors associated with adolescents' self-rated health, determining the most significant factors affecting SRH among adolescents with T1D is important. This study will fill the existing gap in the literature by identifying the most significant factor affecting SRH of adolescents with T1D and the most effective DSME to improve HRQoL among adolescents with T1D.

Study Objectives

Because the number of adolescents with T1D is increasing and their HRQoL is decreasing (IDF, 2015; Kalyva et al. 2011; Nardi et al., 2008; Samardzic et al., 2016), it is important to identify interventions that are effective for improving HRQoL. There are several DSME interventions that have been implemented among adolescents; however, the effectiveness of these interventions on HRQoL is not known. Moreover, SRH, which is an indicator for HRQoL, has been shown to be associated with several factors. No

study has identified, the most important factors affecting the HRQoL of adolescents with T1D. There are two objectives for this study:

Objective (A):

Determine the optimum diabetes self-management educational (DSME) interventions in improving health related quality of life (HRQoL) among adolescents with type 1 diabetes (T1D) and its characteristics. To accomplish this objective, a systemic review (SR) was conducted using the Preferred Reporting Items for Systematic Reviews and Meta-analysis (PRISMA) to guide the process. A review of published research on DSME interventions with a skills development component was conducted to identify the optimum intervention and its characteristics. Six databases were searched for eligible studies between 1994 and 2014. Data were extracted from the eligible studies to answer the research questions.

Objective (B):

Assess the HRQoL of adolescents with T1D using the self-rated health (SRH) question and identify the most significant factors contributing to lower HRQoL. To accomplish this objective, analysis of the T1D Exchange Clinical Registry data for the years 2010-2012 was conducted. The data were collected from individuals with T1D who visited participating clinics and volunteered to participate in the registry upon request (Beck et al., 2012). Only data collected at the time of enrollment of the participant was used in the analysis.

Research Questions

The following research questions informed this study:

1. What is the optimum DSME intervention with a skills development component for improving HRQoL of adolescents with T1D?
2. What are the characteristics of the optimum DSME intervention with a skills development component?
3. What are the characteristics of the adolescents in the T1D Exchange Clinic Registry?
4. What is the proportion of adolescents with T1D who rated their health as poor or fair (P/F)?
5. What are the significant factors contributing to lower HRQoL (SRH= “poor” or “fair”) of adolescents with T1D?

Definition of Study Variables

Conceptual and operational definitions of variables that are used in this study are presented in the Table 1 based on the research questions.

Table 1. Conceptual and Operational Definitions of Study Variables

Variables	Conceptual Definition	Operational Definition
<i>To address objective (A)</i>		
Health Related Quality of Life	Individual sense of well being considering the impact of an illness or treatment on an individual's physical, psychological, emotional, and social functioning (Lin, Lin, & Fan, 2013; Magwood, Zapka, & Jenkins, 2008)	QoL was measured by one of the following measures: Child health questionnaire (CHQ-CF87); Diabetes quality of life (DQOL), Diabetes quality of life for youth (DQO-Y); Diabetes quality of life for youth short form (DQOLY-SF); Epidemiology of diabetes interventions and complications quality of life questionnaire (EDIC-QL); Pediatric quality of life inventory (PedsQL); and Pediatric quality of life inventory diabetes module (PedsQL-DM) Abualula et al. (2016)
Diabetes Educational Intervention	A process where an individual with diabetes gains the knowledge and skills needed to modify behavior and successfully self-manage the disease and its related conditions (American Association of Diabetic Educator)	Relevant studies are those that reported educational programs that target adolescents' knowledge, attitude and skills. Programs include education on at least one of the diabetes related tasks; diet, physical activity, blood glucose monitoring, insulin administration, and any general managing skills: problem solving, coping, communication and reducing risk behavior.
Diabetes Self-Management	Is the ability of an individual to handle daily diabetes tasks in order to optimize health status. (Funnell et al, 2009)	Participants in relevant studies actively self-report or are observed performing any of the diabetes daily life activities, including glucose monitoring, insulin administration, diet control, and physical activity.
Age	A length of time that an individual has lived	Participants in relevant studies self-reported their age as 11 to 21 years.
Gender	An individual social identification	Participants report their gender as female or male.

<i>To address objective (B)</i>		
Glycemic Control (HbA1c)	Is a test that measures the proportion of glucose in the blood over the past 2 to 3 months. (American diabetes association, 2016).	As measured by HbA1c level in the T1D Exchange Clinic Registry reported using the National Glyco-hemoglobin Standardization Program (NGSP) units (%) and collected at the time of completing the consent form or the closest point. Potential range from 6.5% to 16%. (Hanas & Garry John, 2014)
HRQoL	Individual sense of well being considering the impact of an illness or treatment on an individual's physical, psychological, emotional, and social functioning (Lin et al., 2013; Magwood et al., 2008)	Measured by the global Self Rated Health (SRH) item (In general, how would you describe your health?) (Ismail, 2011) 5-point scale; 1= poor, 2= fair, 3= good, 4=very good, 5= excellent. A high score indicates greater perception of self-rating health (better HRQoL) and low score reflects lower self-rating (lower HRQoL).
Stress	“An event or condition which is perceived as threatening to one's well-being and which adversely affects thoughts, emotions, behavior, and/or physiological functioning”. (Kramer, Ledolter, Manos, & Bayless, 2000).	As measured by a single item: “In general, how often do you feel stressed because of your diabetes? in the T1D Exchange Clinic Registry 5-point Likert scale rating; 1= Never, 2= rarely, 3= sometimes, 4= often and 5= very often. Higher scores indicate greater perception of perceived stress related to diabetes.
Insulin Mode of Delivery	The way that insulin is administered to the body	Participants reported administering insulin through: Insulin pump, injection and pen, injection, pen and pump.

Covariates	Conceptual Definition	Operational Definition
Age	A length of time that an individual has lived	Participants in T1D Exchange Clinic Registry reported their age as 13 to 18 years at the time of enrollment.
Gender	An individual social identification	Participants reported their gender as female or male.
Insurance Status	Whether or not individuals have health insurance to pay for health care.	Participants reported their insurance as private, military, Medicaid, MediGap, Medicare, Indian Health Service, other state or government plans, single service plan, no coverage, don't know their insurance status, don't wish to answer.
Race	Social category of people who share biological transmitted traits that are obvious and considered important.	Participants reported their race as white non-Hispanic, black or African non-Hispanic, Hispanic or Latino, native Hawaiian or other Pacific islander, Asian or American Indian or Alaskan native, and those with more than one race.
Years Since Diagnosis of T1D	The duration of time an individual has had type one diabetes since diagnosis.	Determined by subtracting the age at diagnosis of T1D from the adolescent enrollment age.

Study Significance

This is the first study to systematically evaluate a variety of DSME interventions for adolescents with T1D, with the aim of identifying the optimum interventions with a skills development component for adolescents with T1D to improve HRQoL. The study will also identify the most significant factors affecting HRQoL of T1D adolescents. The findings may be relevant to the development of an optimum DSME intervention for adolescents with T1D in order to address the most significant factors that negatively affect their HRQoL.

Chapter Summary

This chapter introduced and described the background of the problem of how HRQoL of adolescents with T1D is decreasing. The chapter also described how T1D is contributing to morbidity, mortality and financial burden of self-managing T1D among adolescent. The objectives, questions, significance, conceptual, and operational definition of the variables used in the study were presented. The next chapter will present a review of literature.

CHAPTER TWO: REVIEW OF THE LITERATURE

The purpose of this review was to identify previous research on DSME interventions targeting HRQoL among adolescents. The characteristics of the optimum DSME interventions were reviewed. This was followed by a review of the most important factors associated with adolescents' HRQoL. Definition of T1D, its impact on adolescents, its prevalence, complications and financial burden were discussed. A review of the concept of HRQoL, its relation to SRH, and how it is measured was also conducted. A case was made for how SRH is considered a comprehensive indicator of HRQoL among adolescents with T1D.

To identify the relevant literature for this study, the following databases were searched: The Cochrane Library, CINAHL, MEDLINE, PsycInfo, Web of Science, and ProQuest. Databases were systematically searched for relevant articles for T1D published between 1994-2016. Articles before 1993 were excluded due to treatment regimen changes, which resulted largely from the findings of the Diabetes Control and Complications Trial (DCCT) (1993). The following key terms were used: Diabetes mellitus Type 1 or diabetes Type 1 or T1D, and intervention and adolescent and quality of life or well-being or self-rated health. References of identified studies that met the search criteria were reviewed for additional articles.

Analysis and Synthesis of the Literature

Physiology and Types of Diabetes

Diabetes is a complex metabolic disorder that is manifested with high glucose levels in blood or urine (Craig et al., 2014). Other symptoms include an increase in thirst (polydipsia), urination (polyuria), and hunger (polyphagia). Diabetes closely correlates with the insulin hormone produced by beta cells in the pancreas that regulates blood glucose levels and production (ADA, 2016; Whiting et al., 2011). When insulin is deficient due to the inability of the pancreas to produce it, type 1 diabetes mellitus occurs. This was formerly known as insulin-dependent or childhood onset diabetes. The occurrence of this type of diabetes can be due to genetic factors, attacks on the immune system, or other unknown causes (ADA, 2016). Type 1 diabetes requires continuous insulin treatment and self-management. In contrast, Type 2 diabetes (T2D) refers to the process in which the pancreas produces insulin that does not cover a person's needs (insulin resistance). This was formerly called non-insulin-dependent, or adult-onset, diabetes, and it results largely from genetic and environmental factors, including excess body weight and physical inactivity. Type 2 diabetes requires oral treatment, an intensive self-management regime, and weight loss. In some cases, an insulin treatment is also necessary. Type 2 diabetes is known to be a disease that impacts mainly adults. However, it is becoming increasingly common in children and adolescents (ADA, 2016).

The Role of Genetics

While there is no certain path of diabetes inheritance, family history can play a major role in developing the disease. First-degree relatives can be the causes of 10% of

T1D cases (Hemminki, Li, Sundquist, & Sundquist, 2009), while extended family accounts for more than 20% of the cases (Parkkola et al., 2013). Children of fathers with diabetes are two to three times more likely to develop T1D compared to children of mothers with diabetes (Craig et al., 2014). For siblings, the risk of developing T1D is around 4% by age 20 years and 9.6% by age 60 years compared to the general population, whose risk is 0.5% (Craig et al., 2014; Harjutsalo, Podar, & Tuomilehto, 2005).

Prevalence of T1D

Worldwide the total young population (0–14 year) in 2013 was estimated at 1.9 billion (IDF, 2015). Of these, 500,000 have T1D, and more than 80,000 are expected to develop T1D each year (IDF, 2015). There is a shortage in epidemiological studies with age specific data, which would provide an estimate of T1D incidence in those between the ages of 15-19 years. While the newly diagnosed T1D cases vary throughout the world, the overall annual increase is around 3%-5% (IDF, 2015). Finland, Sardinia, Canada, Sweden Norway, United Kingdom, and Saudi Arabia are ranked as the seven countries with the highest global incidence rate of T1D between birth and 14 years of age (IDF, 2015). Finland, the country with the highest incidence rate of T1D in the world, has 57.5 cases per 100,000 persons and the number of young Finns with T1D is growing. It is projected that within 15 years, new cases diagnosed before or at the age of 14 years will double, and the age of onset will decrease to the ages of newborn to four years (Harjutsalo, Sjöberg, & Tuomilehto, 2008). Africa and Asia represent low level of incidence rates between 0 to 5 cases per 100,000 persons, which could be underrated

given the less developed health care systems, lack of public health surveillance, and infrastructure for reporting within these regions. Japan has the lowest youth incidence rate with about 2 cases per 100,000 person-years. A report by the DIAMOND (Diabetes Mondiale) project in 2000 described the incidence of T1D in children ≤ 14 years of age in 50 countries including, the US population which was drawn from Pennsylvania, Alabama, and Illinois by 10-20 cases /100,000 per year. The incidences were also related to age; the largest incidents were seen in 10-14 year olds (Maahs, West, Lawrence & Mayer-Davis, 2010).

Morbidity and Mortality of T1D

Managing T1D is critical in reducing morbidity and mortality. However, while T1D care continues to improve, morbidity and mortality in T1D still an issue. Complications of T1D include neuropathy, nephropathy, and retinopathy, known as microvascular complications (ADA, 2016). These complications occur when small blood vessels supplying the nerves, kidney, and eye are damaged, leading to loss of sensation in peripherals, kidney failure and blindness. Macrovascular complications affect large blood vessels mainly in the heart, increasing the risk for cardiovascular disease (CVD) in adolescents who develop diabetes before puberty, compared to those who develop the disease in later years. Most of the symptoms of these complications begin to develop during adolescent years but show up in adulthood. Furthermore, research shows that developing diabetes during adolescence and living with the disease for a long time is associated with increased risk for diabetes complications (ADA, 2016).

Orchard and colleagues (2010) reported survival data on a sample of individuals with T1D between 13 to 39 years of age with 1 to 15 years of diabetes duration who participated in the Diabetes Control and Complication Trial (DCCT) and its observational follow-up study. There were 107 deaths among the 1429 participants. Those randomized to intensive insulin therapy had a lower all-cause mortality (43 deaths), compared to those randomized to conventional therapy (64 deaths) (Katz & Laffel, 2015). In another study, Secrest et al. (2010) used the Allegheny County Type 1 Diabetes Registry (Pennsylvania) to report mortality trend among individuals diagnosed with T1D, (age <18 years) from 1975-1979. Among the sample, those with T1D had 5.6 times higher mortality rate than the general population.

Livingstone and colleagues (2015) estimated life expectancy of 20-year-old individuals with type one diabetes to be decreased by eight years compared to non-diabetes individuals in a Scottish population based sample. Another cohort study for individuals with T1D from Japan ($n = 1,408$) and Finland ($n = 5,126$), found the standardized mortality ratio (SMR) for individuals with T1D at the age of <18 years diagnosed between 1965–1979 and monitored through 1994 was higher in Japan 12 (10.8-15.3) compared to Finland 3.7 (3.3-4.1). The absolute mortality was high in both groups when diabetes was diagnosed during puberty. The findings indicate that increased risk of death is associated with gender, age at diagnosis, and time of diagnosis (Asao et al., 2003). A Norwegian study of 1,906 individuals with T1D diagnosed at <15 years of age between 1973–1982 (46,147 person-years) found SMR of 4 for all mortality causes

and SMR of 20 for ischemic heart disease (Skrivarhaug et al., 2006). Findings of these studies indicate that T1D had an impact on adolescents' morbidity and mortality.

The Financial Burden of T1D

Diabetes poses a financial burden on individuals, their families, and the health care system. Families of adolescents have to deal with the financial burden of daily managing and monitoring of T1D., This often puts them in a serious financial and emotional situation. Adolescents with T1D often face deteriorating condition and outcomes of their disease (Petitt et al., 2009). The estimated global cost of treating diabetes and preventing complications in 2011 was about \$465 billion. By 2030, the cost is expected to be more than \$595 billion (WHO, 2016). For those living in low and middle-income countries, a large portion of health expenditures comes out of peoples' own pockets as they lack access to health insurance and public medical services (WHO, 2016). For example, people living in Latin America pay between 40 to 60% of their medical care expenses from their own pockets (WHO, 2016). The mean annual predicted cost of care for individuals with type 1 diabetes in 2007 was highest among adolescents under the age of 19 years (\$9,333) compared to their peers without diabetes (Shrestha, Zhang, Albright, & Imperatore, 2011). This high cost is mainly attributed to the use of insulin, outpatient care, and visits to specialists. Medical supplies such as syringes and glucose testing strips also add to the financial burden, with insulin contributing the highest cost (Shrestha et al., 2011). This suggests that implementing affordable DSME interventions can reduce the huge financial burden of T1D even in the poorest countries.

Diabetes Self-Management in Adolescents

The self-management of a chronic illness refers to daily activities that individuals undertake to keep illness under control, minimize its impact on physical health and functioning, and cope with the psychosocial effect of the illness (Funnell et al., 2009). Self-management not only involves strictly following a prescribed treatment regimen, but it also includes a high level of collaboration with caregivers, the ability to adjust the regimen, deliberate decision-making, pragmatic problem solving, and setting diabetes specific goals. For example, conscious decision-making among adolescents with T1D includes: measuring blood glucose, recognizing and responding to symptoms of hypo or hyper-glycemia, administering insulin, maintaining proper food choices, portions, physical activity, smoking cessation, managing relations with significant others, and managing the psychological responses to illness (Keough, Sullivan-Bolyai, Crawford, Schilling, & Dixon, 2011).

Among adolescents with T1D, self-management is an important issue not only because of the health risks involved with the disease, but also because research has found that most adolescents that have T1D deal with several treatment, psychological, environmental, and other factors that can influence their diabetes self-management and related outcomes (Bulaclac, 2011). Because of these factors, many adolescents are unable to control their glycemic level (Bulaclac, 2011).

Treatment factors that influence self-management include the complexity of the treatment itself (Coffen, 2009). Treatment factors that may have a negative impact on self-management include failing to: follow a diabetes appropriate diet and exercise plan, monitor blood glucose level, and administer recommended insulin doses. Other self-

management factors that adolescents self-management of diabetes is not self-monitoring and not recording diabetes outcomes such as glucose and ketone levels (Coffen, 2009; Franklin, Waller, Pagliari, & Greene, 2006; Stewart, Emslie, Klein, Haus, & White, 2005).

According to Bollepalli and colleagues (2012), Coffen (2009), and Stewart et al. (2005) psychological factors can influence diabetes management routines, with adolescents with T1D experiencing emotional difficulties including stress, depression and anxiety. Cross-sectional studies report that 10 to 20% of adolescents with T1D have significant depression levels while 13 to 17% have significant anxiety (Herzer & Hood, 2010; Hood et al., 2006; Whittemore et al., 2002). These findings can negatively impact adolescents' self-management behaviors, which increase their risk of negative behavior such as eating disorders. A five-year longitudinal study of female adolescents with T1D found that half of the adolescents in the study sample neglect taking insulin, cut meals, and perform vigorous physical activity just to lose weight (Colton, Olmsted, Daneman, Rydall, & Rodin, 2007). The findings of these studies suggest that a proportion of the adolescents with T1D experiencing psychological strains that affect their diabetes self-management and increases their risk of unhealthy behaviors.

Achieving autonomy is another psychological factor that can affect adolescents' adherence to a self-management regimen (Bulaclac, 2011). According to Hanna and Decker (2010) parents assume that because adolescents have achieved developmental milestones they can handle more responsibilities regarding their diabetes management. Palmer et al. (2004) also support this observation by noting that parents often too quickly

give their adolescents control over their diabetes management. This leads to many parents giving adolescents responsibilities that are beyond their psychological capabilities (Schilling, Knafl, & Grey, 2006). In contrast, other research suggests a gradual transition into independence with strict adult supervision (ADA, 2016). Hanna and Decker (2010) suggest a possible solution that parents should give adolescents, independent decision-making, but not, independent function as a way to achieve improved metabolic control.

Another psychological factor that can influence adolescents to self-manage their conditions is motivation (Berger et al., 2013). Adolescents should be motivated to take an active role in their own care. Coffen (2009) and Stewart et al. (2005) suggest that motivation can influence decision-making related to diabetes care and outcomes. A six-month randomized study of motivational intervention and cognitive behavioral therapy for Austrian adolescents with T1D found that male adolescents show significant reduction in HbA1c level (9.74% vs. 9.14%, $p=0.17$) compared to female who did not experience any improvement (Berger et al., 2013).

Greene, Mandleco, Roper, Marshall, and Dyches (2010) found that environmental factors such as support and stress play a role in influencing self-management of adolescents with T1D. Continuous support from health care providers, family, peers, and school are important to decision-making with regard to adolescents' self-management. Sources of stress that can have an impact on self-management of T1D include school, work, peer pressure, family conflict, and diseases management (Bulaclac, 2011). Increasing the amount and sources of support, decreasing stress triggers, and learning coping skills can positively impact self-management of adolescents with T1D.

Researchers have also argued that there are other forces such as one's values, characteristics, and environment that affect adolescents' self-management behaviors. According to Glasgow et al. (2002) and Frank (2005) adolescents who seem to be more mature and exhibit high self-esteem and competence have been shown to better cope with and manage their diabetes. The more well-adjusted the adolescents are in regular life, the easier they will adjust to a diabetes diagnosis, and vice versa (Frank, 2005). Moreover, the authors report that schools and families impact self-management behaviors, since it is through these agents of socialization adolescents can learn about healthy lifestyles.

There are several other factors associated with the transitional period of the adolescent. Peters and Lafel (2011) identify several factors in the transitional period of self-management, such as differences between pediatric health care providers and adult health care providers; the lack of criteria for determining when the individual is ready for a transition from pediatric health care delivery to adult health care delivery; and changing demographic and social characteristics of adolescents that can influence their health care consumption. Other challenges identified include differences in learning styles of adolescents in the transition period, and training deficiencies among pediatric health care workers (Peters & Lafel, 2011).

The ability to engage in self-management appears to be based on numerous factors. The literature suggests that T1D self-management among adolescents can be influenced by factors such as treatment, psychological, environment, and one's values (Bulaclac, 2011; Glasgow et al., 2002; Greene et al., 2010).

Diabetes Self-Management Interventions

The diabetes self-management daily activities that an adolescent with T1D needs to perform, provide the opportunity for intervening and improving the actions and the behaviors that will affect the diabetes care outcome such as HbA1c and HRQoL. The diabetes interventions include behavioral, psychological, educational, and combined interventions. Literature suggests that the different types of diabetes interventions depend on the setting of the intervention such as home, school, clinic or community; the recipient of the intervention e.g. the adolescent, family, peers or mixed of individual; the outcomes such as knowledge, skills, behavior, clinical outcomes; and finally, the usage of new technology such as Tele-health, text-messaging and online program. The effect of these types of interventions varies across the adolescent population and outcomes (Graue, Wentzel-Larsen, Hanestad, Batsvik & Sovik, 2003; Loding, Wold, Skavhaug & Graue, 2007; Newton, 2008; Whittemore et al., 2012).

Behavioral interventions focus on increasing the habit of monitoring blood glucose level, while improving the adolescents' skills of performance (Hampson et al., 2000). Another intervention may focus on an appropriate diabetes diet including monitoring intake, counting carbs, calculating insulin dosage to match carbs intake and avoiding unhealthy snacks and meals. Physical activity and exercising is another target of behavioral intervention programs (Hampson et al., 2000). These interventions focus on assisting adolescents to improve their diabetes management activities, in order to change behaviors that affect their T1D self-management.

Psychological interventions aim at enhancing communication skills, coping skills,

decision making, problem solving, conflict resolution, motivation and support (Gallant, 2003; Glasgow, Toobert, & Gillette, 2001; Heisler, Vijan, Makki & Piette, 2010; Winkley, Ismail, Landau, & Eisle, 2006). Lack of these skills can often result in a downhill spiral of school, family, interpersonal relationships, and diabetes self-management (Bollepalli, Smith, Vasquez, Rodriguez, & Vehik, 2012). It is difficult for adolescents to follow diabetes management routines, especially when combined with the requirements of school, family, and social life.

Grey, Boland, Davidson, Li, and Tamborlane (2000) conducted an experimental study with the aim of measuring the effect of a diabetes self-management coping skills training (CST) intervention on Adolescents' HbA1c and QoL. The researchers randomly assigned 77 adolescents with T1D to one of two groups: diabetes self-management CST or usual care (UC). The diabetes self-management CST intervention included skills development on social problem solving, cognitive behavioral modification and conflict resolution. The diabetes self-management CST intervention group had a significant improvement effect on HbA1c ($p < .001$) over a 12-month period compared to the UC ($7.5\% \pm 1.1\%$ CST vs. $8.5\% \pm 1.4\%$ UC with a 95% confidence interval)(Grey et al., 2000).

A study by Nansel et al. (2007) suggests that goal setting and problem solving for T1D interventions in adolescents ($n = 81$) resulted in significant ($p = .02$) reduction in HbA1c levels. Older adolescents aged 14-16 had lower HbA1c levels compared to adolescents aged 11-13 years. In the same study, no difference in HRQoL rating was reported between intervention and control group. Both the Grey et al. (2000) and Nansel

et al. (2007) studies suggest that diabetes self-management skills development interventions may have an effect on HbA1c and HRQoL of adolescent.

Diabetes Self-Management Educational (DSME) Interventions

According to the American Association of Diabetes Educators (AADE), diabetes education is also known as diabetes self-management training (DSMT) or diabetes self-management education (DSME). These terms are used interchangeably in the literature. Diabetes education is defined as a continuous process that targets diabetes individuals, or those at risk, to develop knowledge and skills needed to successfully self-manage diabetes (ADA, 2016).

Education about diabetes self-management (i.e., blood glucose testing, insulin delivery, dietary practices, physical activity, problem solving and coping skills) is necessary for the effective treatment of diabetes (Couch et al., 2008) and to prevent or delay the onset of complications (Donaghue et al., 2009). Since diabetes self-management requires lifestyle changes, intensive education is required at diagnosis so that individuals can gain the necessary knowledge about diabetes and skills for self-managing. Once the basic diabetic knowledge and self-management skills are developed, continuous education throughout the individual's lifetime is needed to keep abreast of the new developments in diabetes self-management.

Among all interventions, educational interventions are the most fundamental. To be successful, educational interventions should be consistent with the recent recommendation of the standards of ADA (2016), which indicate that continuous diabetes self-management education (DSME), combined with diabetes self-management support

(DSMS) are the gold standard of interventions. Two types of education are usually provided to diabetes individuals. The most common is the general diabetes education that focuses on providing disease-related information and mastering disease related skills. For example, how to monitor blood glucose levels and administer insulin. The diabetes self-management education (DSME), which focuses on teaching diabetes individuals generalized skills that can utilize to manage their condition. For example, how to solve a problem, cope with a situation and initiate a new behavior. According to Bodenheimer, Lorig, Holman and Grumbach (2002) both type of diabetes education are important however, the major difference is the goal of each education. That former education focuses on improving the diabetes self-management. The latter focuses on increasing self-efficacy and improving outcomes. Both types of education are necessary to achieve a better HRQoL (Newman, Steed & Mulligan, 2004).

Diabetes self-management education (DSME) is identified as the best existing intervention program to help individuals with T1D understand self-management options and make informed decisions about their self-care (ADA, 2016). The U.S. national DSME standards propose the need for a holistic approach in diabetes education that includes both direct and indirect behavioral skills development approaches. This approach targets blood glucose and urine ketone monitoring, insulin administration, problem solving, coping skills, goal setting, and conflict management (ADA, 2016). Implementing this approach more widely could yield beneficial effects on several diabetes outcomes including HRQoL levels of adolescents with T1D (Grey et al., 2013;

Hampson et al., 2001; Murphy, Rayman, & Skinner, 2006; Murphy, Wadham, Hassler-Hurst, Rayman, & Skinner, 2012).

Educational interventions are provided through educational classes, computer games, behavioral training, telephone calls, and online access (Couch et al., 2008).

Diabetes education may target specific persons, such as the diabetes individual, caregiver, peers, or multiple individuals at the same time (Couch et al., 2008). The aim of diabetes education at diagnosis is different from the education that continues throughout the individual's life. At diagnosis, the knowledge and skills that are basic to manage diabetes are first introduced. This is followed by additional education that allows the diabetes individual to adapt to the ongoing challenges that develop during adolescence.

In general, the purpose of diabetes educational interventions is to improve self-management outcomes (control HbA1c levels and improve HRQoL), prevent complications, gain skills, and stay informed about new treatments (Couch et al., 2008). The International Diabetes Federation (IDF) indicates that DSME is a fundamental and essential element in managing diabetes and preventing complications. The aim of diabetes educational interventions should go beyond simply increasing diabetes knowledge and improving HbA1c levels. A study by Wang, Stewart, Mackenzie, Nakonezny, Edwards, and White (2010) shows that adolescents with a high level of HbA1c demonstrate sufficient diabetes knowledge, yet lack the needed skills for T1D self-management. However, Wang et al. (2010) reported that continuous education helped improve adolescents' self-management, especially among those with high HbA1c levels.

The effect of educational interventions on the diabetes outcomes of HbA1c and QoL differs among studies. Grey et al. (2000) reviewed educational interventions in children and adolescents and concluded that educational interventions were useful in improving knowledge of diabetes, but not HbA1c level. Grey et al. further reported, that coping skills training helped adolescents improve their HbA1c levels. Several other studies have reported improvement in HbA1c due to educational interventions (Martin et al., 2012; Northam, Todd, & Cameron, 2006). Tang, Funnell, and Anderson (2006) showed that HbA1c levels decreased from 9.2% to 8.6% after implementing educational self-management interventions.

Research shows the best practice of DSME is an approach that helps diabetes individuals understand the requirements of self-management and help them analyze options to make informed decisions (ADA, 2016). National DSME standards recommend an integrated approach to education that involves skills development, problem solving, behavioral changes, and considering emotional well-being (ADA, 2016). Using this recommendation will result in positive impact on HbA1c and QoL levels of adolescents with T1D, which is the overall goal of the health care system (ADA, 2016; Hampson et al., 2001). There are several types of educational interventions, however, it is not clear which DSME intervention is the most effective to improve self-management amongst adolescents with T1D.

A review completed by Christie (2013) indicates that most effective diabetes interventions are those that are multi-method or use an integrative approach, such as those that combine behavioral, psychological, or educational interventions into one

program. Other studies have found the benefits of integrating a skill development approach in diabetes self-management interventions, especially in adolescents and children (Hood, Rohan, Peterson, & Drotar, 2010; Nansel et al., 2007; Schlundt, Flannery, Davis, Kinzer, & Pichert, 1999). Such skills include communication, conflict resolution, problem solving, goal setting, negotiation and coping skills, which are essentials for effective management of type 1 diabetes during adolescence (Cameron et al., 2014). Studies also show that various interventions can help diabetes adolescents reach a better HRQoL and HbA1c (ADA, 2016). Literature suggests that successful diabetes management must encompass educational interventions in addition to other types of diabetes interventions.

Health Related Quality of Life

Quality of life (QoL) is a concept that encompasses physical, functional, emotional, and psychosocial wellbeing. General QoL tools measure all aspects of an individual's perception of QoL (Testa & Simonson, 1996). Disease-specific instruments related to QoL usually include aspects of health related to certain diseases, such as diabetes. Health-related quality of life (HRQoL) refers to individual sense of well being considering the impact of an illness or treatment on an individual's physical, psychological, emotional, and social functioning (Abualula et al., 2016; Lin et al., 2013; Magwood et al., 2008). The ways individuals identify their health encompass two dimensions, objective and subjective (Felicio et al., 2015). The objective dimension refers to the actual function of individual health while the subjective dimension refers to the individual perception and expectation of health (Testa & Simonson, 1996).

The terms QoL and HRQoL are often used interchangeably in the literature (Fortin, et al., 2004; Snoek, 2000). Quality of life is defined as “individuals’ perceptions of their position in life in the context of culture and value systems in which they live, and in relation to their goals, expectations, standards, and concerns.” (Oort, 2005)

(p.1). According to CDC (2015), QoL is a multicomponent concept that reflects individual assessments of both positive and negative parts of life. It can be measured through different tools, such as the Medical Outcomes Study (MOS) short forms (SF-12 and SF-36) (Webster & Feller, 2016).

The International Society of Pediatric and Adolescent Diabetes (ISPAD) clinical practice consensus guidelines (2015) and the most recent standard of medical care for diabetes published in the United States (2016) indicate the need to routinely monitor HbA1c and HRQoL as part of adolescents’ diabetes care (ADA, 2016; Cameron et al., 2014). However, most interventions focus on improving HbA1c and only a few emphasize HRQoL. Improved HRQoL has been recognized by the U.S. Centers for Disease Control’s *Healthy People 2020* as one of the best indicators of improvement in diabetes management among adolescents and other populations with diabetes (Koh, 2010).

Studies have used quality of life as an outcome measure for the effectiveness of educational intervention on adolescents with T1D (Abolfotouh, Kamal, El-Bourgy, & Mohamed, 2011). Grey et al. (2000) also used HRQoL as an outcome measure for coping skills-training (CST) intervention for adolescents with T1D. However, no statistically

significant differences in HRQoL ratings were reported between intervention and control group.

Experimental studies for improving HRQoL among adolescents with T1D have examined behavioral interventions, such as physical activity (Hampson et al., 2000); psychological interventions such as motivation (Winkley et al., 2006); and social interventions, such as peer support (Gallant, 2003; Glasgow et al., 2001; Heisler et al., 2010). A review of psychosocial and psychoeducational interventions indicates that most effective diabetes interventions in improving HRQoL are those that use multiple approaches, such as those that combine behavioral, psychological, and social interventions into one program (Christie, 2013).

Empirical evidence indicates an association between HRQoL and several factors, such as personal and family characteristics (Bulaclac, 2011), diabetes management styles (Naughton et al., 2014), and environmental conditions (Coffen, 2009). There are disparities in HRQoL among adolescents with T1D based on gender, race, income, insurance coverage, HbA1c, and insulin delivery methods (Graue et al. 2003; Lawrence et al., 2012; Hilliard et al., 2013). Moreover, HRQoL and HbA1c are two outcome measures that have been found to be significantly associated with diabetes self-management (ADA, 2016; Whittemore, Jaser, Guo and Grey, 2010). Studies examining the relationship between diabetes management and HRQoL have shown that adolescents reporting lower HRQoL checked their blood glucose less often and also have higher HbA1c levels (Hilliard, Wu, Rausch, Dolan, & Hood, 2013; Lawrence et al., 2012). There are opportunities to improve QoL in adolescents with T1D through interventions

tailored to this population (ADA, 2016). The Hvidore Study Group on Childhood Diabetes show that decreasing HbA1c levels to normal is associated with increases in HRQoL (Mortensen, 2002). This indicates that, both outcomes should be routinely assessed during diabetes care.

Studies also suggest that there are other influences on the relationship between HRQoL and the noted factors. For example, stress related to diabetes is an important psychological factor that should be assessed, as it is associated with poor glycemic control and coping skills among adolescents with T1D (Hilliard, Joyce, Hessler, Butler, Anderson, & Jaser, 2016; Hood et al. 2010; Jaser et al., 2012;).

Many measures are available to assess HRQoL of children and adolescents either by assessing the several domains and components of health (e.g. diabetes specific quality of life tools) or by using a single question to assess the global perception of health (self-rated health (SRH)). The Diabetes Quality of Life (DQOL) is a disease-specific measure that was developed in 1988 by the Diabetes Control and Complication Trial Research Group (DCCT, 1988). It includes four subscales: life satisfaction, diabetes impact, worries about diabetes, and social concerns (DCCT, 1988). In 1991, Ingersoll and Marrero modified the DQOL questionnaire so that it would be applicable to adolescents, resulting in the DQOL-Y instrument (Ingersoll & Marrero, 1991). Other measures include Pediatric quality of life inventory (PedsQL) that measures physical, emotional, social, and school functioning, while the Epidemiology of Diabetes Interventions and Complications Quality of Life Questionnaire (EDIC-QL) measures disease-related lifestyle, worries, life satisfaction. The DQOL remains the most widely used instrument

(Abualula et al., 2016; Graue, Wentzel-Larsen, Hanestad, Batsvik, Sovik, 2003; Montori, 2007). In addition to assessing various HRQoL constructs, several instruments also assess a global HRQoL by asking a single question related to an individual's health status (DQoLY, DQoLY-SF, and CHQ CF87) (Abualula et al., 2016).

Measuring HRQoL is a challenge because it is defined differently across disciplines and individuals (CDC, 2011). Studies of HRQoL in young people, particularly adolescents with diabetes, are limited (Huang et al., 2004; Mortensen, 2002; Nieuwesteeg et al., 2012). This could be due to the limited tools that are applicable for adolescents. Moreover, available tools do not address changes that accompany youth health over time (Faulkner, 2003). Adolescence involves periods of rapid physical, mental, and social change. Measuring HRQoL during this transitional period presents challenges for researchers (Faulkner, 2003).

Self-Rated Health (SRH)

The self-rated health (SRH) assessment consists of one question on an individual's perception of their health and is widely used in the diabetes population and is considered a universal and inclusive indicator of subjective QoL and HRQoL (Bowling, 2005; Garratt, Schmidt, Mackintosh, & Fitzpatrick, 2002; Huang et al., 2004; Ismail, 2011; Jylhä, 2009; Testa & Simonson, 1996). The SRH reflects the perception of health, taking into account an individual's life experience and health expectation. The SRH question was validated using longitudinal data (Huang et al., 2004), across gender and culture (Jylha, Guralnik, Ferrucci, Jokela & Heikinen, 1998), and in adolescents (Breiblik, Meland, & Lydersen, 2008). Despite the SRH being only one question, it is a

useful measure of overall HRQoL, demonstrating a significant sensitivity to causes, outcomes, diabetes duration, treatment type, lived experience, and individuals' knowledge of diabetes (Ismail, 2011; Shadbolt, 1997).

According to The World Health Organization (WHO), the multidimensional nature of health is encompassed by a single global SRH question on perceived health, and is the main indicator for assessing individual health and quality of life of the population (De Burin, Picavet, & Nossikov, 1996). The relationship between global SRH and health outcomes has been extensively studied. Furthermore, the use of SRH measure is recommended in data estimation to formulate policies in areas of public health, particularly in morbidity and mortality (De Burin, Picavet, & Nossikov, 1996; Robine, Jagger, & Romieu, 2003; Sargent-Cox, Anstey, & Luszcz, 2010).

Some studies report that a single question such as the one asked in SRH, does not provide a good measure of HRQoL. A review by Bowling (2005) for example, cites statistical analysis by Rand Corporation which shows that well constructed multidimensional scales, even if short (5-10 questions) are more sensitive to changes in patient conditions than one question. Furthermore, multi-question responses can provide a more comprehensive profile on an individual's health changes such as psychological and mental health. Bowling also suggests that scales might be better than a single question because more responses are suitable for statistical analysis. A review by Lin, Lin, and Fan (2013) contend that HRQoL and SRH are two independent constructs that do not agree. The authors claim that HRQoL is influenced by different factors while SRH is influenced more by physical factors and less by emotional factors.

Even though these studies report that SRH may not be a comprehensive indicator of HRQoL (Bowling, 2005; Lin et al., 2013), other studies show that SRH provides a comprehensive and universal indicator of HRQoL. For example, a recent qualitative study by Joffer, Jerden, Ohman, and Flacking (2016) exploring SRH among adolescents using a sample of 58 Swedish respondents (distributed equally between boys and girls) ages 12 to 18 years, asked the question, “A person may feel good sometimes and bad sometimes. How do you feel most of the time.?” Results show that among these participants, this question captures a comprehensive view that encompasses social, mental, and physical aspects of “feel.” When participants were asked how their responses would change if the question replaced “feel” with “health”, participants related health to behaviors such as physical activity, food habits, drug use, and health condition. When asked to compare the two terms, “health” and “feel”, participants indicated that the two terms are interrelated, however “feel” captures mental concept while “health” captures physical aspects (Joffer et al., 2016). This suggests that one SRH question does capture a holistic view of an adolescent’s health. However, care should be made to ensure that the question wording is taken into account.

Other studies have also shown that SRH provides a comprehensive indicator of HRQoL. These studies show that responses to the SRH question reflect a comprehensive internal thought process that captures an individual’s lived experience, understanding of the disease and its consequences (Erickson et al., 2001; Huang, Palta, Allen, LeCaire, & D'Alessio, 2004; Ismail, 2011; Jonsson, Nystrom, Sterky, & Wall, 2001; Jylha, 2009; Shadbolt, 1997; Tsai, Ford, Li, Zhao, & Balluz, 2010).

There are several factors that may impact an individual's SRH responses. These factors include but are not limited to age (Benyamin, Blumstein, Lusky, & Modan, 2003), gender (Deeg & Kriegsman, 2003), race and ethnicity (Lee et al., 2007), education (Dowd, & Zajacova, 2007), and duration of chronic illness (Idler, Leventhal, McLaughlin, & Leventhal, 2004). For example, a study by Wennberg et al. (2012) shows that SRH predicts vascular events and major complications in diabetes individuals. The SRH was also associated with increased mortality after controlling for age, gender, education level, body mass index, physical inactivity, smoking, insulin treatment, high blood pressure, history of myocardial infarction, stroke or cancer (Wennberg et al., 2012). Another population based study by Kummer et al. (2014) also looked at additional factors such as physical activity, smoking, as well as computer and television use. The study reports that decreased SRH is associated with less physical activity, active smoking, and long use of computer and television among adolescents with T1D as compared to the general population (Kummer et al., 2014). A cross-sectional study conducted on Norwegian data extracted from the WHO survey also shows that body dissatisfaction is associated with lower SRH in early and mid adolescence. The result is more significant among females (Meland, Haugland, & Breidablik, 2007).

This literature review has explored existing research on self-management and interventions, in particular, education interventions targeting HRQoL among adolescents with T1D. Among the studies reviewed, there were varied DSME interventions, intervention characteristics, and QoL measures. None of the reviewed studies identified optimum DSME intervention targeting HRQoL. Furthermore, no study identified the

characteristics of the optimum DSME intervention. Research on HRQoL measures among adolescents with T1D, and its relation to SRH ,has been reviewed. Studies on the significance of SRH as a measure of HRQoL have also been reviewed. Factors contributing to both measures were then explored. Of the studies reviewed, none identified the most significant predictor of SRH among adolescents with T1D. This study will fill the existing gap in literature by identifying the most significant predictor of SRH and the optimum DSME to address these factors.

Conceptual Framework

The Childhood Adaptation Model to Chronic Illness: Diabetes Mellitus was proposed by Grey, Cameron, and Thurber (1991), based on Roy's Model of Adaptation (1976), Pollock's adaptation Chronic Illness Model (1986), and evidence driven from research on T1D (Grey, Cameron, & Thurber, 1991; Whittemore, Jasser, Guo, & Grey, 2010). The model was developed to identify factors that influence the adaptation of a child to T1D. The framework takes a significant number of internal and external factors into consideration when analyzing the initial response and level of coping or adapting of individuals with T1D. Adaptation is the consideration of the extent of individuals' response, assessed by metabolic control levels, to the stress of living and managing chronic illness such as T1D. The three elements originally contributed to adaptation model presented in Figure (1), were: (1) residual stimuli (age, sex, and time since diagnoses) (2) psychological responses (anxiety and depression), and (3) contextual stimuli (self-management, stressful, and coping) (Grey, Cameron & Thurber, 1991;

Whittemore et al., 2010). These elements are assumed to interact and have a significant impact on an individual adaptation to T1D measured by HbA1c.

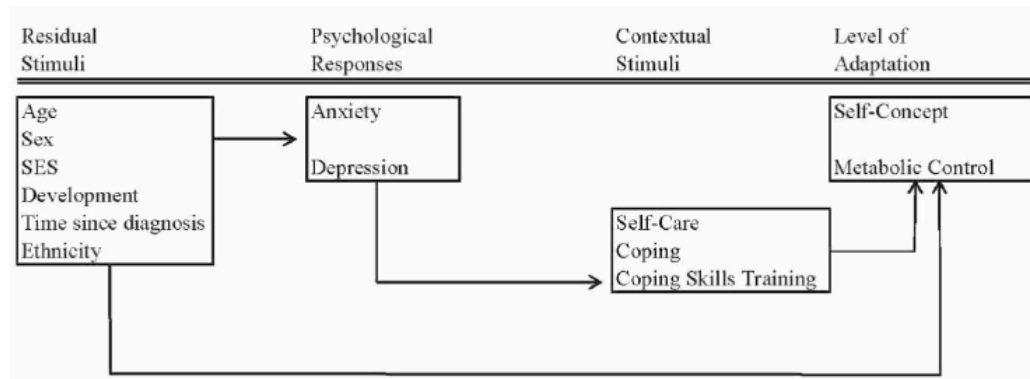


Figure 1: The Original Model of Adaptation to the Stress of Chronic Illness.

As T1D research continued to grow, particularly after the DCCT findings emphasizing on the significance of intensive diabetes management, more factors that influence the adaptation to T1D such as family environment and psychological responses were identified (Whittemore et al., 2010). In 2010, the model was revised (Figure 2), taking into account the new evidence and factors that were identified. In addition, some of the old element labeling was modified. For example, the residual stimuli was replaced by individual and family characteristics; contextual stimuli was replaced by individual and family response; and physiological (HbA1c) and psychosocial (QoL) were the two

outcome indicators of adaptation to T1D. Interaction and association between the variables were noted, making the model more complex (Whittemore et al., 2010).

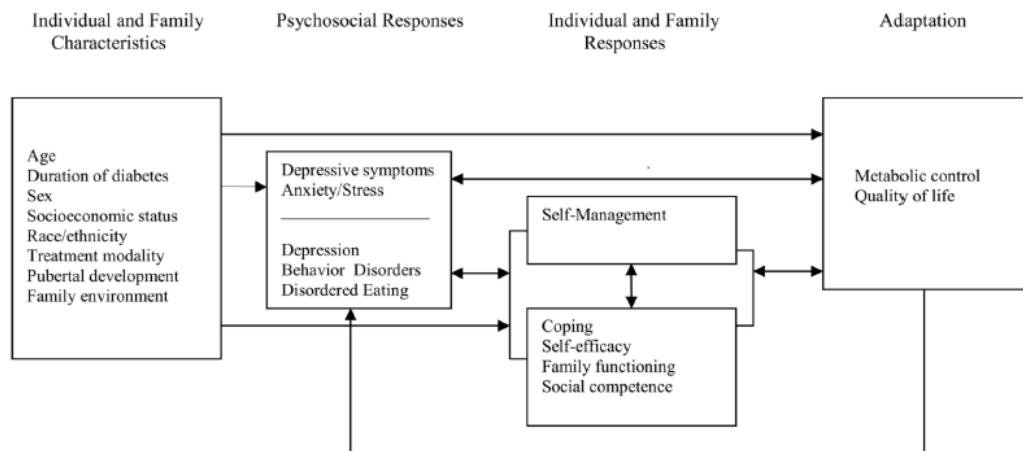


Figure 2: Revised Model Adaptation to the Stress of Chronic Illness

Application of the Model to the Current Study

The original and revised stress-adaptation models describe how factors contributing to coping with T1D among adolescents work together. The models have “stress” in the name because adolescents with T1D must respond to the stresses of living with chronic illness. The word “adaptation” refers to processes by which individuals with T1D adjust to the environment and the challenges of managing chronic illness. In the revised model (Figure 2), adaptation is the degree to which individuals with T1D respond physiologically (HbA1c) and psychologically (QoL) to the stresses of T1D. The initial

model (Figure 1) considered only HbA1c as the main outcome. The revised model applied the coping skills training (CST) intervention and considered HbA1c and QoL as the outcomes. For this study, a new model, Type 1 Diabetes Mellitus Adaptation Model in Adolescents, (Figure 3) will be applied based on the revised model (Figure 2). In applying this conceptual framework, HRQoL will be treated as the overall desirable outcome of adolescents with T1D. Other outcomes, such as HbA1c, will be treated as factors that influence HRQoL. After implementing the optimum intervention with a skills development component identified by the SR (Figure 3), to the new model, the adolescents with T1D will be equipped with the skills for self-management of T1D.

The intervention will modify the impact of the three elements (individual characteristic; age, gender, race, insurance status, duration of diabetes, treatment type; psychosocial response: perceived stress related to diabetes; and individual response: self-management reflected in insulin mode of delivery and HbA1c) on the HRQoL. As indicated in the Figure 3, the intervention will target those aspects of self-management as shown by individual response. The adolescent will be able to better adapt to the stresses of managing T1D. The adolescent will also be able to better monitor HbA1c, make informed decisions about diet, physical activity, and treatment options. With improved self-management, the adolescents with T1D will have better HRQoL. This model has several key features that are not reflected in the original or revised model. First, the model considers HRQoL as the ultimate outcome, all other outcomes are treated as factors that affect the overall HRQoL. Second, stress is considered as a featuring factor that has an impact on the other factors. At the same time these factors have an impact on

stress. For example, stress levels of adolescents with T1D will depend on age, duration of T1D, economic status of the family, type of insurance and other factors. Stress also affects diabetes management and HRQoL. Once the optimum intervention is implemented, the adolescents with T1D will be better able to manage factors such as HbA1c leading to higher HRQoL and reduction in stress levels. At the same time, improved HRQoL will lead to less stress and better management of diabetes related factors. Thus, among all the factors, close attention should be paid to stress as it has an underlining effect on other factors.

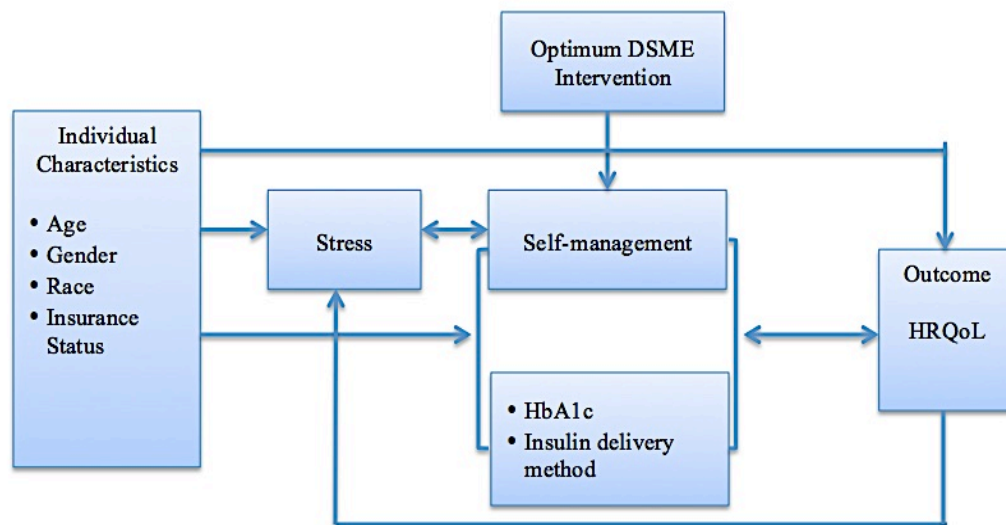


Figure 3: Adolescents Adaptation to the Stress of Type 1 Diabetes- DSME Intervention.

Chapter Summary

The reviewed literature suggests that the increase of global prevalence of adolescents with T1D is contributing to an increase of morbidity, mortality, financial burden, and lowering the HRQoL among adolescents with T1D. There is a need to identify interventions that are effective for improving QoL in this population. Literature indicated that there were several DSME interventions, however, the effectiveness of these interventions on HRQoL is not known. Furthermore, the characteristics of the optimum DSME interventions are not known. Moreover, the most important factors that influence the HRQoL among adolescents with T1D are not known. The goal of this study is to address the existing gap in the knowledge on DSME interventions that are optimum in improving HRQoL among adolescents with T1D, and to identify the factors that are most significant in affecting the HRQoL.

CHAPTER THREE: METHODS

This study employed a systematic review and a secondary data analysis to answer the research questions. The purpose of this chapter is to describe the research designs of (A) and (B). For objective (A), the SR process is described, including: search strategies, inclusion criteria, variables of interest (DSME interventions and HRQoL measures), and studies quality appraisal. For objective (B), the secondary data analysis is described, including: data source, data collection procedures, study sample and setting, and variables of interest (demographic variables, socioeconomic variables, and SRH measurement). The data analysis plan used to answer the research questions is also presented. Limitations of the study and ethical considerations are discussed. The purpose of the review is to identify the optimum DSME intervention and its characteristics. The purpose of the secondary data analysis is to identify the most significant factor impacting the HRQoL as measured by Self-rated health (SRH). The objective of this study is to use the optimum intervention to mitigate the most significant factors impacting HRQoL (SRH) of adolescents with T1D.

Study Design

Systematic Review

The analysis used to address objective (A) was a SR of published research on T1D interventions with a skills development component. The review was used to

determine the optimum DSME for adolescents' HRQoL and to identify the characteristics of the optimum intervention. Six databases were searched for eligible studies between 1994 and 2014. Data were extracted from eligible studies to answer

Inclusion Criteria

To conduct the SR, the Preferred Reporting Items for Systematic Reviews and Meta-analysis (PRISMA) criteria were used to guide the process. The PRISMA tool was developed by several health research institutes and provides guidelines for conducting and reporting systematic reviews (Moher, Liberati, Tetzlaff, & Altman, 2009). The PRISMA is increasingly used because systematic reviews and meta-analyses have become the goal standard for research in the healthcare field (Gopalakrishnan & Ganeshkumar, 2013). Systematic reviews provide the current state of knowledge in the health field and point to areas of research that needs to be addressed. The tool was initially developed for use in evaluating and reporting clinical trials but can also be used in evaluating other research, particularly interventions (Moher et al., 2009). To obtain articles for the SR, the Cochrane Library, CINAHL, MEDLINE, PsycInfo, Web of Science, and ProQuest databases were systematically searched for studies of interventions for T1D published between 1994-2014. Studies before 1993 were excluded due to treatment regimen changes, which resulted largely from the findings of the Diabetes Control and Complications Trial (DCCT, 1993) A combination of the following search terms were used: (*"Diabetes mellitus Type 1" or "diabetes Type 1" or "T1D" or "Diabetes mellitus" or "diabetes " or "diabetes insipidus" or "Insulin-Dependent Diabetes") and "intervention" and (adolescen* or teen* or "young" or "youth" or*

"juvenile" or "school age") and ("quality of life" or "well being") not ("qualitative" or "prevalence" or "cross-sectional" or "observational"). References of identified studies that met the search criteria were reviewed for additional articles. For a global perspective, non-English language studies were eligible and were included in the search criteria.

Eligible studies were those that met all of the following criteria: (1) studies using the following experimental designs: randomized controlled trials (RCTs) in which individuals are randomly assigned to intervention or control groups, quasi-experimental approaches, with no randomization of individuals to the control or intervention groups, and repeated measures designs in which individuals serve as their own controls (with “before” and “after” measures examined using paired-analysis); (2) all participants were within the parameter of 11-21 years of age; (3) all participants were diagnosed with T1D at least six months before the study; (4) the study tested diabetes self-management education interventions that included a skills development component meeting the operational definition; (5) health related quality of life (HRQoL) was measured as the primary outcome or as part of multiple DSME outcomes; and (6) valid and reliable scales were used to assess HRQoL or diabetes specific QoL (Appendix 1-Table 2).

Variables of interest

There were two types of variables analyzed in the SR: types of interventions and health related quality of life (HRQoL) measures. These are described in the following two sections

Types of Diabetes Self-Management Educational (DSME) Interventions

The DSME interventions that targeted adolescents’ knowledge, behavior, and

skills and measured the effect of these interventions on HRQoL were reviewed.

Interventions included education on any of the diabetes related tasks: monitoring blood glucose, administering insulin, taking foods that are consistent with diabetes clinical recommendations, exercising, coping in healthy ways, solving problems, and making informed decisions.

The operational definition of DSME was developed based on the work of Sidani and Braden (1997), Blue and Black (2005), and Fan and Sidani (2009). Educational interventions were of four types: (1) interventions that deliver information aimed at improving the knowledge of the participants; (2) interventions targeting behavioral changes related to diabetes self-management such as appropriate food choice and portion control, physical activity, blood glucose monitoring, and insulin administration; (3) interventions intended for psychological modifications such as coping, problem solving, negotiation, and stress management; and (4) hybrid interventions that incorporate more than one type of DSME. The skills targeted in these interventions can be broadly categorized into two types: (1) direct behavioral skills focusing on a specific task such as blood glucose and urine ketone monitoring, insulin administering, exercising, and foot or eye care; and (2) indirect behavioral skills such as decision making regarding food selection, insulin dosage, problem solving, and coping to facilitate diabetes management.

Health Related Quality of Life (HRQoL) Measures

There reviewed studies used a wide variety of HRQoL measures. The Diabetes Quality of Life (DQOL) is a 60-item instrument (of which 13 are limited to children and adolescents), measures 4 constructs: satisfaction with treatment, impact of treatment,

worries about the future effects of diabetes, and worry about social issues. The Diabetes Quality of Life for Youth (DQOLY) is a 52-item instrument, composed of 3 subscales: disease impact, disease-related worries, and diabetes life satisfaction. The Diabetes Quality of Life for Youth–Short Form (DQOLY-SF) is an 18-item instrument composed of 6 subscales: future worries, parental concern, impact on activities, impact of treatment, symptom impact, and satisfaction. The Pediatric Quality of Life Inventory (PedsQL) is a 23-item generic instrument composed of 4 scales: physical, emotional, social, and school functioning. The Pediatric Quality of Life Inventory–Diabetes Module (PedsQL-DM) is a 28-item multidimensional module composed of 5 scales: diabetes symptoms, treatment barriers, treatment adherence, worry, and communication. The Child Health Questionnaire (CHQ-CF87) is an 87-item generic instrument composed of several constructs: general health, physical health, mental health, change in health, emotional or time impact on the parent, limitation in school work and activities with friends, bodily pain or discomfort, behavior, self-esteem, family cohesion, and limitation in family activities. The Epidemiology of Diabetes Interventions and Complications Quality of Life Questionnaire (EDIC-QL) is composed of 3 subscales: disease-related lifestyle, disease-related worries, and diabetes life satisfaction. Table 2 presents the reported validity and reliability of the used HRQoL measures.

Table 2. Validity and Reliability of HRQoL Measures

Measures	Items and Constructs	Validity and Reliability
<p>Child Health Questionnaire (CHQ-CF87)</p> <p>Graue et al., 2005 De Wit et al., 2008</p>	<p>an 87-item generic instrument composed of several constructs physical functioning (nine items), emotional, behavioral, and physical role functioning (nine items), bodily pain (two items), general behavior (17 items), mental health (16 items), self-esteem (14 items), general health (12 items) and change in health (one item). Higher scores indicating better wellbeing.</p>	<p>Cronbach's α-values were (> 0.70), except for 'physical functioning' (0.56)</p>
<p>Diabetes Quality of Life (DQOL)</p>	<p>a 60-item instrument has 4 scales: satisfaction-17 items, impact-23 items, and worry-11 items.</p>	<p>Internal consistency (Cronbach's $r = 0.66-.92$) Test-retest reliability ($r = .78-.92$)</p>
<p>Diabetes Quality of Life for Youth (DQOLY)</p> <p>Channon et al., 2007 Grey et al., 2000 Lawson et al., 2004 Nansel et al., 2007. Loding et al., 2007 Newton, 2008 Abolfotouh et al., 2011</p>	<p>a 52-item instrument, measures 3 constructs: satisfaction-17 items, impact-23 items, and worry-11 items. In addition, a general self-rating of overall health is included in the measure. Higher scores indicate more favorable ratings.</p>	<p>Impact ($\alpha = 0.79$); worry ($\alpha = 0.84$); and satisfaction ($\alpha = 0.92$)</p> <p>Test-retest reliability was estimated ($r = 0.85$, $P = 0.001$). -Cronbach's internal consistency of 0.83.</p>
<p>Diabetes Quality of Life for Youth-Short Form (DQOLY-SF)</p> <p>Murphy et al., 2012</p>	<p>an 18-item instrument composed of 3 subscales: impact, worry, and parental concern.</p>	<p>Impact ($\alpha = 0.65$); worry ($\alpha = 0.84$); parental concern ($\alpha = 0.79$)</p>

Epidemiology of Diabetes Interventions and Complications Quality of Life Questionnaire (EDIC-QOL) Wang et al., 2010	composed of 3 subscales: disease-related lifestyle; disease-related worries; and diabetes life satisfaction. Each item can be given 1–5 points on a Likert scale. A lower score reflects better QoL	Internal consistency (Cronbach's $r = .66-.92$) and test-retest reliability ($r = .78-.92$)
Pediatric Quality of Life Inventory (PedsQL) Grey et al., 2013 Waller et al., 2008	a 23-item generic instrument composed of 4 scales: physical, emotional, social, and school functioning Higher scores reflect better QOL.	Cronbach's alpha for the sample was 0.87. Internal consistency ($\alpha = 0.88$ child)
Pediatric Quality of Life Inventory–Diabetes Module (PedsQL-DM) Grey et al., 2013 Waller et al., 2008	A 28-item multidimensional module composed of 4 scales: physical, emotional, social, and school.	Internal consistency reliability for the total scale score ($\alpha = 0.88$ child); physical health summary Score ($\alpha = 0.80$ child); and psychosocial health summary score ($\alpha = 0.83$ child) (Average $\alpha = 0.71$ child)

Studies Quality Appraisal

To assess the quality of reviewed studies the quality assessment tool for quantitative studies (QATQS) was used (National Collaborating Centre for Methods and Tools, 2008). The Effective Public Health Practice Project (EPHPP) hosted by McMaster University in Ontario, Canada, developed the QATQS to assess six aspects of pediatric QoL experimental study designs; (1) selection bias, (2) study design, (3) confounders, (4) blinding, (5) data collection methods, and (6) withdrawals and dropouts. Each criterion is

rated on a three-point scale as strong (three points), moderate (two points), or weak (one point) (Appendix 1). The mean value of the six criteria is the global score. An average score of 2.51 to 3.00 is strong, a score of 1.51 to 2.50 is moderate, and a score of 1.00 to 1.50 is weak. The content and construct validity of the tool has been confirmed in systematic reviews of public health nursing research (Abualula et al., 2016; Thomas, Ciliska, Dobbins, & Micucci, 2004). The QATQS has a fair inter-rater reliability for individual constructs (kappa (κ)=0.6) (Armijo-Olivo, Stiles, Hagen, Biondo, Cummings, 2012; Byrt, 1996).

Secondary Data analysis

To address objective (B), cross-sectional cohort data were analyzed. Data were from a registry of individuals with T1D from 67 clinics across the United States. The analysis examined the HRQoL (measured by self-rated health (SRH)) of adolescents with T1D and associated factors. The data were obtained from the T1D Exchange Clinical Registry for the 2010-2012 period. The data were collected from individuals with T1D who visited participating clinics and volunteered to enroll in the registry upon request (Beck et al., 2012). Only data collected at the time of enrolment of the participants was used in the analysis. Descriptive statistics and logistic regression were conducted on a sample extracted from the registry to address the research questions.

Data Source

A central web-based electronic database capture clinical data that typically collected in the medical record as part of usual care, as well as data entered by the 67 participating clinics.

The T1D Exchange Clinic Registry is a longitudinal prospective data contained in a central web-based electronic database, consisting of data normally collected by health care providers as part of usual care. The data contains individuals with T1D aged from less than 1 year to 93 years who volunteer to participate. Data collected includes treatment of T1D, laboratory and other testing, and the frequency of visits performed according to the clinical center's usual routine and not dictated by the study (Beck et al., 2012). The registry was created in 2010 in response to the need to have a public large-scale registry of patients with T1D in the United States. Data collection for the registry started in August 2010. The registry is coordinated by Jaeb Center for Health Research. Jaeb is a nonprofit clinical research based in Tampa, Florida (Beck et al., 2012). Participating clinics were chosen to reflect a broad representation of pediatric and adult patients with T1D. As of 2012, there were 67 clinics throughout the United States participating. The distribution of clinics covers new areas not previously covered by diabetes related registries. Out of the 67 clinics, 52 are institutional based, 14 are community based, 36 are mostly for pediatric patients, 19 are for both pediatric and adult, and one is for managed care. The clinics care for a total of 100,000 individuals with T1D (Beck et al., 2012).

Individuals enrolled in the registry must have a definitive clinical diagnosis of T1D which is defined in one of three ways: 1) age less than 10 years at diagnosis; 2) positive pancreatic autoantibodies at any time or positive anti-insulin autoantibody at diagnosis only; or 3) the presence of two or more of the five suggested clinical indicators set by the registry. Often due to incomplete or missing medical records, an individual

who presents at the clinic is considered to have T1D even in the absence of these criteria. According to Institutional Review Board, adult participants must provide written consent. Minors must provided assent in addition to consent from parents or guardians (Beck at al., 2012).

Data Collection

In addition to data obtained from medical records during regular office, participants are given a questionnaire to complete (Beck at al., 2012). Data not collected during the office visits is obtained from participants by clinical staff over the phone. Data collected through the questionnaires includes: demographic, socioeconomic, psychosocial and quality of life, medical conditions including complications of T1D, medications, and family history. Other data collected includes: information related to the onset and diagnosis of T1D, treatment and management of T1D, problems encountered in self-management of T1D, insulin delivery methods, glucose data, physical examination findings, and laboratory test results. During annual follow-up, some of the questions are re-administered to provide longitudinal data, and new questions are added to address specific objectives. Follow-up may continue for 25 years. It should be noted that the only publically available variable for which longitudinal data is collected is HbA1c. As of August 2012, a total of 25,762 participants had joined the registry and completed the questionnaires electronically or on paper, from home or through the Internet (Beck at al., 2012). The publically available data does not provide a way to determine what month and year a participant was enrolled and for which individual year a participant's data were collected. The data only provides a unique identifier and data points associated with that

identifier. The data used for this analysis, for example, was for the period of 2010 to 2012.

Study Sample Size and Power Analysis

Of the 25,762 participants who had joined the T1D Exchange Clinic Registry, a cross-sectional cohort data of participants enrolled through August 1, 2012 were extracted. The sample included those who met the following criteria: (1) were between 13 and 18 years old at the time of enrollment, (2) were diagnosed with T1D at least one year prior to enrollment in the registry; (3) had HbA1c greater than 6.4%, which indicates not having hypoglycemia; (4) used insulin as a treatment; and (5) had a response to the SRH question in the database. All participants who did not meet the inclusion criteria were dropped. After applying the inclusion criteria, the final sample for the analysis contained 5,799 adolescents, presents in Figure 4, the CONSORT flowchart to determine the study sample based on eligibility criteria.

The analyzed data contained eight variables: SRH (dependent variables), gender, age, race, insurance status, HbA1c levels, stress levels, insulin delivery method (predictors). All the variables were classified into binary. Each of the predictors had more than ten cases, which provided sufficient numbers in both categories of the response (Peduzzi et al., 1996). According to Polit (D.F., 2010), sample size ranging from 10 to 20 cases per predictors is recommended for logistic regression. To get robust results, Broll, Glaser, and Kreienbroch (2002) recommend a large sample size. The sample size depends on the number of explanatory variables used in the analysis; the more the variables the larger the sample size required. In this data set, there is sufficient numbers of responses in

each of the selected variables. According to Hosmer and Lemeshow sample sizes greater than 400 should be used for logistic regression. Hosmer and Lemeshow note that when the sample sizes is small, the Hosmer–Lemeshow test has low power and will not detect small deviations from the logistic model.

Researchers have developed formulas for estimating the minimum sample size for a logistic regression using significance level (α), power ($1 - \beta$), and expected odds ratio (OR) (Hsieh, Bloch, & Larsen, 1998; Self and Mauritsen, 1988; Self, Mauritsen, & Ohara, 1992; Whittemore, 1981). The basic question tackled by this formula is, what should the sample size (n) be, so that the asymptotic test has a predetermined significance level (α) and power ($1 - \beta$)? Alam, Rao, and Cheng (2008) have compared their sample size calculations to those of Hsieh et al. (1998) and Whittemore (1981). The results show that for a significance level of $\alpha = 0.05$, power ($1 - \beta = 0.90$), and odds ratio ($OR \geq 1$), the minimum sample size required is ($n=163$) (Alam, Rao, and Cheng, p.66, 2008). Based on these findings, the determined sample size of this study has adequate strength.

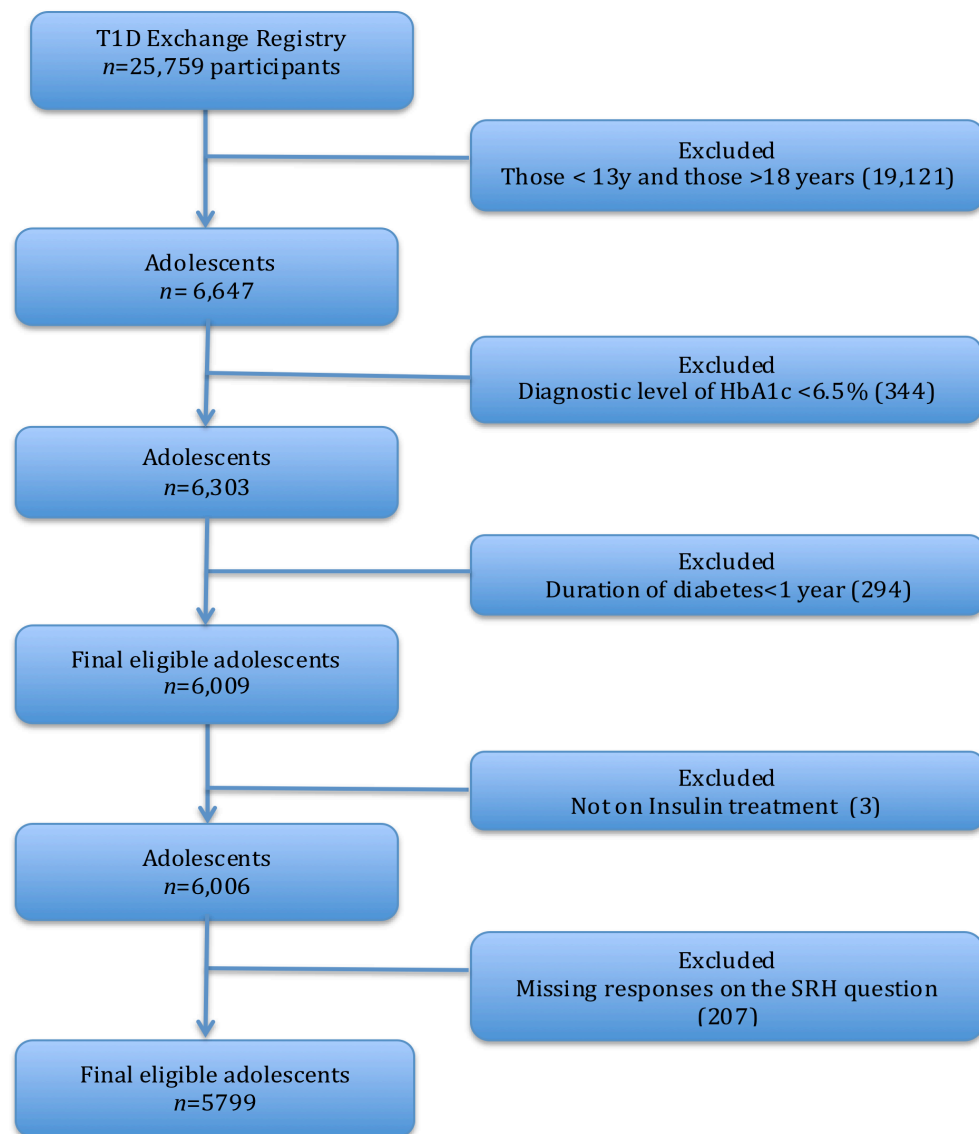


Figure 4. CONSORT Flowcharts for Determining Study Sample.

Variables of Interest and Measurements

The following variables were extracted from the T1D Exchange Clinical Registry to be used in the secondary data analysis.

Demographic Variables

In the registry, gender was reported as female, male, or transgender. Age was reported in years and months on the day the consent was signed. Race was reported as white non-Hispanic, Black or African non-Hispanic, Hispanic or Latino, native Hawaiian or other Pacific Islander, Asian or American Indian or Alaskan native, and those with more than one race. Insurance was reported as private, military, Medicaid, MediGap, Medicare, Indian Health Service, other state or government plans, single service plan, no coverage, don't know their insurance status, don't wish to answer.

HbA1c data were obtained from the medical chart of the participant at the time of data entry into the registry. The HbA1c value entered into the registry was the most recent and closest to the time a participant was enrolled. In cases where they were available, HbA1c values for the past ten years were also collected. For the publicly available data, HbA1c is the only variable for which there is longitudinal data. Stress due to diabetes was measured on a five-level Likert scale as follows: never=1, rarely=2, or sometimes=3, very often=4 or often=5. Data on insulin mode of delivery was reported as: pump=1, injections or pens=2, pump and injections or pens (together on same day)=3, sometimes pump and sometimes injections or pens=4, do not take insulin=5.

Self-Rated Health (SRH) Measurement

The SRH question was used to assess adolescents subjective HRQoL. Participants were asked the question, “In general, how would you rate your health?” The responses were recorded on a five-point scale as follows: poor=1, fair=2, good=3, very good=4, and excellent=5. The SRH data were collected at enrollment using a questionnaire completed by the adolescents or their guardians.

The SRH question has been validated using longitudinal data (Huang et al., 2004), across gender and culture (Jylha, Guralnik, Ferrucci, Jokela & Heikinen, 1998), and in adolescents (Breidablik, Meland, & Lydersen, 2008). Despite the SRH being only one question, it is a useful measure of overall HRQoL, demonstrating a significant sensitivity to causes, outcomes, diabetes duration, treatment type, lived experience, and individuals’ knowledge of diabetes (Ismail, 2011; Shadbolt, 1997). The SRH score had high agreement levels with the health scores of the Short Form 36 health survey (SF-36). The internal consistency of the SRH measurement had a Cronbach’s alpha of 0.83 (Garratt, Ruta, Adballa, Buckingham, Russell, 1993). The SRH has been used in other areas such as prediction of mortality among various population segments globally and in the US and has been found to be reliable (Jylhä, 2009).

According to studies conducted by Wisniewski, Naglieri, and Mulick (1988) and Haugland and Wold (2001) adolescents can evaluate and respond to a health survey question. This is evidenced by a Norwegian study among 16 year olds that showed that a one-question measure is correlated to subjective health complaints and depressed moods and the response is stable over time (Meland et al., 2007).

The decision of selecting the most appropriate measurement tool is based on the study type, purpose, and population size (Testa & Simonson, 1996). For example, when conducting an interventional study for a small sample, assessing several components of HRQoL is more appropriate to reflect exact change in the result. Although it might be limited, the advantages of using SRH question are that it is cost effective, takes less time, easy to administer, answer and interpret. This analysis used the SRH question as an indicator of HRQoL for several reasons. First, it is widely used in T1D literature. Second, it is more applicable to cross-sectional, large sample size, and non-interventional data used in this analysis. Third, it is the only publically accessible HRQoL measure in the T1D Exchange Clinic Registry.

Analysis Plan

To address objective (A), determining the optimum DSME interventions with a skills development component on HRQoL of adolescents with T1D and its characteristics, a SR of eligible studies was conducted and pertinent data extracted using a coding frame developed to facilitate data extraction. A sample of eligible primary studies and frame-books on similar topics was used to develop a draft of the code-frame. The frame was piloted with three primary studies and revised accordingly. To ensure validity, the frame was evaluated and revised by an expert. Extracted data included study location and year conducted, design, sample characteristics such as age and gender, intervention characteristics, HRQoL measures, and pre-and post-intervention outcomes. Intervention data extracted included a description of the DSME intervention types, method, format duration, amount, and the intervention provider. Further, types of skills

development components were also extracted. Data on study quality appraisal such as selection bias, study design, confounders, blinding, data collection methods, and withdrawals and dropouts were also extracted. Where missing data were found, the study correspondence author was contacted for clarification. In one of the studies, information on the dates the data were collected were missing, the corresponding author was contacted but did not respond. The study was included in the SR without the dates of data collection.

To address objective (B), assessing the HRQoL of adolescents with T1D using the self-rated health (SRH) and to determine the significant factors contributing to their SRH, data analysis was employed. Before analyzing the data, a review of the document accompanying the data was conducted to understand how the dataset was organized. The data came in four separate files: the subject main file, HbA1c, medication, and medication condition files. Initial frequencies were conducted to determine any missing data and outliers before merging the data sets. In addition, any missing unique identifiers were noted. The files were then merged and more frequencies conducted to make sure the data were merged correctly.

After merging, the extent of missing data was examined, outliers identified and the variables of interest examined for completeness. The adequacy of fit of the data was assessed for specific statistical tests (Mertler & Vannatta, 2009). Missing data and outliers were identified using frequencies and cross tabulations, and their effects on the planned analysis determined by assessing skewness, means, and standard deviations. The missing data were analyzed to determine if there was any specific pattern or if the values

occurred randomly. It was determined that the missing values occurred randomly and were dropped from the data set. The data were further assessed for outliers using the explore function in SPSS to determine the minimum and maximum values for each of the variables of interest to see if they were outside the range. To deal with the outliers, those participants who had results beyond the inclusion criteria were dropped from the data set. For example, for the HbA1c, those with values less than 6.4% were dropped. The data were also evaluated for normality distribution by using skewness, kurtosis, Kolmogorov-Smirnov statistics, and histograms and it was to be normally distributed. After data cleaning was completed and inclusion criteria applied, a subset of the data was obtained and recoding of the variables of interest was conducted.

Descriptive statistics was conducted to determine the sample characteristics. This included frequencies and percentages for categorical variables. Means and standard deviations for continuous variables (age and HbA1c) were also calculated. Cross-tabulations of the SRH variable (dependent variable) was done with all the independent variables, this also included odds ratios. Correlation test was done using Kendall's tau-b test. For variable measured at nominal and ordinal level, frequencies and percentages were reported. To determine the predictors of SRH logistics regression was employed.

Logistics regression is a statistical technique for predicting the probability of an event, given a set of predictor variables (Sarkar and Midi, 2010). The logistic regression allows one to choose the predictive model for binary dependent variables. The model describes the relationship between a binary response variables and a set of predictors by

estimating the probability of an event (Hosman, 1999; Sarkar and Midi, 2010). The predictors can be discrete or continuous. To use logistic regressions, several considerations have to be made. Logistic regression is sensitive to high correlation among independent (predictor variables). Logistic regression relies on goodness of fit test as a means of evaluating the fit of the model to the data. If the expected frequencies are too small, the analysis may not have enough power. The ratio of variables to be used for prediction to the number of observations is crucial. If there are too many variables and too few observations, the model may not have enough predictive power (Sarkar and Midi, 2010).

For the logistic regression models, SRH responses were recoded into two categories: “very good” or “excellent” (VG/E) versus “poor” or “fair” (P/F). The middle response group “good” was excluded from the regression analysis so that the extreme answers on either end could be compared. This approach has precedent in prior studies (Ismail, 2011; Manor et al., 2000). Gender was recoded as: 1=female, 0=male. Although transgender cases were reported they were not included because there were only two cases. Age was recoded as: 1=late adolescence (16-18 years), 0=early adolescence (13-15 years). Race was recoded as: 1= not white 0=white, non-Hispanic. Insurance status was recoded as: 1=others (Medicaid, MediGap, Medicare, Indian Health Service, other state or government plans, single service plan, no coverage, don’t know their insurance status, don’t wish to answer), 0=private or military. A new variable, years since T1D diagnosis, was created by subtracting age of diagnosis of T1D from the adolescent enrollment age. It was recoded as: 1=13-18 years, and 0=1-12 years. HbA1c was recoded as: 1=HbA1c

>7.5% (59 mmol/mol), 0= HbA1c≤7.5% (58 mmol/mol). This standard was set based on the recommendations of the International Society of Pediatric and adolescent diabetes (ISPAD) (2014) and the ADA (2016). Stress was recoded as: 1= high level of stress (very often or often), 0=low stress level (never, rarely, or sometimes). Insulin delivery was recoded as: 1= injection (injection or pen), 0=insulin pump (partial or complete insulin pump use).

Limitation and Methodological Consideration

Several limitations may have affected the outcomes of this SR. First, a wide range of interventions was used in the reviewed studies, making it difficult to assess the overall impact of particular skills components. Second, all studies used a widely accepted measures of HRQoL, however measurements differed in the constructs being assessed. These measurements are not standardized to enable comparison across measurement scales. Third, most of the studies used small sample sizes. Fourth, there was a wide variation in the duration of the interventions. Making it difficult to determine the optimum duration of an intervention.

A shortcoming of this secondary data is that HRQoL analysis is based on one SRH question. This may lead to under or overestimation of an adolescent's HRQoL depending on how the adolescent feels at the time of the survey. A related limitation is that it is difficult to obtain a complete picture of an adolescent's HRQoL based on one question; an individual's health status may not be successfully encapsulated into one question. For example, the HRQoL measures have several components which, when put together into a composite measure, provide an individual's measurement of quality of

life. Modifications to the T1D Exchange Clinical Registry to account for more quality of life components (e.g., physical, emotional, and social well-being) would help providers gain a better understanding of the factors that may contribute to adolescents' self-rated health status. Another limitation is that this is a cross-sectional survey conducted at a particular point in time and may not reflect an adolescent's improving or declining HRQoL. Cross-sectional studies do not have the ability to account for the effect of time. Longitudinal data may provide the changing HRQoL overtime and the factors contributing to the change among adolescents with T1D.

Human Subject consideration

The George Mason University (GMU) Human Subjects Review Board (HSRB), Office of Research Integrity and Assurance granted an exemption to the study since the study uses pre-existing data and does not involve direct human subjects. The data is de-identified and poses no risk to human subjects. Any fields within the data set that were determined to be unnecessary for analysis are not included in the public data set. Patient IDs, dates and other identifying information has also been removed.

There are no benefits to the subjects associated with this study. However it is expected that the findings may help healthcare providers and diabetes educators to develop programs that may optimally target interventions to adolescents with T1D. The results could also provide individuals with T1D with options for better self-management with the aim of improving HRQoL. The goal of this research was to address the existing gap in the knowledge on DSME interventions that are optimal in improving HRQoL

among adolescents and to identify the factors that are most significant in negatively affecting the HRQoL.

Chapter Summary

This chapter described the research design, methods, and data analysis used to address the study objectives. For objective (A), the SR process is described, including: search strategies, inclusion criteria, variables of interest (DSME interventions and HRQoL measures), and studies quality appraisal. For objective (B), the analysis process for the cross-sectional data , population of interest, sample, variables of interest, measuring instruments, and data collection procedures were discussed. Limitations of the study and ethical considerations were also addressed. The next chapter will present the study results.

CHAPTER FOUR: RESULTS

The goal of the study was to address existing gaps in knowledge about adolescents with T1D. The study specifically addressed DSME interventions that optimized health related quality of life (HRQoL) and identified factors most significant in negatively impacting HRQoL measured by the one self-rated health (SRH) question on the Registry.

A systematic review (SR) was conducted to determine the optimal DSME for improving HRQoL of adolescents with T1D and to identify its characteristics. An analysis of cross-sectional data was conducted to examine the HRQoL of adolescents with T1D and associated factors. This chapter presents the results of the analyses utilized to answer the research questions.

Question 1: What is the optimum DSME intervention for improving HRQoL of adolescents with T1D?

Out of the 14 eligible studies in the SR (Appendix 1), four studies reported interventions with promise to improve HRQoL in the intervention compared to the control. Of these, the Channon and colleagues' RCT study (2010), had only an indirect behavioral skills focus, reported significant improvements in all three constructs of HRQoL outcomes for impact, satisfaction, and worry for the intervention group compared to the control at 12 months. Another quasi-experiment study by Grey and

colleagues (1999, 2000) used a sample of 77 adolescents between 12 and 20 years, with an intervention that focused on development of indirect behavioral skills, particularly coping skill training (CST). The study reported significant improvement on the impact and worry constructs for the intervention group compared to the control at 6 months. For the remaining two studies, Abolfotouh, Kamal, El-Bourgy, and Mohamed (2011) quasi-experiment study, provided support and counseling for 503 adolescents with T1D and Graue, Wentzel-Larsen, Hanestad, and Sovik (2005) RCT study, provided coping and problem solving skills for 116 adolescents with T1D. Both studies had indirect behavioral skills focus. The change in satisfaction was significant ($p<0.002$) in the intervention group in the Abolfotouh and colleagues (2011) study compared to the control. The other study measured only the impact construct and showed significant reduction in the impact of diabetes on intervention participants ($p<0.05$) (Graue et al., 2005).

Three studies (Boogerd, Noordam, Kremer, Prins, Verhaak, 2014; De Wit et al., 2008; Waller et al., 2008) reported improved QoL outcomes only within the intervention group. Boogerd et al. study (2014) comprised 62 participants and Waller et al. study (2008) had 48 participants. Both studies had direct and indirect behavioral skill foci and used PedsQL. Both studies had an overall significant change in HRQoL ($p<0.05$, $p<0.001$ respectively). The last study, De Wit et al. (2008), had a sample of 91 adolescents with T1D and had indirect behavioral skill focus. The study reported significant psychosocial health improvement within the intervention at $p<0.006$.

Question 2: What are the characteristics of the optimum DSME intervention with a skills development component?

The SR suggested that successful interventions provided a combination of direct and indirect behavioral skills or, at the very least, indirect behavioral skills such as stress reduction, coping strategies, problem solving, conflict resolution, goal setting, and avoidance of confrontation. All the four successful programs were between 2 to 15 months in duration.

Question 3: What are the characteristics of the adolescents in the T1D Exchange Clinic Registry?

Based on the secondary data analysis, of the 5799 adolescents with T1D included in the analysis, 51% were male, 53.7%, 13 to 15 years, 77.5% white non-Hispanic; and 64.3% had private or military insurance; 88.6% had T1D for 1 to 12 years; 78.8% had HbA1c levels >7.5%, indicating poor T1D management; 92.3% reported having low diabetes-related stress (indicated as sometimes, rarely or never); and 53.6% used insulin pump rather than injections or pens. Of the total sample, 37.6% ($n=2181$) rated their health as very good, 30.4% ($n=1760$) as good, 21.7% ($n=1258$) as excellent, 8.9% ($n=516$) as fair, and only 1.4% ($n=84$) as poor (Table 3).

Table 3. Sample Demographic and Diabetes Characteristics Across the Five Self-Rated Health Groups.

Self-Rated Health		Poor SRH	Fair SRH	Good SRH	Very Good SRH	Excellent SRH
Total Population (5799)		1.4% (84)	8.9% (516)	30.4 (1760)	37.6% (2181)	21.7% (1258)
Gender	Female (2842)	1.9% (53)	11.3% (320)	33.6% (954)	35.6% (1011)	17.7% (504)
	Male (2956)	1.0% (31)	6.6% (196)	27.3% (806)	39.5% (1169)	25.5% (754)
Age (years)	16-18 (2686)	2.2% (58)	11.0% (295)	34.2% (918)	36.6% (982)	16.1% (433)
	13-15 (3113)	0.8% (26)	7.1% (221)	27.0% (842)	38.5% (1199)	26.5% (825)
Race	Non-white (1306)	3.8% (49)	17.2% (43.4)	37.6% (491)	27.1% (354)	14.4% (188)
	White (4493)	0.8% (359)	6.5% (292)	28.2% (1269)	40.7% (1827)	23.8% (1070)
Health insurance	Other* (2070)	2.5% (51)	15.6% (323)	36.9% (763)	31.3% (674)	13.8% (286)
	Private or military (3729)	0.9% (33)	5.2% (193)	26.7% (787)	41.1% (1534)	26.1% (972)
Glycemic control (HbA1c levels)	Uncontrolled (> 7.5%) (4569)	1.7% (78)	10.5% (481)	33.3% (1523)	36.5% (1666)	18.0% (821)
	Controlled (\leq 7.5%) (1230)	0.5% (6)	2.8% (35)	19.3% (237)	41.9% (515)	35.5% (437)
Stress due to diabetes	Very often or often (1203)	4.9% (59)	21.6% (260)	38.8% (467)	26.7% (321)	8.0% (96)
	Never, rarely, or sometimes (4596)	0.5% (25)	5.6% (256)	28.1% (1293)	40.5% (1860)	25.3% (1165)
Insulin regimen	Injection or pen (2688)	2.3% (63)	12.4% (64.7)	34.6% (931)	32.8% (883)	17.7% (477)
	Pump (3111)	0.7% (21)	5.9% (182)	26.6% (829)	41.7% (1298)	25.1% (781)

*The “other” category for insurance includes those insured through Medicaid (SCHIP or CHIP), the Indian Health Service, or other funding mechanisms that are not private or

military insurance plans as well as those who are uninsured or did not know the answer to this question. Private health insurance includes a diversity of HMOs, PPOs, and other commercial plans. Military health care includes TRICARE and other providers of care to service members and their families.

Question 4: What is the proportion of adolescents with T1D who rated their HRQoL as poor or fair (P/F)?

After dropping those with “good” self-health rating, 14.9% of the remaining adolescents rated their health as poor or fair (P/F) SRH ($n=600$). Sixty two percent of the adolescents in this sample were female, 59% were aged 16-18 years, 66% had public or no insurance, and 93% had high HbA1c.

Question 5: What are the significant factors contributing to lower HRQoL (SRH= “poor” or “fair”) of adolescents with T1D?

This group was more likely than those with very good or excellent (VG/E) SRH ($n= 3438$) to be female (aORs=1.7 (1.4, 2.1)), 16 to 18 years old (aORs=2.1 (1.7, 2.5), non-white (aOR=2.7 (2.2, 3.4)), without private or military insurance (aORs=2.4 (2.1, 3.0)), have HbA1c levels $>7.5\%$ (aOR=3.3 (2.4, 4.7)), use an injection or pen rather than a pump (aORs=2.1 (1.6, 2.4)) report having diabetes-related stress often or very often (aORs=6.1 (5.1, 7.2)) (Table 4). Stress related to diabetes was the most significant predictor of SRH. The overall model was significant (Nagelkerke $r^2 = 0.358$; $p < 0.001$), and the Hosmer-Lemeshow’s goodness-of-fit test ($p = 0.66$) indicated a good model fit.

Table 4. Odds Ratios of Predicting Variables for the Two Self-Rated Health Groups.

		Poor or Fair SRH	Very Good or Excellent SRH	Bivariate ORs (95% CI)	Multivariate ORs (95% CI)
Total Population (4038)		(n=600)	(n=3438)		
Gender	Female (1888)	19.8% (373)	80.2% (1515)	2.1 (1.7, 2.5)	1.7 (1.4, 2.1)
	Male (2151)	10.9% (227)	89.4% (1923)	(Reference)	(Reference)
Age (years)	Mean \pm SD	15.7 \pm 1.6	15.2 \pm 1.7	--	--
	16-18 (1768)	20.0% (353)	80.0% (1414)	2.0 (3.7, 5.4)	2.1 (1.7, 2.5)
	13-15 (2271)	10.9% (247)	89.1% (2024)	(Reference)	(Reference)
Race / ethnicity	Non-white (815)	33.5% (273)	66.5% (542)	4.5 (2.1, 2.9)	2.7 (2.2, 3.4)
	White (3224)	10.1% (327)	89.9% (2896)	(Reference)	(Reference)
Insurance	Other (1497)	26.3% (393)	73.7% (1104)	4.0 (3.3, 5.0)	2.4 (2.1, 3.0)
	Private or military (2542)	8.1% (207)	91.9% (2335)	(Reference)	(Reference)
	Mean \pm SD	10.3 \pm 2.1	8.4 \pm 1.3	--	--
Glycemic control (HbA1c)	Uncontrolled (>7.5) (3046)	18.4% (559)	81.6% (2486)	5.2 (3.8, 7.2)	3.3 (2.4, 4.7)
	Controlled (≤ 7.5) (993)	4.1% (41)	95.9% (952)	(Reference)	(Reference)
Stress due to diabetes	Very often or often (736)	43.3% (319)	56.7% (417)	8.2 (7.0, 10.1)	6.1 (5.1, 7.2)
	Never, rarely, or sometimes (3303)	8.5% (281)	91.5% (3022)	(Reference)	(Reference)
Insulin regimen	Injection or pen (1757)	22.6% (397)	77.4% (1360)	3.0 (2.5, 3.6)	2.1 (1.6, 2.4)
	Pump (2282)	8.9% (203)	91.1% (2078)	(Reference)	(Reference)

CHAPTER FIVE: Discussion

The systematic review revealed that there was a wide range of interventions and diverse mix of skills emphasized in the DSME. Studies varied in the type of intervention provided. Some studies offered behavioral intervention; others psychological intervention; and a few more offered a mix of psychological-behavioral interventions. In almost all of the studies, a team of health professionals with varied backgrounds provided the interventions. Studies also varied by setting, intervention format and duration. There was also a wide range of skills provided. Some studies provided direct and indirect behavioral skills while others provided one or the other. Studies also varied in the HRQoL outcome measurements and the constructs of HRQoL reported.

Studies that reported improvements of the intervention compared to the control had indirect behavioral skills development components such as coping skills. Those that reported improvements within the intervention had both indirect and direct behavioral skills development component such as insulin administration and portion meal control. Interventions that had only a direct behavioral skill focus did not report significant improvement in HRQoL outcomes. This may be due to the developmental stage of the adolescents. At this stage, adolescents have mastered direct behavioral skills such as blood glucose monitoring and insulin administration yet they are still dealing with the social and emotional demands of adolescence. As a result, indirect behavioral skills such

as problem solving, conflict resolution, goal setting, and avoidance of confrontation may be the most useful new tools.

The diverse nature of the studies, skills provided and the QoL constructs measured, made it difficult to determine the effects of the interventions and to identify which interventions were optimal in improving HRQoL. Furthermore, the heterogeneity in the tools and measurements used made comparison among interventions challenging. However, the four successful interventions point to key characteristics of beneficial programs for improving HRQoL among adolescents with T1D. Successful programs provided a combination of direct and indirect behavioral skills or, at the very least, indirect behavioral skills such as stress reduction and coping strategies and lasted for at least two months.

The purpose of the SR was to determine the most effective intervention in improving HRQoL and the characteristics of that intervention. The purpose of the secondary data analysis was to determine the most important factors contributing to lower HRQoL for which the most effective intervention can be designed.

The analysis of T1D Exchange Clinical registry suggested that lower HRQoL among adolescents with T1D is associated with not having military or private insurance, high HbA1c levels, high stress levels and using injections or pens instead of insulin pumps. High stress levels were found to be the most significant predictors of lower HRQoL among adolescents with T1D. It is notable that both the systematic review and secondary data analysis results suggests that stress is significant in affecting HRQoL.

Reducing stress and modifying other factors (insurance, HbA1c, insulin delivery method) may lead to higher HRQoL.

The unexpected result of many adolescents rating their HRQoL as “good”, “very good”, or “excellent” while their HbA1c is high may lead to several explanations. One possible explanation is that the adolescents may be answering this question either in the presence of parents, questionnaire administrators, or peers. Adolescents may not want to appear unable to self-manage their T1D in the presence of others. Another explanation is that adolescents do not perceive high HbA1c as a serious issue or because they do not experience the complication related to high HbA1c level yet. The responsible health care provider may need to discuss with the adolescents and re-educate them about the consequences of having high HbA1c levels, emphasizing intensive self-management and suggesting specific DSME interventions.

Having determined that stress is the most important factor contributing to lower HRQoL, health care providers should design optimum stress reduction DSME interventions focusing on indirect behavioral skills component. To improve HRQoL of adolescents with T1D, annual HRQoL assessment should be conducted to obtain a comprehensive understanding of adolescents’ quality of life, followed by ongoing assessment in order to understand changes in HRQoL during the year. In addition, psychosocial assessment, particularly for stress in adolescents with T1D, should be conducted regularly. In order to help adolescents with T1D manage their stress, indirect skills development such as coping skills training and problem solving skills are recommended. Future studies should include more comprehensive socio-demographic,

psychosocial, and family related factors in their designs, and should implement and test HRQoL interventions in more diverse adolescent populations with T1D.

APPENDIX 1

Reference	Selection bias	Study design	Confounders	Blinding	Data collection	Withdrawals and drop outs	Overall rating
Abolfotouh et al., 2011	Moderate	Strong	Moderate	Moderate	Strong	Weak	Moderate
Boogerd et al., 2014	Weak	Strong	Moderate	Moderate	Strong	Weak	Weak
Channon et al., 2007	Weak	Strong	Strong	Strong	Strong	Strong	Moderate
De Wit et al., 2008	Weak	Strong	Moderate	Moderate	Weak	Strong	Weak
Graue et al., 2005	Moderate	Strong	Strong	Moderate	Weak	Strong	Moderate
Grey et al., 2000	Moderate	Strong	Strong	Moderate	Strong	Strong	Strong
Grey et al., 2013	Moderate	Strong	Moderate	Moderate	Strong	Moderate	Strong
Lawson et al. 2005	Strong	Strong	Strong	Moderate	Strong	Strong	Strong
Loding et al., 2007	Weak	Strong	Weak	Moderate	Strong	Moderate	Weak
Murphy et al., 2012	Weak	Strong	Moderate	Moderate	Weak	Moderate	Weak
Nansel et al., 2007	Moderate	Strong	Strong	Moderate	Strong	Strong	Strong
Newton, 2008	Moderate	Strong	Strong	Weak	Moderate	Moderate	Moderate
Waller et al., 2008	Weak	Moderate	Moderate	Moderate	Strong	Strong	Moderate
Wang et al., 2010	Moderate	Strong	Strong	Moderate	Weak	Strong	Moderate

APPENDIX 2

Query Follow-up

Inbox x

George Serbedzija <GSerbedzija@t1dexchange.org>

to nabualul, Liz

Oct 9

Dear Ms Abualula,

Thank you for your interest in the **T1D** Exchange public data set.

I would like to get permission to use the **T1D** Exchange Registry public database for a dissertation project about quality of life among **T1D** adolescents.

I was able to recognize some questions that are related to quality of life. However, I would also like to know if there are identified questions/variables related to quality of life in this dataset?

The dataset is freely available for research, all we ask is that:

- 1) the data source is acknowledge,
- 2) a disclaimer is added to any publication that the analysis is yours and not from the T1DS Exchange, and
- 3) that you notify us of any publication.

Regarding the QOL questions; I don't have that information, but will ask my colleague, Liz Bevilacqua, to follow up with you to clarify what you need.

George

George N. Serbedzija, PhD
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APPENDIX 3



Office of Research Integrity and Assurance

Research Hall, 4400 University Drive, MS 6D5, Fairfax, Virginia 22030
Phone: 703-993-5445; Fax: 703-993-9590

DATE: January 19, 2016

TO: Renee Milligan, PhD
FROM: George Mason University IRB

Project Title: [849362-1] Factors Associated with Glycemic Control and Quality of Life Among Adolescents with Type One Diabetes.

SUBMISSION TYPE: New Project

ACTION: DETERMINATION OF NOT HUMAN SUBJECT RESEARCH

DECISION DATE: January 19, 2016

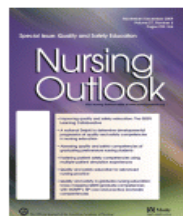
Thank you for your submission of New Project materials for this project. The Office of Research Integrity & Assurance (ORIA) has determined this project does not meet the definition of human subject research under the purview of the IRB according to federal regulations.

Please remember that if you modify this project to include human subjects research activities, you are required to submit revisions to the ORIA prior to initiation.

If you have any questions, please contact Katherine Brooks at (703) 993-4121 or kbrook14@gmu.edu. Please include your project title and reference number in all correspondence with this committee.

This letter has been electronically signed in accordance with all applicable regulations, and a copy is retained within George Mason University IRB's records.

APPENDIX 4



Title: A conceptual model of childhood adaptation to type 1 diabetes
Author: Robin Whittlemore, Sarah Jaser, Jia Guo, Margaret Grey
Publication: Nursing Outlook
Publisher: Elsevier
Date: September–October 2010
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BIOGRAPHY

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