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Type 1 Diabetes: Factors That Affect Youth/Parent Dyads' Health Related Quality of Life and Youth Metabolic Control

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TYPE 1 DIABETES: FACTORS THAT AFFECT YOUTH/PARENT DYADS' HEALTH
RELATED QUALITY OF LIFE AND YOUTH METABOLIC CONTROL

by

Joan Pennington Totka

A Dissertation Submitted in
Partial Fulfillment of the
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ABSTRACT

TYPE 1 DIABETES: FACTORS THAT AFFECT YOUTH/PARENT DYADS' QUALITY OF LIFE AND YOUTH METABOLIC CONTROL

by

Joan Pennington Totka

The University of Wisconsin-Milwaukee, 2016
Under the Supervision of Professor Julia Snethen

Type 1 Diabetes (T1D) is one of the most psychologically and behaviorally demanding of all chronic illnesses for youth (preadolescents and adolescents) with T1D and their primary caregivers. T1D affects one out of every 400 to 600 youth, making it one of the most common chronic conditions in school-aged youth in the United States. Advances in technology and treatment continue; however, more than 80% of youth do not meet goals for metabolic control measured by glycosylated hemoglobin (A1c test result). A higher A1c increases the risks for blindness, nephropathy, neuropathy, amputations and heart disease. The purpose of this secondary analysis was to explore associations of the health-related quality of life (HRQOL) survey and subscales of youth/parent dyads and the A1c of youth with T1D. Additionally, the study examined associations between other individual, family, and diabetes specific factors such as age, gender, ethnicity, socioeconomic status (SES), and use of technology with both HRQOL and A1c of youth with T1D. Results of this study indicate that the youth with T1D's A1c is predicted in part by the youth's HRQOL and their ethnicity. Poor A1c was associated with lower HRQOL of youth with T1D. Analysis of preadolescents aged eight to twelve and adolescents aged thirteen to sixteen indicated that their A1c was predicted by different factors. The factor most significantly predictive of A1c of preadolescents was SES; however, the need to eliminate

all diversity from this analysis due to the outlier status of non-white youth suggested particular vulnerability associated with ethnicity in that age group. The factors most predictive of A1c results in adolescents were two subscale scores; adolescent HRQOL Treatment 1 subscale and parent HRQOL Social Functioning subscale were predictive of A1c, which may have clinical implications. Tailored interventions based on developmental and individual needs may impact outcomes for youth with T1D and their parents.

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To

My husband Vince Totka, as this would have never happened without his love, help and support,

My parents, the late Ken and Grace Pennington, who considered public education a right and a gift,

My brothers Dr. Kenneth Pennington, PhD, Dr. Michael Pennington, PhD and Dr. William Pennington, MD who blazed the path before me,

My children Vincent and Alaina who loved me and encouraged me through this journey,

The children with T1D and their families that I have been honored to work with for over two decades, who have shared their lives, struggles and successes with me.

My furry study buddy Gizmo, and our PhD pups Hana and Otto

And especially the late Hugo.

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LIST OF ABBREVIATIONS

ADA- American Diabetes Association

A1c- Glycosylated Hemoglobin test

CGM- Continuous Glucose Monitor

DKA- Diabetic Ketoacidosis

HRQOL- Health-Related Quality of Life

ISPAD- International Society for Pediatric and Adolescent Diabetes

IDF – International Diabetes Federation

IFSMT- Individual and Family Self-Management Theory

MD- Mood Disorders

MDD- Major Depressive Disorders

Parent- primary caregiver, mother, father, grandparent, stepparent

SES- Socioeconomic status

T1D- Type 1 Diabetes

T2D- Type 2 Diabetes

Youth (preadolescents and adolescents)

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CHAPTER 1: Introduction

This chapter begins by introducing the problem, significance, diagnosis, and incidence of Type 1 Diabetes (T1D) in children and adolescents (youth). To familiarize the reader with how T1D impacts youth with T1D, their family, and their overall health-related quality of life (HRQOL) and their metabolic control, the theoretical framework of the Individual and Family Self-Management Theory (IFSMT) (Ryan & Sawin, 2009) will be introduced as the conceptual framework for the study design. Next, the major concepts that will be explored in this study will be defined. Finally the purpose, hypotheses, research questions, overview of methodology, as well as the gaps and contribution to professional nursing knowledge and practice addressed by this study will be described.

Problem Statement and Significance

T1D is considered one of the most psychologically and behaviorally demanding of all chronic illnesses for both youth with T1D and their primary caregivers (Graue, Wentzel-Larsen, Hanestad, & Sovik, 2005; Whittemore, Jaser, Chao, Jang, & Grey, 2012). Youth with T1D sustain their lives with exogenous insulin injections. There has been great advances in the technology used to support the delivery of insulin and glucose measurement to achieve within goal metabolic control (Daneman, 2006). However, even with better technology and more stringent guidelines, more than 80% of youth are unable to meet national and international goals for metabolic control (Wood, et al., 2013). Metabolic control is represented by the glycosylated hemoglobin (A1c) test result, and metabolic goal is based on national and international guidelines. At the time of this study the goal for metabolic control was an A1c result of less than 7.5% for all people with T1D (Chaing, et al., 2014).

There is no cure for T1D. Continuous infusion or injections of insulin are needed every day to sustain the life of a person with T1D (Atkinson, Eisenbarth, & Michels, 2014; Daneman, 2006; Eisenbarth, 1986). Youth could experience short-term and long-term risks associated with poor metabolic control of T1D. In the short-term, poor metabolic control in youth with T1D increases the risk of their death due to diabetic ketoacidosis (DKA). DKA is the primary cause of death for youth less than twenty years old with T1D, and is caused by a lack of insulin (Katz, 2015; Randall et al., 2011). Long-term risks of poor metabolic control in people with T1D include blindness, nephropathy, neuropathy, amputations and heart disease (Diabetes Control and Complications Trial (DCCT), 1993; The Diabetes Control and Complications Trial/Epidemiology of Diabetes Interventions and Complications (DCCT/EDIC, 2005). The physical, emotional, and social impact T1D has on youth and their families can affect their health-related quality of life (HRQOL) (Malakonaki, Eiser, & Mamoulakis, 2011).

Background and Diagnosis

T1D is an autoimmune condition that destroys the beta cells that produce insulin in the pancreas. Although there must be a genetic predisposition for T1D to occur, more than 80% of families are not aware of their genetic link to T1D (Parkkola, Harkonen, Ryhanen, Ilonen, & Knip, 2013b). The autoimmune process must be triggered, probably by one or more environmental factors (Atkinson, Eisenbarth, & Michels, 2014). Although T1D can be triggered in any decade, it is most often triggered during childhood, either when children are between the ages of five to seven years old or at the start of their puberty (Atkinson et al., 2014). Symptoms of T1D at diagnosis reflect the lack of insulin and typically include: weight loss, thirst, high blood sugar, glycosylated hemoglobin (A1c) greater than 6.35, and ketones in the urine, which are the first signs of metabolic decompensation (Ehehalt, et al., 2010). Left untreated, T1D

symptoms progress to severe dehydration, diabetic ketoacidosis, coma, and death (Ehehalt et al., 2010). Before insulin was isolated in 1921, T1D was fatal within eight to twelve weeks of the onset of symptoms, this continues to be true in countries without access to insulin (Beran, Yudkin, & Atkinson, 2013). Scientists understand the pathophysiology behind what happens when the autoimmune process that occurs in T1D is triggered; however, they continue to struggle in understanding the potential environmentally based triggers of T1D (Atkinson et al., 2014; van Belle, Coppieters, & von Herrath, 2011).

Incidence and Significance

T1D affects one out of every 400 to 600 youth, making it one of the most common chronic conditions of youth in the United States (Reid, et al., 2013; International Diabetes Federation (IDF) Atlas, 2013). The overall incidence of T1D is rising at a rate of 3% per year, with the highest rate increases in children under five years old (Patterson, Dahlquist, Gyürüs, Green, & Soltész, 2009). Because of the dramatic rise in incidence in T1D in children less than five years old, it is estimated that by 2020 there will be a 70% increase of children less than fifteen years old with T1D (Patterson et al., 2014).

Introduction of the Individual and Family Self-Management Theory (IFSMT)

Ryan and Sawin (2009) identified IFSMT as a descriptive middle-range theory related to the individual and family self-management of chronic illness. Within this theory, Ryan and Sawin identified their assumptions, defined their concepts, and proposed the relationships between those concepts related to family and individual self-management and short-term (proximal) and long-term (distal) outcomes of self-management in chronic illness. IFSMT added to the self-management literature by focusing on individuals, relationships within families, or the

family unit as a whole, however that family defines itself (Ryan & Sawin). In particular, this theory emphasized how the family impacted and is impacted by the person with chronic illness. The IFSMT supports the use of individual and family-centered interventions to impact both the context, which are the risk and protective factors, and the process, which is the self-management process (Ryan & Sawin, 2009). For the purposes of this study, the risk and protective factors, the self-management process, and the proximal and distal outcomes associated with T1D to illustrate the fit of this model adapted for use for youth with T1D and their families were identified and these will be discussed fully in Chapter 2. (Figure 1 p. 115).

Assumptions of IFSMT

Ryan and Sawin (2009) identified that self-management included the purposeful incorporation of health related behaviors into daily functioning. Families engaged in self-management lessened the impact of illness, and supported and/or facilitated the management of complex medical conditions (Ryan & Sawin). An important aspect of this assumption was that how the family managed the health condition of their child reflected that family's individual and overall values in ways that are meaningful to that family (Ryan & Sawin). Families of youth with T1D need to incorporate health-related behaviors of T1D into every aspect of their daily functioning.

Risk and Protective Factors of Successful Self-Management in Chronic Illness

There are risks and protective factors that relate to the condition of T1D itself, the physical or social environment, and the individual or family factors that either support or are barriers to the youth and families' physical, emotional and social well-being (Ryan & Sawin). There are also factors related to the self-management process, short-term (proximal), and long-

term (distal) outcomes that impact health, health-related quality of life, and financial impact of T1D outlined in the IFSMT. Variables that represent individual, family, and diabetes related attributes that may be risk or protective factors for long-term outcomes of health related quality of life and metabolic control were identified in the literature, and will be described in Chapter 2.

Conceptual Definitions of terminology used in this study

Well-being of youth with T1D and their primary caregivers. The term well-being matches the World Health definition which is that health is a state of complete physical, mental, and social well-being, not merely the absence of disease or infirmity (*Declaration of Alma-Ata*, 1978; Samarasekera, 2008). Ryan and Sawin (2009) described the IFSMT framework as focusing on the youth with chronic illness and their families; not only the health and well-being of the youth with chronic illness, but how the families' health and well-being are impacted as well by the youth's chronic illness.

Health-Related Quality of Life. The over physical, psychological, and social health and well-being of youth with T1D or other chronic illness, is described as the Health-Related Quality of Life (HRQOL). HRQOL has emerged as an informative and widely accepted health outcome measure to assess the multidimensional impact of a chronic illness on the well-being of families (Ingerski, 2010). HRQOL includes physical, mental, social well-being, functioning domains, and is an important concept assessing the impacts of the youth and their families' current health status and its treatment on the youth's everyday living (Knez, Stevanovic, Vulić-Prtorić, Vlašić-Cicvarić, & Peršić, 2013; Varni, Burwinkle, & Lane, 2005).

Metabolic Control. The overall metabolic control in T1D is based on the results of glycosylated hemoglobin (A1c) blood test results, which represent the average blood sugar levels over a ninety day period (Lenters-Westra & Slingerland, 2014). The international standards for

diabetes metabolic control are based on the results of the Diabetes Care and Complications Trial (DCCT, 1993). In 2014, the metabolic control standards for T1D in youth in the United States moved from the previous age-based standards to the international standard for all people of A1c result of less than 7.5% (Chiang et al., 2014).

Purpose of the Study

The purpose of this study was to explore associations of the HRQOL of youth/parent dyads and the metabolic control of youth with T1D. Additionally, the study examined associations between the youth/parent HRQOL survey and subscales with the metabolic control of youth with other individual, family, and diabetes specific factors such as age, gender, ethnicity, socioeconomic status, and use of technology.

Research Questions and Hypotheses

Research Questions.

1. What is the association between diabetes treatment complexity (pump and/or continuous glucose monitor vs. injections) and metabolic control in youths with T1D?
2. What is the association between diabetes treatment complexity (pump and/or continuous glucose monitor vs. injections) and health-related quality of life of youth with T1D?
3. What is the association between individual factors (youth age, gender) on metabolic control and health-related quality of life of youth with T1D?
4. What is the association between family factors (ethnicity, family social economic status) on metabolic control and health-related quality of life of youth with T1D?

5. What is the association between youth with T1D health-related quality of life and the health-related quality of life score of their parent?
6. What is the association between the metabolic control of youth with T1D and their parent's health-related quality of life?
7. Is the youth's metabolic control associated with the psychosocial subscales of the parent's health-related quality of life survey?
8. What is the association between the youth with T1D's health-related quality of life and metabolic control of the youth with T1D?

Hypotheses.

1. There will be an association between diabetes treatment complexity (pump/continuous glucose sensor vs. injections), and youth with T1D's health-related quality of life and ability to meet metabolic treatment goals.
2. There will be an association between gender, age, ethnicity and socioeconomic status and youth with T1D's health-related quality of life and ability to meet metabolic control goals in youth with T1D
3. Youth with T1D with higher health-related quality of life will have parents with higher health-related quality of life.
4. Youth with better metabolic control will be associated with parents with higher health-related quality of life.
5. Youth with T1D with higher health-related quality of life will be associated with better metabolic control.

Overview of the Methodology

This study was a secondary analysis of the baseline data from a multi-site interventional study of youth with T1D and their parents (N = 214). Four of the dyads were eliminated from

the analysis as three were missing the A1c results of the youth and one was missing the HRQOL scores of the parent, so the final data set included 210 youth/parent dyads. Individual, family, and diabetes specific factors such as age, gender, ethnicity, socioeconomic status, and use of technology were analyzed with the total score data from the youth with T1Ds' HRQOL, the parents' HRQOL, and baseline A1c results for all youth.

The youth with T1Ds' HRQOL was measured by the Diabetes PedsQL™ surveys (Varni et al., 2003) and the parent's PedsQL™ Family Impact Module of PedsQL™ surveys (Varni, Sherman, Burwinkle, Dickinson, & Dixon, 2004). Both of these tools are reliable and valid measures for assessing HRQOL. Analysis was performed using both the total scores and subscales of these surveys.

Gaps in Nursing Knowledge

Wood et al. (2013) identified that over fifty percent of youth overall and almost 80% of youth ages thirteen to eighteen did not meet A1c goals, which increased their risk of both short term and long term complications of T1D. More than 80% of all youth fail to meet the metabolic control guidelines identified in 2014 (Chiang et al., 2014). Due to the significant morbidity and mortality associated with poor metabolic control it is imperative that nurses understand the impact T1D has on the family as a whole. In many clinics, nurse practitioners, clinical nurse specialists, and nurse educators are the primary care providers to families and youth with T1D; providing ongoing assessment as well support of the care provided both at home and at school (Chiang et al., 2014; Siminerio et al., 2014). T1D is a chronic illness for which there is no cure. Supporting the metabolic control and the health-related quality of life of youth and families with T1D are at the core of addressing the health care needs and outcomes of those with T1D. Therefore, although nurses are uniquely qualified to provide ongoing management, support, and

education of youth with T1D and their families, the factors that improve the quality of life and metabolic control in youth with T1D are not well understood. It is also not understood how psychological health of the parent might impact the quality of life or metabolic control of the youth with T1D.

Contributions to Nursing Knowledge

Nursing must play a central role in helping those with chronic illness meet the challenges they face in the care and management of their illness, as the focus on health and well-being are core activities of nursing (Grey, et al, 2015). The science of self-management in chronic illness continues to be a priority for the National Institute of Nursing Research (NINR), with a focus on improving quality of life and reducing the burdens of illness (Grey, et al., 2015). Some studies have found associations between the negative health outcomes of youth with T1D and the depressive symptoms in parents (Butwicka, Zalepa, Fendler, Szadkowska, & Mlynarski, 2013; Clayton et al., 2013; Wu, Hilliard, Rausch, Dolan, & Hood, 2013). The current study proposes that the HRQOL and the metabolic control goals of youth with T1D may be impacted by supporting the psychosocial health of parents of youth with T1D. If the hypotheses of this study are supported, it may suggest that there are benefits to the provision of targeted family-centered interventions that support the health-related quality of life of youth and families, which may in turn improve the metabolic control of youth with T1D. Subsequently, this improved metabolic control of youth with T1D may lead to decreased morbidity and mortality as well as decrease in overall health care costs in this population.

Researcher assumptions

The assumptions of the IFSMT was used as the conceptual framework of this study, including the impact of individual, family and diabetes related contextual attributes as risks or

protective factors to distal or long-term outcomes of the youth's well-being represented by health-related quality of life an overall metabolic control.

Chapter Summary and Organization of the Dissertation

This chapter introduced the issue of the inability of youth with T1D and their parents to meet within metabolic control standards in the majority of youth with T1D, even with continuous improvement of the tools available to support their control. This chapter suggested that there might be an association between health-related quality of life in both parents and youth with T1D, and the metabolic control of those youth. The Ryan and Sawin (2009) IFSMT suggested that contextual factors, such as treatment complexity, socioeconomic issues, age, and ethnicity of the youth with chronic illness impacted both the parent and youth quality of life, as well as the youth's overall ability to meet goals of metabolic control. If the hypotheses for this study are supported, it may suggest that the health-related quality of life and overall metabolic control of youth with T1D may be impacted by interventions targeted to the psychosocial health, social functioning, family relationships, as well as health-related quality of life of parents of youth with T1D. Chapter 2 will include an expanded review of the literature that is directly related to the purpose of this study and the conceptual framework. The conceptual framework of IFSMT will guide the structure of the literature reviews for this study. In Chapter 3 the methodology and rationale for this secondary analysis of baseline data of a quantitative study is described. Included is a description of the research setting and sample from which the data was obtained, as well as the data collection de-identification and analysis procedures.

CHAPTER 2: Review of Literature and Conceptual Framework

Introduction

The purpose of this study was to explore associations of the health-related quality of life (HRQOL) of youth/parent dyads and the metabolic control of youth with Type 1 diabetes (T1D). Additionally, the study examined associations between the youth/parent HRQOL survey and subscales with the metabolic control of youth with other individual, family, and diabetes specific factors such as age, gender, ethnicity, socioeconomic status, and use of technology.

It has been established in the literature that in the United States 80% of youth with T1D do not meet the current goals for metabolic control that have been established by national and international guidelines as protective of long-term complications of their disease (Wood et al., 2013). It has also been established that the long-term complications of T1D are linked to metabolic control (DCCT, 1993; DCCT/EDIC, 2005). Additionally, the importance of looking beyond metabolic control to the overall HRQOL with youth with T1D and their families is recognized as an important measure for youth with T1D and their families (Varni & Limbers, 2009). Therefore, an in-depth review of the literature was completed in order to review factors that may impact the overall well-being and HRQOL of youth with T1D and their families and subsequently the affect of these factors on metabolic control.

Chapter 2 begins by describing the conceptual framework that grounds this study, the Individual and Family Self-Management Theory (IFSMT) (Ryan & Sawin, 2009). Self-management of T1D is an ongoing, unrelenting process for youth with T1D and their families. The diagnosis of T1D is the primary antecedent for the self-management of T1D, so a brief review of the diagnosis and differentiating factors, as well as the literature that has explored individual factors associated with the successful self-management, will be synthesized. The

conceptual framework of IFSMT was based on the literature related to individual and family self-management, and brings the perspective of total family impact that adds to the literature. Accordingly, the self-management and family systems literature as it is related to T1D was reviewed to gain a better understanding of how that literature might inform the study of youth with T1D and their families. Next, the outcomes of self-management described in IFSMT, health status and the concept of self-management will be described. These outcomes are 1) short-term, and long-term complications; and 2) health-related quality of life (HRQOL), perceived as well-being, or physical, emotional and social health; and 3) the cost of care and disability as it is impacted by short-term and long-term complications of diabetes self-management. Finally, there will be a review of literature related to the science behind the primary outcomes addressed in this study, which are HRQOL, and metabolic outcomes. Thus, research related to the factors that impact HRQOL in the study of youth with chronic illness and their families and factors that impact the outcome of metabolic control of T1D will be reviewed in-depth.

Conceptual Framework: Individual and Family Self-Management Theory (IFSMT)

Ryan and Sawin (2009) identified IFSMT as a descriptive middle-range theory related to the individual and family self-management of chronic illness. Within this theory, as shared in Chapter 1, Ryan and Sawin identified their assumptions and their definition of self-management. There are aspects of this theory that are similar to many of the ideas presented in other frameworks and models of self-management described in the literature (Drotar, et al., 2013; Gray, Knafl, & McCorkle, 2006; Grey, et al., 2015; Lorig & Holman, 2003; Marrero, et al., 2013). However, IFSMT added to the self-management literature by focusing on individuals, relationships within families, or the family unit as a whole, however that family defines itself (Ryan & Sawin). This study will use data from dyads of youth with T1D and their primary

caregiver; which although designated as “parent” in this narrative, could be a mother, father, step-mother, step-father, grandparents, or other care provider. To test the fit of the IFSMT model with youth with T1D and their families, the model was adapted with permission from the original authors to identify T1D specific examples in all of the areas of IFSMT (See Figure 1 p. 115).

IFSMT emphasized how the family impacts and is impacted by the person with chronic illness. IFSMT interpreted process components of self-management and proposed the use of both proximal (short-term) and distal (long-term) outcomes (Ryan & Sawin, 2009). The context, or risk and protective factors included; 1) condition specific factors, 2) physical and social environment factors, and 3) individual and family factors. The self-management process had three components; 1) knowledge and beliefs, 2) self-regulation skills and abilities, and 3) social facilitation. The proximal (short-term) outcomes included individual and family self-management behaviors that supported health maintenance, and the cost health maintenance services. Distal (long-term) outcomes were described as; 1) the health status, 2) quality of life, and 3) the cost of health related resources.

Context or Risk and Protective Factors

Risk or protective factors are divided into three categories: 1) Condition-specific factors; 2) Physical and Social Environment Factors; and 3) Individual and family factors. The following section introduces these aspects of IFSMT with some brief examples related to T1D.

Condition specific. Ryan and Sawin (2009) describe these factors as representing the physical, structural, or functional characteristics of a condition. This included the prevention of the condition (if applicable), its treatment, or the behaviors needed to manage the condition. Management during wellness and illness, changes in treatment, as well as usual condition

trajectory (stability of physiologic health status of the condition), were all factors of the IFSMT (Ryan and Sawin). In T1D there is currently no prevention or cure, however there are treatments unique to this disease process such as daily insulin injections or use of an insulin pump, and blood sugar monitoring or use of a continuous glucose monitoring (CGM) device (Atkinson et al., 2014). There are also physical, emotional, and social factors for both individual youth with T1D and their family that impact the severity of the illness (Whittemore et al., 2012).

Physical and Social Environment. The descriptions of physical and social environmental factors of IFSMT bring in many of the aspects outlined in the ecological model (Marrero, et al, 2014). These are the physical or social factors such as access to health care or specialty healthcare providers, transitions to new providers or care settings, transportation, neighborhoods, schools, work, culture, and social support that either enhances or impedes the individual and/or family self-management (Ryan & Sawin, 2009). In T1D, access to pediatric diabetes expertise can be difficult to find, especially in rural areas, which could result in families having long commutes to access appropriate care (Chiang, et al, 2014). The lack of access to insulin and healthcare is still the primary cause of death for youth with T1D globally (Beran, 2014).

Individual and Family Factors. Ryan and Sawin (2009) described characteristics of the individual and family that enhance or diminish self-management. These characteristics are cognitive status, developmental stages, family cohesion, literacy and resourcefulness. In T1D Drotar (2013) described family conflict as predictive of a decreased level of metabolic control, as well as the child's level of puberty (increased hormones of puberty decreases metabolic control). Issues such as gender, age, cognitive ability and residual insulin production have also been described as having relationships with overall metabolic control in T1D.

Process. This section of IFSMT identified the knowledge and beliefs that impacted self-management including information about the health condition, self-efficacy, desired outcomes and congruence of personal goals with treatment goals (Ryan & Sawin, 2009). This section also identified skills and abilities needed to support self-management such as goal setting, decision-making, self-evaluation and emotional control (Ryan & Sawin). All of these aspects are important in the self-management of T1D. This study is not focused on the process of self-management; however, many of the individual and family-centered interventions that support outcomes of care in T1D are focused on this area of the theory, and may be suggested by study results.

Proximal Outcomes. The proximal outcomes reflect the short-term goals and care of T1D and include performing daily treatments, attending clinic visits, and managing symptoms (Ryan & Sawin, 2009). In T1D, the proximal outcomes are what lead to positive or negative long-term or distal outcomes. In general, the short-term complications of T1D that youth experience after diagnosis are hypoglycemia (low blood sugar) reactions that result from too much insulin; and hyperglycemia (high blood sugar) that results from too little insulin to meet the body's needs. Hypoglycemia can result from a mismatch of the insulin dose with food or exercise. An extended period of insufficient insulin can that be triggered by rapid growth, illness, or missed injections that could develop into diabetic ketoacidosis (DKA) and death if not well managed (Chiang, et al., 2014).

Distal Outcomes. The distal outcomes reflect long-term results of self-management. Overall health status and/or the disease trajectory are reflected in this category (Ryan & Sawin, 2009). In T1D improved youth and parent HRQOL has been associated with increased self-management behaviors (Fisher, et al., 2005; Marrero, et al., 2013). Glycosylated hemoglobin, or

A1c test result, has been a standard long-term measure for overall metabolic control (ADA, 2014). The cost of care related to T1D can be impacted by frequent hospital or emergency room (ER) visits which can sometimes be attributed to poor self-management, lack of resources, or emotional issues in the youth or parent (Butwicka, et al., 2013; Clayton, et al., 2013, Randall et al., 2011).

Self-management of chronic conditions and T1D

Schilling, Grey and Knafl (2002) used a rigorous process of concept analysis identified by Rodgers (2000) to identify the antecedents, attributes and consequences of self-management of T1D. In their analysis of self-management, Schilling et al. reviewed ninety-nine articles from nursing, medicine, and psychology related to self-management. They found no significant differences in how self-management was described across disciplines. Therefore, Schilling et al. created a definition and identified three essential attributes: process, activities, and goals. After reviewing the current literature related to self-management and incorporating the factors of the IFSMT, this researcher created a concept map for self-management of T1D. The concept map included the processes and essential attributes identified by Schilling, Grey and Knafl, and added current care practices. This author also identified affecting factors, which are part of the risk and protective factors of the IFMT theory, but are not antecedents or process related. This process helped to clarify what parts of self-management this study would address, specifically the antecedents, affecting factors and the consequences (Figure 2 p. 116).

Antecedents to Self-Management of Type 1 Diabetes

Diagnosis of T1D

The primary antecedent to the care of youth with T1D and their parents is the diagnosis of T1D. T1D in youth is diagnosed as a result of the combination of high blood sugar, ketones in

the urine, and the presence of autoantibodies (Kuhreiber, et al., 2015). The risk of delayed treatment for T1D can be devastating for both short-term and long-term complications. Short-term risk is potentially life-threatening DKA (Cameron, et al., 2014; de Vries et al., 2013; Lokulo-Sodipe, Moon, Edge, & Davies, 2014); while long-term risk of DKA at diagnosis could be a persistent result of “metabolic memory” that contributes to the development of future long-term complications of T1D (Ceriello, Ihnat, & Thorpe, 2009).

The primary differentiating diagnosis for T1D in non-obese youth with a blood glucose of greater than 200 is transient hyperglycemia. Eehalt et al. (2010) studied 184 youth in Germany who presented to the emergency room with a blood glucose greater than 200. All of the youth had an A1c test and it was determined that any youth with T1D tested higher than 6.35% on their A1c test with 100% sensitivity and specificity. This result was lower than the 6.5% originally identified by the expert panel, and is much more effective for early identification of T1D than an oral glucose tolerance test. This is important because early diagnosis of T1D is protective for preventing DKA and potentially supports life-long benefits of increased residual insulin production (Eehalt et.al.).

Heredity. Although T1D is a genetic auto-immune disease, the family link to the diagnosis is usually unknown or not present at diagnosis (Parkkola, Harkonen, Ryhanen, Ilonen, & Knip, 2013a). Parkkola et al. conducted a study using national registry data that included 92% of the population of youth with T1D in Finland. The total population of the registry was 2,663 youth diagnosed from 2002 to 2006. Those youth diagnosed at age fifteen years old or less, with complete records, met the inclusion criteria of the study, leaving a sample of 1,488 youth. The first child to be diagnosed from each family was considered an index case. Of these index case youth, 324 children (22%) were considered familial as they had either a first or second-degree

relative with Type 1 at diagnosis. The remaining 1,164 (78%) youth had no known first or second-degree relative, so were considered sporadic cases; however, the HLA typing of the autoimmune process across both familial and sporadic cases of T1D were similar, suggesting similar pathology across the two groups.

Having a first or second-degree relative in the Parkkola, et al. study and other studies was protective in that the newly diagnosed child was less likely to present in diabetic ketoacidosis (DKA). When the family was aware of the symptoms of T1D, they sought health care before the disease had advanced to DKA (de Vries et al., 2013; Parkkola et al., 2013a; Usher-Smith, Thompson, Ercole, & Walter, 2012). Usher-Smith et al. conducted a systematic review of 65 studies of newly diagnosed youth with T1D that included 29,000 children in 31 separate countries. The rate of DKA at diagnosis ranged from 13% to 80% in those countries, and was more frequent in poorer countries. This is significant not only due to the risk of mortality associated with DKA, which would be an immediate danger; but children with more severe presentation at diagnosis are more likely to have less residual insulin production which is protective of both severe hypoglycemia and long-term complications (Kuhntreiber et al., 2015; Sorensen et al., 2013).

Condition-Specific Factors

Insulin Requirements. After the remission period, when T1D is normally much easier to manage, there are two factors that emerge that could impact self-management. The first is residual insulin production. Residual insulin production can vary from person to person and can strongly affect insulin dosing needed due to sensitivity factors as well as increase the difficulty that patients and families have when attempting to maintain overall blood sugar control (Kuhntreiber, et al., 2015; Neylon, et al., 2013). The unit of insulin per kilogram of weight ratio is

an indicator of how much endogenous insulin is available. Pre-pubertal children need approximately 0.5-0.75 units of exogenous insulin per kilogram. Due to hormonal changes, adolescents often require 1.5 units per kilogram or greater of exogenous insulin (Atkinson et al., 2014). The unit per kilogram of insulin drops to about 1.0 unit per kilogram for adults (Chiang, et al, 2014).

Residual Beta-cell Function. C-peptide production indicates residual endogenous insulin production in the beta cells of the pancreas. Improved technology has resulted in evidence that while c-peptide levels decrease across the lifespan of someone with T1D, low levels of c-peptide can exist well beyond the theoretical one to two years immediately following diagnosis (Kuhreiber et al., 2015; Sorensen et al., 2013). When youth and adults with T1D continue to produce even a small amount of endogenous insulin, reflected by c-peptide levels from 51- 200 pmol/l, they are more likely to meet metabolic control goals which reduce the risk for complications. They are also less likely to have severe hypoglycemic reactions, as their bodies are able to support the regulation of their blood sugar (Kuhreiber et al.). This may indicate benefits in treatments designed to target the preservation of even a small amount of insulin production could have significant impact on metabolic outcomes and HRQOL. Most children on higher than normal doses of exogenous insulin for their size have lower levels of remaining endogenous insulin, but this could also be caused by other insulin resistant factors, such as family history of type 2 diabetes (T2D) or metabolic syndrome (Chiang, et al., 2014, Drotar, et al., 2013).

Short-term complications T1D

For youth with T1D and their families, the effect of insulin must be continuously monitored in order to balance the short-term effects of too much insulin (hypoglycemia), which

can lead to coma and/or death; and too little insulin (hyperglycemia) or diabetic ketoacidosis (DKA) which continues to be the leading cause of death in youth with T1D (Katz, 2015).

Diabetic Ketoacidosis. Children are most at risk for DKA at time of diagnosis. They are even more at risk if they present in diabetic ketoacidosis at a non-pediatric facility, and are treated with adult guidelines. Adult guidelines do not differentiate treatment by weight and grossly overload most children with insulin and fluids, this can result in cerebral edema which causes ongoing morbidity or death (Cameron, 2014). The risk of death in DKA varies from 13 to 80 percent depending on the country, region and/or state and family history of T1D (de Vries et al., 2013; Lokulo-Sodipe et al., 2014; Rewers, 2015).

Severe hypoglycemia. Another risk factor or barrier to self-management is the youth's reactions to hypoglycemia. The most significant risk factor for severe hypoglycemia is a previous incidence of severe hypoglycemia (Chaing, et al. 2014, Feckelton, Sharp & Mullan, 2013). Fear of hypoglycemia by parents and youth is well documented in the literature as a barrier to self-management (Haugstvedt, et al., 2010, Feckleton, Sharp, & Mullan, 2013; Little, et al., 2015). Children less than five years of age are most at risk for residual complications of hypoglycemia (Little, et al., 2014; Siminerio, et al., 2014, Sorensen, et al., 2013). Severe hypoglycemia has also been linked to low levels of residual insulin production, as measured by low levels of c-peptide (Kuhtreiber et al., 2015; Sorensen et al., 2013).

Long-term outcomes of self-managed T1D

Complications. Long-term complications of hyperglycemia first affect the micro-vascular systems. Damage to these small vessels result in retinal bleeds and blindness (retinopathy); kidney damage (proteinuria) and kidney failure (nephropathy); as well as well as damage to neurological systems, causing neuropathy and circulatory impairments (neuropathy

and amputation) (DCCT, 1993). Long-term complications of T1D, like T2D, can result in damage to the macro vascular systems, resulting in cardiac disease (cardiac myopathy) (DCCT/EDIC, 2005). Using current methods of treatment for T1D effectively, youth with T1D can expect that their lifespan will be decreased by ten years (Vehik & Dabelea, 2010).

Cost of Care. Loss of health and resulting costs of care are important negative outcomes of T1D that may be able to be mitigated by interventions that support the emotional, psychological and physical health of youth with T1D and their families. Randall et al. (2011) identified that one out of four dollars spent on diabetes care in the United States was spent on the care of DKA. DKA is caused by the lack of insulin, which can be caused by accidental or intentional insulin omission due to emotional, psychological reasons or lack of access to healthcare resources. Randall et al. further identified that one out of two dollars spent overall for diabetes care are spent on people with T1D that have repeated DKA episodes. It has also been found that healthcare costs for youth with T1D increased with the presence of depressive symptoms in parents (Butwicka, et al., 2013; Clayton et al., 2013).

The most important long-term outcomes, and the primary focus of the current study of youth with T1D and their parents, are HRQOL and metabolic control. Therefore, it is important to explore the literature for factors that impact the HRQOL of youth with T1D and their families as well as factors that impact the metabolic control of youth with T1D. It is hoped that if those factors are studied and understood, interventions to support improved outcomes can be developed. For that reason, more extensive literature reviews of factors that impact HRQOL of youth with T1D and their families and metabolic control of youth with T1D are included in this next section.

Review of Literature: Factors that Impact HRQOL in Youth with T1D

Introduction

Monitoring health-related quality of life (HRQOL) of adolescents in clinical practice is increasingly recommended for many chronic illnesses, but it is becoming a standard of care in T1D (de Wit, Delemarre-van de Waal, Pouwer, Gemke, & Snoek, 2007; Malakonaki et al., 2011). Both generic HRQOL tools and diagnosis specific HRQOL tools are important to use when assessing those with chronic illness for different reasons. De Wit, et al. suggested that generic HRQOL tools have the advantage of being used for healthy controls. De Wit, et al. also suggested that disease specific tools can give information that is specifically relevant to the youth with T1D and their parents and healthcare providers who care for this vulnerable population. de Wit et al. reviewed four generic and five diabetes specific questionnaires. The result of the study was that the PedsQL and the KINDL-R were identified to be the most suitable instruments (de Wit et al.). In another review of these measures, there was criticism related to the lack of congruence between the youth's assessment of their HRQOL and their parents' assessment of the youth's HRQOL. There was also concern that both youth and parents must be included in the assessment of HRQOL (Upton, Lawford, & Eiser, 2008). Varni and Limbers (2009) suggested that, "part of the process of improving the quality of health care includes measuring HRQOL outcomes from the perspective of children and their parents on a routine basis, consistent with a consumer-based health care system approach (p. 858)." Both parents and youth with T1D are involved in the youths' daily care and management of the disease, so it is important to assess and understand the factors that impact of HRQOL in youth with T1D and their parents.

Methods Used to Conduct This Review

Search for Evidence

In order to identify literature relevant to factors that impact HRQOL, a search using CINAHL Plus with Full Text, MEDLINE, and PsycInfo databases was conducted. These

databases were chosen due to their inclusion of academic nursing, medical, and allied health journals. The following keywords were used in the review: quality of life, type 1 diabetes, children and adolescents.

Inclusion and Exclusion Criteria

Inclusion criteria include (a) research conducted on human subjects, (b) in English (c) published between January 2006 and January 2016 (d) in academic, peer-reviewed journals. The initial search yielded 370 results, but adding the keywords like outcomes and/or factors, appeared to change the article set in a way that did not capture the topic of interest. Therefore, all 370 abstracts were reviewed to assess if each article met the aim of the review. From that group, 58 were reviewed further to try to isolate HRQOL as the primary outcome. From that secondary review, ten articles best met the objective of the review, which was to explore factors that impact health-related quality of life as an outcome for care in youth with T1D and their families. Those ten articles were included in this review.

Compilation of Evidence

Table of Evidence

The research literature was reviewed, synthesized and leveled using The U.S Preventive Task Force Levels of Evidence (Table 1, p. 120). A table of evidence was created (Table 2, p. 121), which included information on title, author name as well as level of evidence, aim of the research, sample size, results and strengths and limitations of each study. All ten articles were quantitative in nature, and were population-based. The studies represented one of the following designs: observational, multi-site cross-sectional; meta-analysis; longitudinal, observational, cohort; non-randomized control trials, multi-site data. The countries in which the data were gathered were United States of America (USA), Italy, Sweden, Greece, Germany and Turkey.

These designs were appropriate for this review. Experimental designs, such as randomized control trials do not easily lend themselves to this area of study.

Critical Appraisal of the Evidence

Synthesizing the Evidence

The following review assessed ten studies that looked at factors that may influence HRQOL of youth with T1D across the six countries between 2006 and 2016 had varying results related to outcomes. The studies measured HRQOL using various tools. When other measures were used in a study besides those that measure HRQOL, understanding how variables impacted HRQOL was sometimes difficult. Most studies also looked at variables of age, gender, duration of diabetes, complexity of treatment (pump vs. multiple daily injections), and metabolic control.

T1D compared to Other Pediatric Chronic Illness. In a meta-analysis in the USA by Ingerski, et al. (2010), HRQOL outcomes were compared across eight pediatric chronic conditions. Studies included in their analysis represented a total of 589 patients and caregivers across eight descriptive studies and conditions including T1D. In this meta-analysis it was found that chronically ill youth across all disease groups had lower HRQOL than healthy youth. It was also found that parent proxy reports were lower across all subscales of the HRQOL tool than the youth perceptions, except for the school functioning scale.

HRQOL of Youth with T1D Compared to Healthy Controls. Three of the studies compared youth with T1D with healthy controls related to HRQOL (Malakonaki et al., 2011; Nardi et al., 2008; Sahin, Oztop, Yilmaz, & Altun, 2015). These studies were conducted in Greece, Italy and Turkey. Malakonaki et al. studied 117 youth with T1D with matched healthy controls and found that youth with T1D scored lower in all areas of the HRQOL tool except for the social subscale. Nardi, et al. found that 70 youth with T1D did not have lower HRQOL scores than the matched healthy controls. However, the parents of the youth with T1D in the

Nardi, et al. study, did score the youth's HRQOL lower than the healthy controls, especially as the youth with T1D entered adolescence. Sahin, et al. (2015) compared 50 youth with T1D with a matched control group and found that there was no significant difference in their general scales of HRQOL. Outcomes in these studies suggest that cultural differences may affect impressions of HRQOL in youth with T1D and their parents.

Complex treatment regimen. Three of the studies looked at HRQOL related to the use of insulin pumps versus multiple daily injections to deliver insulin to youth with T1D. As more youth use insulin pumps and continuous glucose monitors (CGM), there is interest in studying the effect of increased technology, or complex treatment regimens on HRQOL. Cherubini et al. (2014), Mueller-Godeffroy, et al. (2009), and Valenzuela, et al. (2006), examined the impact the complexity of the diabetes treatment regimen had on HRQOL. These studies represent 880 youth with T1D from 34 different sites in Italy, Germany, and the USA. All of the youth were on the pump at least 3 months. Two of the studies also included parent's HRQOL (Mueller-Godeffroy, et al.; Valenzuela, et al.). HRQOL was not impacted in two of the studies. However, Mueller-Godeffroy found that although the general HRQOL score did not improve, the Diabetes HRQOL score did improve when youth with T1D used an insulin pump to manage their diabetes. Additionally, parents reported fewer concerns related to mealtime and fear of hypoglycemia when using an insulin pump in the management of diabetes for their youth with T1D. Overall in these studies, the care regimen of insulin pump versus multiple daily injections was not a significant factor in the outcome of HRQOL for youth with T1D or their parents.

Psychological adjustment and HRQOL. Valenzuela et al. (2006) reported that HRQOL was better predicted by measures of psychological adjustment than the diabetes clinical measures only. Reid, et al. (2013), studied 70 youth with T1D and their parents in the USA and found that

the physical and psychosocial well-being subscales of the PedsQL (general) module were associated with both improved A1c and adherence to treatment regimen. In Nardi et al.'s (2008) study in Italy, the only variable that had an impact on HRQOL was duration of T1D. Duration of T1D was only significant on the parent reports, and correlated with the psychological adjustment subscale. Additionally in that study, adolescents had worse HRQOL as well as increased psychological disturbances and problem scores (Nardi, et al.). Sahin et al. (2015) studied 50 youth with T1D in Turkey in order to assess how participants HRQOL may be impacted by psychopathology and parental attitudes. Sahin et al. found that although youth with T1D did not have more incidents of depression or anxiety than healthy controls, the youth with T1D had higher scores for both of those scales. When youth with T1D were assessed along the full spectrum of psychopathology, 68% of the youth with T1D had psychiatric disorders. In fact, 38% of youth with T1D had one disorder, 16% had two disorders and 10% of the youth with T1D had three psychiatric disorders. A limitation of the Sahin et al. study was that the healthy controls were not given the assessment across the full spectrum of psychopathology; therefore, no comparison could be made between the youth with T1D and the normal controls related to full spectrum psychopathology.

Factors that predict HRQOL. Hanberger, et al. (2009) conducted a study of 400 youth with T1D and their parents in Sweden. Their hypothesis was that metabolic control, gender, age and socioeconomic status predict HRQOL. In the Hanberger et al. study, boys with T1D did have a higher HRQOL than girls, especially as girls reported more psychosocial issues, which were associated with lower HRQOL. Youth with T1D did have decreased HRQOL in adolescence. The proxy for socioeconomic status was the educational level of the mother, and youth did have increased HRQOL when the mother had increased education. In this and other

studies parents' assessment of their youth with T1D's HRQOL was lower than the youth with T1D's assessment of their own HRQOL (Hanberger, et al.; Malakowaki, et al., 2011).

Malakowaki et al. also identified metabolic control, number of high and low blood sugars, duration of T1D, and gender as predictive of HRQOL. Nardi, et al. (2008) identified that in youth with T1D and parents, higher A1c correlated with higher problem scores and lower HRQOL. However, none of these factors were supported across all of the studies.

Longitudinal data and factors that impact HRQOL. Jacobson, et al. (2013) examined the longitudinal effects of T1D diabetes treatment, metabolic control and complications on HRQOL in the USA. In a follow up study with the same 1441 participants of the DCCT (1993), the seminal study that validated that improved metabolic control leads to decreased complications, the original group of thirteen to thirty-nine year olds were followed for over twenty-three years. Jacobson, et al. found that over time, as metabolic control decreased, and complications increased, there was also an increase in severe hypoglycemia and decrease in overall HRQOL.

Summary of Research Conclusions

HRQOL is emerging as an important indicator of the overall health and well-being of youth with chronic illness and their families. While the factors that impact HRQOL are important indicators for screening, it is imperative that researchers design interventions to support and facilitate improving the HRQOL of youth with T1D and their families. There may be evidence to suggest that support of metabolic control and HRQOL could be realized by focusing on the physical and psychosocial aspects of support for youth with T1D and their families. Evidence suggests that both adherence to treatment plans, family relationships and

family communication may improve metabolic control of youth with T1D and the whole family's HRQOL.

Implications for Clinical Practice. Healthcare providers and clinical teams need to consider including screening for HRQOL as an outcome of overall HRQOL for youth with T1D and their families. Teams that support youth with T1D often include nurses, social workers, and psychologists who are well suited to support the psychosocial health of youth with T1D and their families. In order to improve care outcomes and reduce long-term complications and cost of T1D, research-based interventions to support increased HRQOL should be part of the standard care of families that are affected with T1D. Supporting the HRQOL of youth with T1D and their families, especially their emotional and psychosocial health could not only improve their metabolic control, resulting in fewer long-term complications, but could impact the overall cost of care through decreased hospitalizations and emergency room visits.

Limitations of the studies. Overall, there were a limited number of studies that examined the factors that predict HRQOL of youth with T1D and their families. Many of the studies were population-based and did not use control groups. The data related to psychiatric disorders would have been strengthened by a control group of healthy youth as a comparison. Additionally, though many of the studies had good sample sizes, they were not randomized, and predominantly did not include healthy control groups.

Review of Literature: Risks and Protective Factors for Metabolic control

Introduction

The original Diabetes Control and Complication Trial (DCCT, 1993) was a randomized trial that ran from 1983 to 1989. The DCCT followed 1,441 participants with T1D, 13-39 years

old for an average of 6.5 years to prove what most health care providers that work with youth with diabetes suspected, that if blood control could be kept at near-normal levels many of the complication related to T1D could be reduced. This randomized control trial recruited highly-selected patients, and randomly assigned them to conventional therapy, which was at that time one to two injections of insulin per day or intensive therapy, three or more injections of insulin per day or insulin pump. These patients were closely monitored for complications. Those patients treated intensively had a 76% reduction in retinopathy, a 39% reduction in micro-albuminuria (which leads to kidney disease), and reduced clinical neuropathy by 60%. After that study, conventional therapy in pediatrics became intensive therapy, and even newly diagnosed patients were started on insulin therapy of three to four injections per day. The recommendations that developed out of the DCCT, and subsequent follow-up epidemiological trials, have become the gold standard of metabolic control, which is to keep the average blood glucose, measured by the glycosylated hemoglobin (A1c) test result at or below 7.5%.

Since the DCCT, most studies of T1D in youth assess metabolic control as a parameter for successful care outcomes. Although the DCCT had a limited number of pediatric patients, all the standards for metabolic continue to be based on those set on that study. Additionally, since the tools to care for diabetes have improved, it is may be easier for patients to meet the goals set by the DCCT. This review will look at the factors that have been identified to impact metabolic control.

Methods Used to Conduct This Review

Search for Evidence

In order to identify literature relevant to factors that impact metabolic control, a search using CINAHL Plus with Full Text, MEDLINE, and PsycInfo databases was conducted. These databases were chosen due to their inclusion of academic nursing, medical and allied health

journals. The following keywords were used in the review: metabolic control, type 1 diabetes, children and adolescents.

Inclusion and Exclusion Criteria

Inclusion criteria include (a) research conducted on human subjects, (b) in English (c) published between January 2006 and January 2016 (d) in academic, peer-reviewed journals. The initial search yielded 48 results. Therefore, the abstracts were reviewed to assess if each article met the aim of the review. From that group, 20 studies were reviewed further to try to isolate factors that impact metabolic control as the primary outcome. From that secondary review, fourteen studies best met the objectives to explore factors found to impact metabolic control in youth with T1D. Those fourteen articles from five countries were included in this review.

Compilation of Evidence

Table of Evidence

The research literature was reviewed, synthesized and leveled using The U.S Preventive Task Force Levels of Evidence (Table 1, p. x). A table of evidence was created (Table 3, p. x). The table includes information on title, author name as well as level of evidence, aim of the research, sample size, results and strengths and limitations of each study. All fourteen articles were quantitative in nature and are one of the following designs; meta-analysis, longitudinal population-based data base studies (multi-site), population based longitudinal prospective with youth or youth/parent dyads, cross-sectional youth, or parent/youth dyads, meta-analysis measures. The data in these studies were gathered in the USA, Slovenia, Germany, Austria, and Sweden. These designs were appropriate for this review. Experimental designs, such as randomized control trials with control groups do not easily lend themselves to this area of study.

Critical Appraisal of the Evidence

Synthesizing the Evidence

Since the DCCT trials, many pediatric diabetes centers now gather ongoing longitudinal data of their patient groups to assess ongoing trends and outcomes of care. Many of the studies in this group looked at data gathered by national or multi-site databases in order to track factors that affect the metabolic control of their patients with T1D with the hope of creating interventions to better support them. Others looked at cross-sectional groups of youth with T1D or youth/parent dyads. The themes of the studies were 1) trends of care and metabolic control over time; 2) adherence, factors that impact metabolic control; and 3) individual and family factors, what cognitive/ psychosocial behaviors appear to have the most impact in the outcomes of care.

Trends of Care. Four studies looked across population groups to assess trends and outcomes of care. Rosenbauer et al. (2012) looked at data from 30,708 patients from 305 centers, 211 pediatric centers, across Germany and Austria. The data assessed was collected during the years of 1995 to 2009, and represented a population that was 52% male with a mean age of 14.6 years and a mean age of onset of T1D of 7.9 years. The average mean A1c decreased from 8.7% to 8.1%, and the incidence of severe hypoglycemia was significantly reduced. The investigators found that the A1c was impacted by age, gender, ethnicity, BMI, and daily insulin dose. Increasing the complexity of the regimen did not significantly improve A1c. Gerstl et al. (2007), looked at the same group of youth with T1D from Germany and Austria between 1995-2005 and found over that time the average number of youth with T1D with A1c results in the goal range of less than 7.5% increased from 25% to 45% of youth. Moreover, the number of youth with T1D in poor control, defined as A1c greater than 9%, decreased from 40% to 16% of youth. Svoren, et al. (2007) looked at data from a cross-sectional longitudinal study in 1997 and 2002 in the USA. They also found a significant improvement in metabolic control over the two cohorts with

decreased severe hypoglycemia and ER visits, and an increase in the use of insulin analogs, intensive therapy and blood sugar tests. Dovc et al. (2014) studied the data from 884 patients with T1D from 0 to 17 years at diagnosis followed by at least one year from 2000 to 2011 in Slovenia. The median A1c result in youth with T1D decreased from 9.26% to 7.75%. The average age of diagnosis of youth with T1D in that study decreased from 12.68 to 7.53 years old. Additionally, the daily insulin dose decreased from .76 to .7 units/kg. All youth in that study were using multiple daily injections or an insulin pump to deliver insulin for at least one year by 2011. Variables that significantly impacted the A1c result of youth with T1D in that study were gender, age, treatment, daily insulin dose, and duration of T1D. Overall, improvements in insulin and insulin delivery have impacted the metabolic control and outcomes of youth with T1D.

Adherence. Four of the studies looked at adherence to treatment regimen as a factor of metabolic control outcomes. Ziegler et al. (2011) correlated the frequency of blood glucose testing to both metabolic control and short-term outcomes such as severe hypoglycemia and DKA. Their study contained 26,723 youth with T1D who represented 85% of youth with T1D in Germany and Austria over an eleven-year period. The investigators found that those youth who tested their blood glucose less than three times per day had significantly poorer metabolic control than those who tested more often. In fact, the A1c of youth with T1D decreased significantly with each test up to five tests per day. However, more than five tests per day did not significantly improve the participant's outcomes (Ziegler et al.). Olinder, Kernell and Smide (2009) studied 90 youths with T1D in Sweden and their adherence in giving boluses of insulin to cover the food they eat. In their study 38% of the youth missed greater than 15% of the mealtime insulin doses, which was resulted in significantly higher A1c results, and was

correlated with less blood sugar tests (Olinder, Kernell & Smide). Rausch et al. (2012) followed 240 youth with T1D in the USA, age eleven to fourteen, for two years to study changes in behaviors with the transition to adolescence, which often aligned with decreased metabolic control. In their study, the average A1c of their group of youth with T1D rose significantly from 8.2% to 8.6%, while the number of blood sugar tests decreased significantly from 4.9 to 4.5 checks per day (Rausch et al.). Hood et al. (2009) conducted a meta-analysis to determine the magnitude of the link between adherence and glycemic control in youth with T1D. The twenty-one studies in the analysis included 2,492 youth with T1D. Across all factors, such as SES or ethnicity, adherence to the treatment plan was the greatest predictor of metabolic control. Adherence to treatment plans plays a significant role in care outcomes; perhaps a greater role than other factors that impact metabolic control. These studies indicate that youth with T1D that test their blood sugars less than five times per day may also be missing a significant amount of their insulin injections at the same times. This combination of missed blood glucose checks and missed insulin doses reduced their overall metabolic control. Since metabolic control is the primary outcome that predicts long-term complications, this would be an important factor to address with creating interventions to supporting the health of youth with T1D.

Family Factors (parenting). Duke, et al. (2008), in a cross-sectional population based study of 120 youth with T1D/parent dyads in the USA, studied predictive and mediated relationships among youth with perception of critical parenting. In this study, the age of the youth with T1D correlated with critical parenting; more critical parenting and less parent reported adherence to tasks related to their diabetes care regimen was seen with adolescent youth. Youth perception of critical parenting led to youth externalizing behavior and non-adherence with the tasks related to their diabetes care regimen. Meanwhile, the adherence

mediated critical parenting and metabolic control. Therefore, it was suggested that negative behaviors of youth were influencing the negative behaviors of the parents as negative behaviors of the parents were influencing negative behaviors of the youth (Duke et al.). King et al. (2013) studied a longitudinal population-based cohort of 252 youth with T1D ages ten to fourteen and their parent over 2.5 years in the USA. Using multilevel modeling, researchers' analyses indicated significant average declines over time in adherence and most indicators of parental involvement. Lewin et al. (2006) studied 109 youth with T1D ages eight to eighteen and their parents in the USA. This was a cross-sectional, prospective study that examined family factors as predictors of metabolic control. Four family functioning variables: parental warmth, critical and negativity, guidance, and responsibility explained 34% of the variance of metabolic control. Adherence results in this study combined with family factors explained 49% of the total variance of metabolic control (Lewin et al., 2006). These studies suggest that support of family communication and functioning may improve adherence and metabolic control of youth with T1D.

Individual Factors (intelligence). Berg, et al. (2014) studied 252 youth with T1D ages ten to fourteen in the USA. They followed the youth with T1D over 2.5 years to assess their transition into adolescence. The goal was to assess if intelligence influenced metabolic control across time, and whether the effect of intelligence was mitigated by greater self-control (regulation of cognitions, emotions, and behaviors). In this study higher intelligence was associated with better metabolic control through better self-control. Viklund (2014) studied 204 patients with T1D ages 12-17 in a cross-sectional prospective multi-site study in Sweden. Their aim was to explore which factors of health and HRQOL correlated or predicted metabolic control. Age, physical health, social relations, problem solving, goal achievement, and diabetes

evaluation predicted 25% of the variation in metabolic control. The care regimen of youth with T1D is complicated and requires continuous problem solving. Hood, et al. 2009, suggested that the decreased adherence and metabolic control might be a weakness of the intensive insulin regimen. Those youth with T1D and their families, who do not have strong problem solving skills, or a high enough level of intelligence or critical thinking, may be at risk for decreased metabolic control. Or as Hood et al. (2009) stated, ‘this is because of a mismatch between what scientists and clinicians know is the best way to manage pediatric type 1 diabetes and the capabilities of youth and their families (p. 1171).’

Summary of Research Conclusions

Since the DCCT outcomes were published in 1993, pediatric diabetes healthcare teams have sought to support better overall metabolic control in youth with T1D. Longitudinal studies looked at the overall trends and outcomes of care and identified factors that impacted metabolic control. Many of those factors have been supported throughout these studies, such as the impact of age, gender, ethnicity, SES, duration of diabetes on metabolic control. However, these factors do not emerge as significant across all studies. Many of the studies suggest that adherence to treatment plans have an impact on outcomes, specifically the testing of blood glucose up to five times a day, which correlated with insulin dosing at meal and snacks. Family relationships are suggested to play a role in metabolic outcomes, with positive communication and supportive behaviors impacting adherence and therefore metabolic control. It has also been suggested that the complicated regimen required in the care of T1D requires intelligence and problem solving abilities that could be a barrier for success in some families.

Implications on Clinical Practice. While age, gender, SES, and ethnicity often correlated with metabolic control outcomes, these factors do not lend themselves to the

development of interventions, only screening for risks. The studies of adherence behaviors, impact of problem solving, goal achievement, family involvement, and parenting styles and their affect on metabolic outcomes, suggest that interventions in those areas may be effective in improving the metabolic control of youth with T1D. Most pediatric diabetes teams have the combination of health care professionals, such as nurses, social workers, and psychologists who are ideally suited to develop and test interventions to support these factors. Standard interventions to support family communication and problem solving may be successful in supporting the metabolic control of youth with T1D, and subsequently may support both decreased complications and increased HRQOL. Improvements in insulin types and delivery methods appear to only improve care if these other factors that support family relationships and functioning and HRQOL are supported.

Limitations of the studies. All of the studies that were reviewed were descriptive. To support families in successfully mitigating those factors that can be controlled, interventional studies are needed. The appropriate use of control groups to look for differences between youth with T1D and normal controls is another important limitation of many of the studies, especially in those areas of emotional and psychological health, where information related to healthy controls is not readily available.

Chapter Summary

Since the DCCT (1993) health care providers of youth with T1D have implemented the guidelines for the use of multiple daily doses of insulin or insulin pumps to improve the HRQOL and metabolic control of youth with T1D. However, despite improvements in insulin, tools to deliver insulin and test blood glucose, 50% of youth overall and almost 80% of adolescents with

T1D fail to meet the metabolic treatment goals of A1c less than 7.5% that were indicated by that study (Wood et al., 2013). New guidelines endorsed by the ADA call for children less than thirteen to meet the same guidelines as adolescents (American Diabetes, 2015; Chiang et al., 2014). Because few youth with T1D were included in that seminal study DCCT study (1993), researchers have continued to assess longitudinal cohort data, as well as cross-sectional studies to better understand the risk and protective factors that are barriers or supports to the improvement of metabolic control and HRQOL in youth. While many of the factors, such as age (older youth had poorer metabolic control and HRQOL) and gender of the child (females had worse metabolic control and HRQOL) emerge in most studies, the specific causes and/or potential interventions to support change and/or improvement in care are not known. Some of the factors that were identified; such as support of family relationships and communication, and a focus on strategies that improve adherence may be instrumental in supporting the improvement of both the metabolic control of youth with T1D, and the overall HRQOL of both youth with T1D and their families.

CHAPTER 3: Methodology

Introduction and Purpose

In 1921 Banting and Best isolated insulin as a treatment for Type 1 Diabetes (T1D) dramatically improving outcomes of individuals diagnosed with T1D (Joslin, 1924). Insulin allows for this once fatal disease to be managed. However, the day-to-day management of this disease comes at great cost to children and adolescents (youth) with T1D and their families. Because the care needed to manage diabetes is constant and unrelenting, T1D is considered one of the most psychologically and behaviorally demanding of all chronic illnesses for both youth with T1D and their primary caregivers (Graue et al., 2005; Whittemore et al., 2012). Although scientists now understand the auto-immune process that results in the destruction of the insulin producing beta cells of the pancreas, they are no closer to understanding what triggers this process, nor are they any closer to identifying a pathway to cure (Atkinson et al., 2014; van Belle et al., 2011). The Individual and Family Self-management Theory (IFSMT) identified individual and family factors that are either a risk or protection for youth with chronic illness (Ryan & Sawin, 2009). Because at the time of this writing, a cure for T1D is unlikely, it is important to examine the risk and protective factors in the management of T1D. Youth with T1D and their families need support in the process of self-management of this chronic condition to achieve optimum health outcomes. Health-related quality of life (HRQOL) and metabolic control (A1c test result) to avoid short- and long-term complications of T1D reflect the overall health and well-being of youth with T1D, and are outcome variables in the IFSMT.

Individual and family risk factors are particularly salient in the study of youth with T1D and their families. Youth with T1D and their families must incorporate complicated treatment

plans and technology to control the balance of food and insulin in their bodies. Although there continues to be breakthroughs in the use of insulin analogs, and technological support has increased the life expectancy of individuals with T1D, over 50% of youth overall and almost 80% of adolescents do not meet the identified national and international metabolic care goals (Wood et al., 2013). Not meeting these goals can result in serious short and long-term complications of T1D (van Belle et al., 2011; Wood et al., 2013). The psychological and physical barriers to successful management of T1D are well documented (Cox et al., 2014; Grey et al., 2009; Guo, Whittemore, & He, 2011; Herrman, 2006). However, interventions have not yet been identified to support youth with T1D and their families overcome these barriers (Cox et al., 2014). Beyond the issue of poor metabolic control, there is also concern surrounding the overall well-being of youth and families dealing with T1D. Well-being encompasses the physical, emotional, and social health of the youth with T1D and their family, these factors all have been shown to play a key role in the family's quality of life (*Declaration of Alma-Ata*, 1978). In the context of youth with chronic illness, this well-being has been termed health-related quality of life (HRQOL). Literature is lacking that describes how the HRQOL of youth with T1D impacts their metabolic control or the HRQOL of their parents. It is also not clear how HRQOL of youth with T1D may correlate with individual, family, and condition specific factors, such as complex treatment regimen of T1D.

The purpose of this study was to explore associations of the HRQOL of youth/parent dyads and the metabolic control of youth with T1D. Additionally, the study examined associations between the youth/parent HRQOL survey and subscales with the metabolic control of youth and with other individual, family, and diabetes specific factors such as age, gender, ethnicity, socioeconomic status, and use of technology.

This chapter will describe the research design, hypotheses, and the conceptual framework for the study. Furthermore, this chapter will provide definitions for variables, and eligibility criteria for subjects used in the primary study. Finally, the measurement tools used in the primary study will be described, the data management plan for the secondary analysis will be outlined, and how the secondary data was analyzed will be further described.

Research Design

This secondary analysis used a quantitative subset of de-identified baseline data gathered from a primary study. The primary study was a multi-site interventional study of youth with T1D and their parents, and baseline data of participants was gathered from September 2014 to May 2015. Data collection for the longitudinal primary study continued through June of 2016. The principle investigator (PI) from the primary study was consulted when identifying the research questions, approved the questions for the secondary study, and gave access to the requested baseline data to this researcher. This researcher was part of the IRB for the primary study, and developed the materials to support one of the interventional arms of the study, but was not part of the recruitment or data collection for the primary study. A sub-set of the baseline data was used for the secondary analysis. This baseline data was gathered from all participants of the primary study, including families randomized to the interventional and the control groups. The data gathered was baseline measures of youth with T1D including their individual factors that included the youth's age, and gender. There was also data related to the condition specific factor of diabetes treatment complexity (use of technology, no technology), as well as the outcome variables of the metabolic control, measured by glycosylated hemoglobin (A1c result), and the HRQOL (measured by the Diabetes PedsQL™ survey) of youth with T1D. Additionally, baseline data was collected related to the parents of the youth with T1D. This included family factors,

such as ethnicity and socioeconomic status (SES), and the parent HRQOL (measured by the PedsQL™Family Impact Module survey).

The current study analyzed results from the PedsQL™Family Impact Module related to the parents HRQOL (total score and subscales), as well as the Diabetes PedsQL™scale (total score and subscales), which measured HRQOL for youths with T1D. The study analyzed individual, family, and treatment factors and tested their associations with the HRQOL and metabolic control of the youth with T1D based on the Individual and Family Self-Management Theory (Ryan & Sawin, 2009).

Strengths and Limitations of this Secondary analysis

Strengths of Secondary Analysis. According to Hulley, et al. (2013) the primary advantage of using existing data is that research questions can be answered more quickly and in a more cost effective manner. In many studies, researchers collect more data than can be analyzed, and often there is an opportunity for the collected data to be analyzed differently (Polit & Tatano, 2012). Secondary analysis poses less risk to patients, as the data analysis is typically de-identified, and may result in important new findings through analysis of relationships of data that were not previously examined (Conn et al., 2015; Dunn, Arslanian-Engoren, DeKoekkoek, Jadack, & Scott, 2015). Dunn, et al. cited that the use of secondary data in nursing research fosters inter- and intra-professional relationships both within and outside the discipline of nursing. According to Dunn, et al., secondary data analysis can provide rich learning opportunities and firsthand experience with nursing research without the need to apply for research funding. In the case of this study, by participating in the original study, this researcher developed interdisciplinary relationships across health care systems, universities, and with other pediatric diabetes care providers. An additional strength to this secondary analysis was that the

baseline data for this study was a subset of the dataset for a study that was still being analyzed during the analysis. This afforded the additional benefit that the researcher had access to the research team from the primary study for verification, questions, or concerns while the data were being analyzed.

Limitations of Secondary Analysis. The main disadvantage of using a secondary data set is that the investigators for the primary study select all of the variables, subjects, and measurement tools. Therefore, the data may not include all the confounders and data that may have been included if the study was designed to answer the secondary question (Hulley, et al., 2013; Polit & Tatano, 2012). Nurse scientists using secondary data must have the ability to analyze data quality, accuracy, and usability and check for appropriateness to address the research question that they are proposing (Conn, et al., 2015; Dunn, et al., 2015).

In the case of the current study, the investigator was given access to the methods and processes of data collection, the research tools and equipment used in the primary study, and the ability to personally assess the reliability and validity of the collected data. Doolan and Froelicher (2009) warned that the use of previously collected data could mean difficulty in the storage of data and its transfer to the researcher's database. All of the data from the primary study was housed in a password-protected server that this researcher accessed for the analysis. The de-identified data requested was stored within a specific file within that site. Tools for the analysis were housed on the site itself and only a research assistant from the primary study could transfer the output tables out of the site. Additional data management considerations will be outlined in the data management plan.

Conceptual Framework

Individual and Family Self-management Theory (IFSMT) was used as a conceptual framework for this secondary study analysis. The IFSMT was used to assess the risk and protective factors that may influence youth with T1D and their parent HRQOL as well as the outcome variable of metabolic control (measured by A1c) of youth with T1D (Ryan & Sawin, 2009). In the IFSMT model, risk and protective factors challenge or protect individuals' and families' engagement in self-management (Grey, et al., 2010). The risk and protective factors, identified as context factors, are described as condition specific, physical and social environment, and individual and family factors. The IFSMT model supports the use of individual and family-centered interventions to impact both the context, which are the risk and protective factors, and the process, which is the self-management process, and the short- and long-term outcome factors (Grey, et al.; Ryan & Sawin). The study will examine the association of the youth with T1D context variables to look at the potential impact of the outcomes variables represented by metabolic control (measured by A1c result) and HRQOL. Associations between individual factors of gender and age, a condition-specific factor of treatment complexity (use of technology, no technology), family factors of ethnicity and socioeconomic status, and their impact on long-term outcome variables of the youth with T1D's HRQOL and metabolic control were examined. The association of the outcome variables of youth's HRQOL and the HRQOL of their parents were analyzed to discover any correlations between them. Additionally, the association of HRQOL of the youth with T1D and the youth with T1D's metabolic control (measured by A1c result) was analyzed to better understand how those two outcomes factors correlate. Further exploration of associations also included the subscales of the youth/parents dyads' HRQOL related to the youths' metabolic control. A concept map that was informed by the Ryan and Sawin framework, and is focused on the individual, family and condition factors

that will be explored in this study and their association with youth and family's HRQOL and the youth's metabolic control was created to support this analysis (Figure 3, p. 117).

Research Questions and Hypotheses

Research Questions.

1. What is the association between diabetes treatment complexity (pump and/or continuous glucose monitor vs. injections) and metabolic control in youth with T1D?
2. What is the association between diabetes treatment complexity (pump and/or continuous glucose monitor vs. injections) and health-related quality of life of youth with T1D?
3. What is the association between individual factors (youth age, gender) on metabolic control and health-related quality of life of youth with T1D?
4. What is the association between family factors (ethnicity, family socioeconomic status) on metabolic control and health-related quality of life of youth with T1D?
5. What is the association between youth with T1D health-related quality of life and the health-related quality of life of their parent?
6. What is the association between metabolic control of youth with T1D and the parent health-related quality of life?
7. Is the youth's metabolic control associated with the psychosocial subscales of the parent's health-related quality of life survey?
8. What is the association between the youth with T1D's health-related quality of life and metabolic control of the youth with T1D?

Hypotheses.

1. There will be an association between diabetes treatment complexity (pump/continuous glucose sensor vs. injections), and youth with T1D's health-related quality of life and ability to meet metabolic treatment goals.
2. There will be an association between gender, age, ethnicity and socioeconomic status and youth with T1D's health-related quality of life and ability to meet metabolic control goals in youth with T1D
3. Youth with T1D with higher health-related quality of life will have parents with higher health-related quality of life.
4. Youth with better metabolic control will be associated with parents with higher health-related quality of life.
5. Youth with T1D with higher health-related quality of life will be associated with better metabolic control.

Measurement tools and variables for secondary analysis

Since the current study was a secondary analysis, it was important to study and understand the reliability and the validity of the tools used in the primary study that would be used for this analysis. Table 4 (p. 133) includes summary of the variables that were used in the study. Although a subset of the baseline primary data was used in this study, the data represented all participants of the primary study, both those youth/parent dyads that were randomized to the interventional group and those that were randomized to the control group. Doolan and Froelicher (2009) suggested that it was important for a researcher doing a secondary analysis to verify the quality of the measurements and data to be used. In the primary study the protocol was for the research staff to coordinate data collection. Time between visit components (e.g., meter and pump downloads, blood draws for routine tests, or provider encounter) was to be used for

research staff to administer study instruments. Before families left the clinic, the research assistant was to check the data accuracy and completeness. Preliminary studies of the data suggested all items were completed by > 95% of participants. Any completed paper surveys were to be taken to the research office by research assistants immediately after each clinic session. Range checks and consistency checks were to be performed at data entry. Research assistants were to enter all data into databases that were merged to create analyzable datasets. Final data was housed in a database with identifying information removed. The variables and tools that were studied are described more fully in the following paragraphs.

Family Impact Module of the PedsQL.™ Although a relatively new measure at the time of this writing, the initial results of reliability and validity reported by Varni, et al. (2004) were notable. According to Varni et al., the Family Impact Module was developed to address the family impact of pediatric chronic health conditions on the family and assess the family's health-related quality of life (HRQOL). The scale used in the primary study included twenty nine items in six subscales: 1) Emotional Functioning (5 items); 2) Social Functioning (4 items); 3) Communication (3 items); 4) Worry (5 items), 5) Daily Activities (7 items); and 6) Family Relationships (5 items). This Family Impact Module was developed through focus groups, cognitive interviews, pre-testing measurement development protocols, prior research, and clinical experiences with children with chronic health conditions and their families.

Scale internal consistency reliability was determined by calculating Cronbach's coefficient alpha (Varni, et al. 2004). Internal consistency is the degree in which test takers respond in like ways to the items in a set of questions (Meyers, Gamt & Guarino, 2013). According to Varni (2004) scales with reliabilities of 0.70 or greater are recommended for comparing patient groups, while a reliability criterion of 0.90 was recommended for analyzing

individual patient scale scores. Meyer, Gamst and Guarino stated that a reliability of 0.90 or better is outstanding, with middle 0.80's being very good, 0.80 good, and high to middle 0.70's acceptable. Whatever the source used for criteria, the internal consistency reliability demonstrated using the PedsQL™ Family Impact Module Cronbach's alpha scale was strong with a Total Scale Score ($\alpha = 0.97$), Parent HRQOL Summary Score ($\alpha = 0.96$), Family Functioning Summary Score ($\alpha = 0.90$), and Module Scales (average $\alpha = 0.90$, range = 0.82 – 0.97).

Scoring for the PedsQL™ Family Impact Module. The PedsQL™ Family Impact Module was developed as a parent-report instrument. A 5-point response scale is utilized (0 = never a problem; 4 = always a problem). Items are reverse-scored and linearly transformed to a 0–100 scale (0=100, 1=75, 2=50, 3=25, 4=0), so that higher scores indicate better functioning (less negative impact). Scale Scores are computed as the sum of the items divided by the number of items answered (this accounts for missing data). If more than 50% of the items in the scale are missing, the Scale Score is not computed (Varni et al., 2004).

The PedsQL™ Family Impact Module distinguished between families with children in a long-term care facility and families whose children resided at home, demonstrating that it could differentiate between groups. This meant that the test appeared to be able to measure what it was supposed to measure, which was the health-related quality of life of families with children with chronic illness. Varni et al. (2004) demonstrated the preliminary reliability and validity of the PedsQL™ Family Impact Module in families with children with complex chronic health conditions. Since that time, the Family Impact Module of the PedsQL™ inventory has been found to have substantial internal consistency and reliability across many cultures and conditions (Chen, et al, 2011; Mano, et al., 2011; Knez, et al., 2013; Medrano et al., 2013; Rahman et al.,

2011; Panepinto et al., 2009; Scarpelli, et al., 2008). The Family Impact Module of the PedsQL™ is one of the few measures available used to assess parent self-report measures of the impact of pediatric chronic health conditions on parents' HRQOL and family functioning (Mano, et al., 2009). Medrano et al. (2013) tested the Family Impact Module of the PedsQL™ in a community setting. The results of the Medrano, et al. study suggest the Family Impact Module of the PedsQL™ is a reliable and valid measure of parent HRQOL and family functioning within a community sample, and supports its use in comparative studies.

The PedsQL™Diabetes module. The PedsQL™Diabetes module was designed to measure HRQOL dimensions tailored to pediatric diabetes (Varni, Burwinkle, & Seid, 2005). This 28-item test was used for youth in the primary study, there were separate surveys for preadolescents eight to twelve and adolescents aged thirteen to sixteen. The reliability coefficient for the eight to twelve year-old group was 0.90 and for the thirteen to sixteen year-old group was 0.89. The total score validity was established through comparison with healthy controls (those with T1D scored lower) and the total score correlated with A1c, adherence, and treatment barriers (Varni, Burwinkle, & Seid, 2005). The PedsQL™Diabetes module has been validated in other countries and studies (Boogerd, Noordam, Kremer, Prins, & Verhaak, 2014; de Wit et al., 2007; Nansel, Weisberg-Benchell, Wysocki, Laffel, & Anderson, 2008).

Scoring for the PedsQL™Diabetes module. A five- point response scale is used (0 = never a problem, 4 = almost always a problem). Items are reverse-scored and linearly transformed to a 0– 100 scale (0 = 100, 1 = 75, 2 = 50, 3 = 25, and 4 = 0), so that higher scores indicate better HRQOL. Scale scores are computed as the sum of the items divided by the number of items answered. If 50% of the items in the scale are missing, the scale score is not computed. (Varni, et al., 2003).

Glycosylated hemoglobin (A1c) test. The glycosylated hemoglobin (A1c) represents the overall metabolic control of youth with T1D. The A1c is a blood test that reflects the average blood sugar in the body for the past eight to twelve weeks (Sacks, 2012). The A1c test became the standard for tracking and predicting risks of complications in patients with T1D based on the Diabetes Control and Complications Trial (DCCT) in 1993 (Sacks). To decrease missing data and maintain standardization across patients, the primary study provided standard point of care (POC) A1c testing for all study participants. The POC test used was the DCA Vantage. The DCA Vantage™ (Siemens Medical Solutions Diagnostics) is based on latex agglutination inhibition immunoassay methodology, provides results in 6 minutes, and met generally accepted performance criteria for A1c (Lenters-Westra & Slingerland, 2014). Additionally, in recent CAP (College of American Pathologists) surveys DCA 2000, and DCA Vantage showed excellent results; even better than some laboratory based methods (Lenters-Westra & Slingerland). Due to these tests and recommendations, it seemed that the A1c results from this method supported the reliability and validity of the data. Comparisons of youth results are strengthened in the primary study because the A1c results of all youth were gathered using the same method.

Socioeconomic status. The link between SES and outcomes of care in diabetes and other chronic conditions as well as overall health has been established in a few studies for diabetes and other chronic illness (Anderson & Armstead, 1995; Litzelman et al., 2013). SES has been linked to lower HRQOL as well as increased psychiatric and depressive symptoms in type 1 diabetes (Braveman et al., 2005; Hassan, Loar, Anderson, & Heptulla, 2006; Kakleas, Kandyla, Karayianni, & Karavanaki, 2009). However the measures often used, parent education, family income, or neighborhood are less than ideal (Braveman, et al., 2005). Using insurance

type (commercial or publically funded) as a proxy for SES is not without limitations; however, it had face validity to indicate lower SES of the family and has been suggested as an alternative proxy for SES (National Forum on Education Statistics, 2015; Shavers, 2007).

Diabetes treatment complexity. Diabetes treatment complexity was defined in the current study as technology use versus no technology. Technology use was defined as the use of an insulin pump and/or a continuous glucose monitor (CGM). No technology is the use of insulin injections and blood sugar tests using finger pokes. The association between high treatment complexity (use of technology) and low treatment complexity (no technology) in the management of T1D and HRQOL is unclear. An insulin pump is an insulin delivery device that is attached to the body of the youth with T1D throughout the day and night. The insulin pump administers a type of fast-acting insulin through a catheter dwelling in the youth's subcutaneous tissue in two ways: 1) as a basal delivery of low dose background insulin continuously; and 2) as a bolus (burst) dose of insulin to be delivered with meals or snacks. According to the DirecNet Study Group (2007) the CGM is a device that continuously measures the blood sugar levels of the youth with T1D. CGM devices have three parts, a glucose sensor, a transmitter, and receiver, which may or may not be integrated with insulin pumps. The sensor is inserted into the subcutaneous tissue under the skin; however, delay between the glucose read by the monitor and glucose from a fingerstick can range between five to fifteen minutes, which can impact care (DirecNet Study Group).

Studies were reported with mixed results related to HRQOL metabolic control and insulin pump use (Alsaleh, Smith, & Taylor, 2012; Muller-Godeffroy, Treichel, Wagner, & German Working Group for Paediatric Pump, 2009; Nuboer, Borsboom, Zoethout, Koot, & Bruining, 2008; Valenzuela et al., 2006). Continuous glucose meters have also been studied related to

HRQOL and metabolic control with varied results, but most often no significant differences between standard care and technology use (Direct Group, 2007; Langendam et al., 2012; Mauras, Fox, Englert, & Beck, 2013). A recent study has suggested that the level of complexity of care of T1D, which included use of an insulin pump, had a significant impact on self-management behaviors, but not on metabolic control (Verchota, 2014). Both modes of insulin delivery, whether using insulin pumps and/or CGM, or injections and manual blood sugar tests, necessitate manual interventions for youth with T1D throughout the day. It is interesting to note that in studies looking at insulin pump logs, there were as many injections missed when an insulin pump was used to deliver insulin by pushing a button as when insulin was manually injected in a syringe (Burdick et al., 2004; Olinder, Kernell, & Smide, 2009).

Age. The age of the youth participants reflected age in years since birthdate until enrollment in the study. Youth were analyzed as a whole group, and when numbers meet the assumptions of statistical tests, they were analyzed by age group; preadolescents eight to twelve, and adolescents thirteen to sixteen. Reports in the literature suggested that there would be a difference in the ability to achieve A1c goals between preadolescents and adolescents (Hesketh, 2004; Polfuss, Babler, Bush, & Sawin, 2015; Schober et al., 2011; Young et al., 2013).

Gender. The gender of youth was documented as male or female based on the family's identification of their gender. There have been studies in which outcomes suggested that females have more difficulty achieving metabolic, especially in the thirteen to eighteen age group (Polfuss et al., 2015; Rosenbauer et al., 2012; Schober et al., 2011). There are also studies that suggest that males have higher overall HRQOL than females (Hanberger, Ludvigsson, & Nordfeldt, 2009; Malakonaki et al., 2011).

Ethnicity. Parent/primary caregiver identified ethnicity from the following categories; White (1), African American/Black (2), Native Hawaiian or other Pacific Islander (3), Asian (4), Native American or Alaskan Native (5), Other (6) If other, please specify. Due to the small number of diverse families, ethnicity was reported in two groups white, and non-white. Some study outcomes suggested that the metabolic control of minority patients are statistically lower than those of white, non-Hispanic patients (DCCT, 1993; Reid, et al., 2013). However, in one study, when ethnicity was looked at separately from SES, only SES was significant (Springer et al., 2006).

Setting for the primary study

The data for the primary study were gathered in two academic pediatric diabetes clinics within one Midwestern State. The secondary study analyzed a subset of the baseline data gathered from both the youth/parent dyads randomized into the intervention groups and the control youth/parent dyads randomized as controls recruited for the primary study. Access to a subset of baseline data from the primary study was given for this secondary study by the principle investigator of the primary study.

Sample and Power analysis

The sample of the primary study was 214 youth/parent dyads attending a usual care visit for routine diabetes management at one of two clinical sites. The primary study recruited a purposive sample of 60 minority families to ensure representativeness of the total sample. Eighteen families of minority status participated in the study, which matched the percentage of those with minority status in the state that the study occurred. The sample size of the original study was based on the power needed to evaluate effects on glycemic control and quality of life measures. Using a repeated measures approach and considering outcomes as continuous,

samples of 100 families per site with a total of 200 families, provided 80% power to detect small to moderate differences on A1c results and quality of life measures.

For the secondary analysis, data from four youth/parent dyads were eliminated due to missing data, so the sample size was data from 210 youth/parent dyads. The sample size needed for a 95% power level of the regression analysis of youth/parent dyads, based on 4 independent variables, to detect a .15 medium effect size at a .05 significance level was 129 youth/parent dyads to predict metabolic control. After one outlier youth/parent dyad was removed the sample size for this regression analysis was 209.

Sample inclusion criteria for the primary study

1. Youth included in the study were eight to sixteen years old
2. Youth diagnosed with T1D for greater than 12 months.
3. English speaking family.
4. Youth were also assessed for their ability to participate in a group setting.

Human Subjects Considerations and Research Procedures

Because the data used in this study was de-identified, additional IRB approval for a secondary study was not necessary by the University of Wisconsin, Milwaukee IRB office. The researcher for the secondary study was included on the IRB of record at the University of Wisconsin, Madison.

Data Management Plan

The data management plan included the following steps (as suggested by Doolan and Froelicher (2009):

1. De-identified data will be obtained from the primary study group. The researcher worked with a PhD prepared statistician from the University of Wisconsin Milwaukee to suggest a de-identification plan per the request of the PI of the primary study. This plan was as follows:
 - a. Any family names, birthdays, medical record numbers, social security numbers were not included in the data.
 - b. Families were identified numerically as so that parent and youth data were paired but not identified by family name.
 - c. Birthdate was substituted by age of the youth (in whole numbers). This data was then separated into age categories, preadolescents and adolescents.
 - d. Public and private insurance was sorted into two categories, public versus private, versus names of insurance companies.
 - e. Ethnicity, gender, technology vs. no technology, A1c results, and survey results can be shared as is as long they are associated with the new family numbers.
 - f. Measurement data maintained the separate scores from the subscales and totals so the overall integrity of the data could be assessed by this researcher before the secondary analysis.
 - g. The PI for the primary study kept the record of the de-identified data plan and linking data with the primary study data. The researcher for this study only had access to the primary study data that were de-identified for this study.
2. Data was accessed through a secure server at the primary study site. The baseline data identified for use for this study were put into first an excel spreadsheet and then an SPSS file by the research team from the primary study.

3. The researcher for the secondary analysis had access to the study server, but only to a separate folder that contained only the files and codebook for the secondary study.
4. Outcome tables were transferred to word documents and then put in a shared folder to be sent to this researcher by another member of the research team from the primary study. It was not possible for this researcher to save, store or print any data outside the secure study server.
5. To be included in the analysis, every case needed scores for both the context and outcome variables. Thus, any case with missing outcome scores or 5% or more of the context scores was excluded.
6. Only analyzed output data was shared with anyone not part of the primary study IRB.

Data Analysis Plan

1. The latest version of SPSS was used to analyze the data for the secondary study. This tool was supplied on the secure study server.
2. Correlations between context variables and outcome variables were made using Chi squares, t-tests, or ANOVA as appropriate for the type of variables. For this part of the analysis, all of the context variables were treated as independent variables and the outcome variables of HRQOL and metabolic control were treated as dependent variables.
3. Youth were analyzed as a whole and then analyzed by separate age categories, preadolescents and adolescents.
4. Gender was separated into male and female groups.
5. Ethnicity was separated into white and non-white because of low diversity numbers

- and for ease of analysis.
6. Socioeconomic status (SES) was represented by insurance type. Report of insurance by families was separated into two groups, private insurance (which was used as a proxy for higher SES) and public insurance (which was used as a proxy for lower SES) for ease of analysis.
 7. Treatment complexity was represented by technology use (insulin pump and or continuous glucose monitor (CGM) or no technology use (insulin injections and finger poke blood sugar checks).
 8. Glycosylated hemoglobin (A1c) scores were described using the mean and standard deviation and checked for skew/errors in data. A categorical A1c Control Group was created that divided the continuous A1c results into three clinically significant groups: within goal range (< 7.5%); moderate control (7.5-8.5%); and poor control (> 8.5%), to support ANOVA analysis.
 9. The total scores of the Family Impact Module of the PedsQL™ represented the parent HRQOL. The total scores of the PedsQL™Diabetes module represents the HRQOL of youth with T1D. HRQOL was used first as dependent variables when testing correlations with the independent variables. Then the total scores and subscales of HRQOL of youth with T1D and their parents were associated with each other and the metabolic control of the youth with T1D.
 10. Using all the associated independent variables and the HRQOL scores, a regression analysis was completed for the total youth with T1D (n = 210), and then analyzed separately by youth age groups, preadolescents (n = 93) and adolescents (n = 117) to

- assess the impact of the independent variables on the outcome their metabolic control.
11. According to Pallant (2013), multiple regression is very sensitive to outliers, which are scores that are very high or very low compared to the rest of the data. Pallant suggested that outlier data should be either eliminated or changed to closer match the rest of the data. This researcher made the choice to eliminate the outlier youth/parent dyad outlier data when final results differed when the outliers were removed.

Chapter Summary

The purpose of this study was to explore associations of the HRQOL of youth/parent dyads and the metabolic control of youth with T1D. Additionally, the study examined associations between the youth/parent HRQOL survey and subscales with the metabolic control of youth with other individual, family, and diabetes specific factors such as age, gender, ethnicity, socioeconomic status, and use of technology. This study was a secondary analysis of the baseline data gathered from all participants (study and control group) of a randomized control interventional study (See Appendix on page 160 for a more complete description of the primary study).

In order to develop interventions to impact health outcomes in families of youth with T1D it is important to identify individual youth and family factors, as well as diabetes specific factors that impact the metabolic control of youth with T1D. Looking at the HRQOL of both youth and their parents are important ways to assess and test interventions to support patient and family-centered care. It is hoped that this study will add to the emerging literature that is focusing on family risk and protective factors that impact metabolic control of youth with T1D

as well as support the care of youth with T1D and their families as they cope with this challenging and life changing condition.

CHAPTER 4: Findings

Introduction

This chapter presents the findings of this secondary analysis, “Type 1 diabetes: factors that affect youth/parent dyads’ health related quality of life and youth metabolic control.” The purpose of this study was to explore associations of the health-related quality of life (HRQOL) of youth/parent dyads and the metabolic control of youth with type 1 diabetes (T1D). Additionally, the study examined associations between the youth/parent HRQOL survey and subscales with the metabolic control of youth with other individual, family, and diabetes specific factors such as age, gender, ethnicity, socioeconomic status, and use of technology. The youth’s HRQOL was measured using The PedsQL™ Diabetes survey for the youth, and the parents’ HRQOL was measured using the PedsQL™ Family Impact Module. Metabolic control was measured using A1c results. After analyzing all the data from youth/parent dyads, data was divided into two age groups of youth/parent dyads based on the age of the youth. The two groups were separated into preadolescents aged eight to twelve and their parents and adolescents aged thirteen to sixteen and their parents to compare the association between the preadolescent and adolescent youth with the overall results of the youth.

The data set of 214 youth/parent dyads was carefully reviewed for any missing data per the data analysis plan outlined in Chapter 3. Data from any youth/parent dyad that was missing the A1c result, which represented the metabolic control of the youth, was eliminated from the data set. Additionally, the youth/parent dyad HRQOL total scores and subscale scores were

carefully reviewed to verify that at least 50% of the items in the scales were present, because if there were less than 50% of the items present, the scale score was not computed. Any youth/parent dyads that were missing HRQOL total scores or subscale scores were removed from the secondary data set. Data from individual, family, and diabetes related factors were reviewed for missing data as well but none of this data was missing.

Less than 2% of the 214 youth/parent dyads from the primary study's baseline data had missing data (n = 4). Three of the youth/parent dyads were missing youth A1c results, and one of the youth/parent dyads was missing parent HRQOL scores. Therefore data from 210 (98%) of 214 youth/parent dyads were used in this secondary analysis. No data related to age, gender, ethnicity, socioeconomic status (SES), or technology use were missing from the data set. Results presented are associations between:

- Treatment complexity and youth HRQOL and metabolic control
- Context variables of age, gender, ethnicity, socioeconomic status (SES) and the HRQOL and metabolic control of youth with T1D
- HRQOL of youth with T1D and the HRQOL of their parents
- Metabolic control of youth with T1D and HRQOL of their parents
- HRQOL of youth with T1D and their metabolic control

Demographic characteristics of study participants and categorical variables

The categorical variable frequencies were analyzed, including gender, age group, ethnicity, family SES (public or private insurance), treatment complexity (use of insulin pump and/or continuous glucose monitor), and three A1c Control Groups representing metabolic control levels. The youth/parent dyads (n = 4) that were removed from the secondary analysis

were also analyzed to see how the missing data might have impacted the number of youth/parent dyads represented in the categorical data. These results are included in the following paragraphs.

The four deleted data sets of youth/parent participants (due to missing A1c and HRQOL data) included data from three males and one female youth; therefore there were data from 106 (50.5%) males and 104 (49.5%) females represented in the secondary study, making the gender more balanced than the total data set. Additionally, there was an equal amount of youth in each age group (preadolescent and adolescent) that were removed from the data set due to missing data. Data from the four deleted youth/parent dyads included two preadolescent, and two adolescent youth /parent dyads. This left data for 93 (44.3%) preadolescent youth/parent dyads aged eight to twelve, and data for 117 (55.7%) youth/parent dyads of adolescents aged thirteen to sixteen. All four of the youth/parent dyads with missing data were identified as white by their parents. Therefore, there was no loss of diversity in the final sample with 91.4% of the youth identified as white and 8.6% of the youth identified as non-white racial groups in the final data set.

Insurance type was used as a proxy for family SES. Private insurance was used to represent youth/parent dyads with higher family SES, and public insurance was used to represent those youth/parent dyads with lower family SES. There were 154 (73.3%) of the families in the higher family SES (private insurance) group, and there were 56 (26.7%) of the families in the lower family SES (public insurance) group.

Treatment complexity was defined by the use of technology to support the youth's diabetes treatment. Youth in the group of high treatment complexity used insulin pumps and/or continuous glucose monitors (CGM). Youth in the group of low treatment complexity were the youth that used no technology for their diabetes cares; identified as those who injected insulin by

syringe and tested blood sugar with a finger poke. There were 140 (66.7%) youth in the high treatment complexity group (used the technology of insulin pumps and/or CGM), and 70 (33.3%) youth in the low treatment complexity group (no technology use).

A variable was created that divided A1c results into three groups. Within goal was an A1c result of less than 7.5% (Chiang et al., 2014). Data from thirty-nine (18.6%) included A1c results in the within goal range. Moderate control was identified as an A1c between 7.5-8.5%. Data from seventy youth (33.3%) included A1c results in moderate metabolic control range. Poor control was identified as an A1c result of greater than 8.5%. There were data from 101 youth in the poor control range (48.1%). All demographic and categorical data are represented in Table 5, p. 134.

Analysis and Correlation of the Continuous Data

Preliminary analyses were performed to ensure there was no violation of the assumptions of normality, linearity and homoscedasticity of the continuous data. The continuous data included youth A1c results, and both the youth and parents HRQOL total scores and subscale scores (Table 6, p. 135). All of the continuous variables met these assumptions except the A1c results. The A1c results were skewed; so the data were transformed into a new variable named A1c Log for the correlation calculations. Transforming the data corrected the skew and improved the Normal P-Plot of Regression (Figure 4 & Figure 5, p. 118). The A1c and A1c Log were highly correlated at .993; however, the results of the analysis using A1c and A1c log were not equivalent. Because there were times when the significance of the correlations changed when using A1c versus A1c Log, only the A1c Log results are reported in this analysis. However, it should be noted that the transformed A1c log has a different numerical range than the usual A1c results. The A1c results in this analysis (5.7-14, $M = 8.9$) will be represented by

the transformed A1c Log range (.76 – 1.15, $M = .94$). Table 7, p. 138, represents the numerical comparisons between A1c and A1c log for youth, preadolescents and adolescents.

Youth HRQOL data was obtained from The PedsQL™Diabetes survey. The youth HRQOL total score was a combination of all of the youth HRQOL subscales. The five subscales in The PedsQL™Diabetes survey were; About My Diabetes, Treatment –I, Treatment –II, Worry, and Communication. Data analyzed to measure the Parent’s HRQOL was obtained from the PedsQL™ Family Impact Module survey. The parent HRQOL total score was a combination of all the subscales. The six subscales in the scores of the PedsQL™ Family Impact Module were; Emotional Functioning, Social Functioning, Communication, Worry, Daily activities, and Family Relationships.

HRQOL surveys for the youth/parent dyads had total scores and scores for subscales. Preliminary analysis included correlations between the youth HRQOL (measured using The PedsQL™Diabetes survey) and the parent HRQOL (measured using the PedsQL™ Family Impact Module) and the youth’s metabolic control (measured by A1c result). The total HRQOL scores and subscale scores that were associated with A1c results were used in the final standard regression analyses in order to identify those factors that were most predictive of the youth’s A1c.

Reliability estimation of survey tools

The two survey tools used in this study were The PedsQL™Diabetes survey, and PedsQL™ Family Impact Module. Both of these surveys have been validated as able to differentiate between youth with diabetes and their parents and healthy control youth and their parents. This meant that the test appeared to be able to measure what it was supposed to

measure, which was HRQOL of families with children with chronic illness. As shared in detail in Chapter 3, these surveys have been tested in many studies and in many countries, demonstrating reliability and validity (Ferreira, Baltazar, Cavaleiro, Cabri, & Goncalves, 2014; Knez et al., 2013; Medrano, Berlin, & Davies, 2013; Panepinto, Hoffmann, & Pajewski, 2009; Varni et al., 2003).

In Chapter 3 the reliability and internal consistency, as reported by the Cronbach's alpha coefficient, for the total scores for The PedsQL™Diabetes survey and PedsQL™ Family Impact Module was shown to be very good or outstanding. The previously reported reliability coefficient for the preadolescent group was 0.90 (Varni, Burwinkle, & Seid, 2005). In the current analysis, the Cronbach's alpha coefficient for preadolescents for the PedsQL™Diabetes survey was 0.87, which was slightly lower than previously reported. For the adolescents, the previously reported Cronbach's alpha coefficient was 0.89 for the PedsQL™Diabetes survey (Varni, Burwinkle, & Seid, 2005). In the current analysis the Cronbach's alpha coefficient for adolescents aged thirteen to sixteen for the PedsQL™Diabetes survey, was 0.91, which was slightly higher than previously reported. The PedsQL™ Family Impact Module Cronbach's alpha scale reported in Chapter 3 was strong with a Total Scale Score of ($\alpha = 0.97$) in previous literature (Varni, et al. 2004). In the current analysis, the Cronbach's alpha coefficient for the total score for the Parent HRQOL survey, the PedsQL™ Family Impact Module, was 0.95, which was slightly lower than previously reported but still strong. The Cronbach's alpha scores, which were used to assess internal consistency and reliability, match the Meyer, Gamst and Guarino (2013) criteria of 0.90 or better (outstanding), and middle 0.80's (very good) in both the previously reported studies and the current analysis.

Findings related to the Research questions to test Hypotheses

Table 8.4

Hypotheses and Associated Research Questions

Hypothesis 1: There will be an association between diabetes treatment complexity (pump/continuous glucose sensor vs. injections), and youth with T1D's health-related quality of life and ability to meet metabolic treatment goals.

1. What is the association between diabetes treatment complexity (pump and/or continuous glucose monitor vs. injections) and metabolic control in youths with T1D?
 2. What is the association between diabetes treatment complexity (pump and/or continuous glucose monitor vs. injections) and health-related quality of life of youth with T1D?
-

Hypothesis 2: There will be an association between gender, age, ethnicity and socioeconomic status and youth with T1D's health-related quality of life and ability to meet metabolic control goals in youth with T1D

3. What is the association between individual factors (youth age, gender) on metabolic control and health-related quality of life of youth with T1D?
 4. What is the association between family factors (ethnicity, family socioeconomic status) on metabolic control and health-related quality of life of youth with T1D?
-

Hypothesis 3: Youth with T1D with higher health-related quality of life will have parents with higher health-related quality of life.

5. What is the association between youth with T1D health-related quality of life and the health-related quality of life score of their parent?
-

Hypothesis 4: Youth with better metabolic control will be associated with parents with higher health-related quality of life.

6. What is the association between the metabolic control of the youth with T1D and the parent's health-related quality of life?
 7. Is the youth's metabolic control associated with the psychosocial subscales of the parent's health-related quality of life survey?
-

Hypothesis 5: Youth with T1D with higher health-related quality of life will be associated with better metabolic control.

8. What is the association between the youth with T1D's health-related quality of life and metabolic control of the youth with T1D?
-

Hypotheses 1

There will be an association between diabetes treatment complexity (technology use, no technology), and youth with T1D's health-related quality of life and ability to meet metabolic treatment goals.

Research Question 1

What is the association between diabetes treatment complexity (technology use, no technology) and metabolic control (A1c) in youths with T1D?

Technology use and A1c. The metabolic control of youth with T1D who cared for their diabetes using technology was compared with the metabolic control of youth who cared for their diabetes using no technology. Metabolic control was analyzed using both the categorical variables representing three levels of metabolic control groups: within goal (< 7.5%); moderate control (7.5-8.5%); and poor control (> 8.5%); as well as the continuous A1c data (represented by the A1c log). Technology was defined by youth using an insulin pump and/or a continuous glucose monitor (CGM) for daily care. No technology was defined as youth using insulin injections and blood sugar testing using finger pokes. A Chi square for independence test was conducted and no significant association was found between diabetes treatment complexity and the three A1c Control Groups: within goal (< 7.5%); moderate control (7.5-8.5%); and poor control (> 8.5%). $\chi^2 (2, n = 210) = .097, p. = .097, phi = .149$.

An independent samples t test was conducted to compare the mean of A1c results based on youth diabetes treatment complexity (technology use, no technology). No significant difference was found between the mean A1c results for youth who used technology (insulin

pump and/or CGB) ($M = 8.88$, $SD = 1.57$) and youth who used no technology (insulin injections and finger poke blood tests) ($M = 9.17$, $SD = 1.99$); $t(208) = 1.218$, $p = .226$, two-tailed).

Moreover, when preadolescents aged eight to twelve and adolescents aged thirteen to sixteen were analyzed separately no significant difference was found between the mean of their A1c results and the use of technology versus no use of technology. Youth who used technology had lower mean A1c scores (indicating better metabolic control), but that difference was not found to be significantly different in the current study.

Research Question 2

What is the association between diabetes treatment complexity (technology use, no technology) and the health-related quality of life (HRQOL) of youth with T1D?

Technology use and youth HRQOL. An independent samples t test was conducted to compare the mean HRQOL scores of youth (measured using The PedsQL™Diabetes survey) with youth treatment complexity (technology use, no technology). Technology was defined by the youth using an insulin pump and/or a continuous glucose monitor (CGM) for daily care. No technology was defined for the current analysis as youth using insulin injections and blood sugar testing using finger pokes. No significant difference was found between the youth Mean HRQOL scores for those with youth who used technology (insulin pump and/or CGM) ($M = 67.02$, $SD = 12.63$) and those youth who used no technology (insulin injections and blood sugar testing using finger pokes). ($M = 64.54$, $SD = 12.43$); $t(208) = -1.351$, $p = .178$, two-tailed). Moreover, when preadolescents and adolescents were analyzed separately no significant difference was found between the mean of their HRQOL scores. Youth who used technology had higher HRQOL scores (indicating better health-related quality of life), but that difference was not found to be significantly different in the current study.

Hypotheses 2

There will be an association between age, gender, ethnicity and socioeconomic status (SES) and the youth with T1D's health-related quality of life (HRQOL) and the ability to meet metabolic control goals in youth with T1D.

Research Question 3

What is the association between individual factors (youth age, gender) on metabolic control (A1c) and health-related quality of life (HRQOL) of youth with T1D?

The metabolic control of youth separated into preadolescent and adolescent age groups was analyzed to test the association between the age of the youth and youth A1c results using both the categorical variable of A1c Control Groups to represent different three levels of metabolic control (within goal, moderate, and poor), as well as A1c results (A1c Log). Youth age groups were separated into preadolescent and adolescents.

Age and Youth A1c Control Groups. Chi square for independence tests were conducted and a small association was found between preadolescents and adolescents and their A1c Control Group results. The three A1c Control Groups were defined as: within goal range (< 7.5%); moderate control (7.5-8.5%); and poor control (> 8.5%), $\chi^2 (2, n = 210) = 7.12, p = .028, phi = .184$. Preadolescents had fewer participants in goal range (< 7.5%), and also had fewer participants in poor control (> 8.5%).

Age and Youth A1c. An independent sample t test was conducted to compare the mean of the A1c results based on youth age. No significant difference was found between the mean of the A1c results for those preadolescents ($M = .94, SD = .07$) and the A1c test results of adolescents ($M = .95, SD = .08$); $t (208) = -1.212, p = .227$, two-tailed).

Gender and Youth A1c Control Group. The metabolic control of youth separated into male and female gender groups was analyzed to test the association of gender and A1c results using both the categorical variable of A1c Control Groups to represent different levels of metabolic control (goal range, moderate, poor) and A1c results (A1c log). A Chi square for independence test results was conducted and no significant association was found between males and females and A1c Control Group results. A1c Control Group was defined as goal range (< 7.5%); moderate control (7.5-8.5%); and poor control (> 8.5%), $\chi^2 (2, n = 210) = 1.49, p = .476, phi = .084$.

Gender and Youth A1c. An independent sample t test was conducted to compare mean A1c result (A1c Log) based on youth gender. No significant difference was found between the mean of the A1c results for males ($M = .95, SD = .085$) and the mean A1c results of females ($M = .94, SD = .07$); $t (208) = .325, p = .745$, two-tailed). Mean scores of A1c test results for male youth were higher (indicating worse metabolic control) than mean scores of A1c test results for female youth; however, this analysis showed no significant difference between them.

Age and Youth HRQOL. Independent samples t tests were conducted to compare the HRQOL (measured using The PedsQL™Diabetes survey) of preadolescent and adolescent youth. No significant difference was found between the mean of the HRQOL scores for preadolescents ($M = 66.55, SD = 12.65$) and the mean HRQOL scores of adolescents ($M = 65.91, SD = .12.58$); $t (208) = .367, p = .714$, two-tailed). Mean scores for the HRQOL of preadolescents were higher (indicating better HRQOL) than mean HRQOL scores for adolescents; however, this analysis found no significant difference between them.

Gender and Youth HRQOL. Independent samples t tests were conducted to compare the HRQOL of male and female youth. The mean of the HRQOL scores (measured using The

PedsQL™Diabetes survey) was compared based on the gender (male, female) of the youth. No significant difference was found between youth mean HRQOL scores (measured using The PedsQL™Diabetes survey) for males ($M = 67.18$, $SD = 12.22$) and mean HRQOL scores for females ($M = 65.18$, $SD = 12.92$); $t(208) = 1.15$, $p = .251$, two-tailed). Moreover, no significant difference was found between the HRQOL scores of males and females when HRQOL scores of preadolescents and HRQOL scores of adolescents were analyzed separately. However, the difference between the mean of the HRQOL scores of the adolescent males and HRQOL scores of adolescent females approached significant difference at $p = .053$, with the adolescent male HRQOL scores being higher (reflecting better quality of life) than the HRQOL scores of the adolescent females.

Research Question 4

What is the association between family factors (ethnicity, family socioeconomic status) on metabolic control (A1c) and health-related quality of life (HRQOL) of youth with T1D?

Ethnicity and Youth A1c. The relationship between the parents' identification of ethnicity (white, non-white) and the A1c results of the youth was investigated using Pearson product-moment correlation coefficient. A small negative correlation was found between youth who were identified as white versus youth identified as non-white and the A1c of youth, $r = -.258$, $n = 210$, $p < .001$. Results indicated youth who were identified as white had lower A1c results (better metabolic control) than youth identified as non-white.

Youth were then separated into two age groups for further investigation of whether there was an association between their identified ethnicity (white, non-white) and their A1c results based on youth age. The two age groups were preadolescents, and adolescents. The A1c data from those two groups were analyzed using Pearson product-moment correlation coefficient. A

medium negative correlation was found between preadolescents who were identified as white versus those preadolescents identified as non-white and their A1c score, $r = -.392$, $n = 93$, $p < .001$; indicating that preadolescents identified as white had better metabolic control than preadolescents identified as non-white. Additionally, a small negative correlation was found between adolescents who were identified as white versus adolescents identified as non-white and the adolescent's A1c score, $r = -.186$, $n = 117$, $p = .044$. These results suggested that adolescents identified as white had lower A1c results (better metabolic control) than those adolescents identified as non-white.

An independent samples t test was conducted to compare mean A1c results of youth identified as white versus mean A1c results of youth identified as non-white. There was a significant difference between the mean A1c results for youth who were identified as white ($M = .938$, $SD = .074$) and the mean A1c result of youth who were identified as non-white ($M = 1.010$, $SD = .085$); $t(208) = 3.85$, $p < .001$ two-tailed). Results suggested that youth identified as white had lower mean A1c results (better metabolic control) than the mean A1c results of youth identified as non-white.

Youth were then separated into two age groups to compare their mean A1c results between their identified ethnicity (white, non-white) and their age (preadolescents and adolescents). Looking at the preadolescents and adolescents, there was a significant difference found between the mean A1c results for preadolescents who were identified as white ($M = .931$, $SD = .063$) and the mean A1c result for preadolescents who were identified as non-white ($M = 1.051$, $SD = .087$); $t(91) = 4.07$, $p < .001$ two-tailed). There was also a significant difference between the mean A1c results for adolescents who were identified as white ($M = .945$, $SD = .083$) and the mean A1c result for adolescents who were identified as non-white ($M = .994$, $SD =$

.082); $t(115) = 2.03, p = .044$ two-tailed). In both cases the A1c results of youth identified as white were lower (better metabolic control) than the A1c results of youth identified as non-white.

Ethnicity and Youth A1c Control Group. In order to compare the level of metabolic control (within range, moderate, poor) using the A1c Control Group variable and the identified ethnicity of the youth with T1D, a Chi Square analysis was conducted. However, there were no youth identified as non-white in goal metabolic control (< 7.5); and there were less than five youth identified as non-white in moderate metabolic control (7.5-8.5). This did not meet the assumptions for use of Chi Square (at least 5 participants per square). Therefore, this researcher was unable to compare A1c Control Groups based on youth and ethnicity (white, non-white) using the Chi Square test.

Ethnicity and Youth HRQOL. The relationship between the parent identified ethnicity (white, non-white) and the HRQOL survey score of youth with T1D (measured using The PedsQL™Diabetes survey) was investigated using Pearson product-moment correlation coefficient. Preliminary analyses were performed to ensure no violation of the assumptions of normality, linearity and homoscedasticity. There was a small positive correlation between youth identified as white and youth identified as non-white and youth HRQOL scores, $r = .189, n = 210, p = .006$, meaning that youth who were identified as white had higher HRQOL scores (better health related quality of life) than youth who were identified as non-white.

Youth were then separated into two groups for further investigation of the associations between their identified ethnicity (white, non-white) and their HRQOL scores and their age (preadolescents and adolescents). HRQOL scores from preadolescent and adolescent groups were analyzed using Pearson product-moment correlation coefficient. No association was found between the HRQOL scores of preadolescents who were identified as white and the HRQOL

scores of preadolescents who were identified as non-white, $r = .140$, $n = 93$, $p = .282$. However, a small positive correlation was found between the HRQOL scores of adolescents who were identified as white and the HRQOL scores of adolescents identified as non-white, $r = .219$, $n = 117$, $p = .018$, meaning that the HRQOL scores of adolescents identified as white were higher (better health-related quality of life) than the HRQOL scores of adolescents who were identified as non-white.

To compare the mean HRQOL score (measured using The PedsQL™Diabetes survey) between youth with T1D identified as white and the HRQOL of youth identified as non-white, independent samples t tests were conducted. A significant difference was found between the mean HRQOL scores for youth who were identified as white ($M = 66.92$, $SD = 12.81$) and the mean HRQOL scores for youth who were identified as non-white ($M = 58.43$, $SD = 12.83$); $t(208) = 2.781$, $p = .006$, two-tailed). The HRQOL of youth identified as white was higher (better health-related quality of life), than the HRQOL of youth identified as non-white.

In order to investigate if there were age related differences of HRQOL (measured using The PedsQL™Diabetes survey) between youth with T1D identified as white compared to the mean HRQOL scores for youth with T1D identified as non-white, data from youth was divided into preadolescent and adolescent groups. First, an independent samples t test was used to compare the mean HRQOL scores between preadolescents identified as white and the mean HRQOL scores of preadolescents identified as non-white. No significant difference was found between the mean HRQOL scores for preadolescents who were identified as white ($M = 66.97$, $SD = 12.49$) and the mean HRQOL scores for preadolescents who were identified as non-white ($M = 59.17$, $SD = 14.76$); $t(91) = -1.35$, $p = .182$, two-tailed).

Next, an independent sample t test was used to compare the HRQOL between adolescents who were identified as white with the HRQOL of adolescents who were identified as non-white. There was a significant difference in the mean HRQOL score for adolescents who were identified as white ($M = 66.88, SD = 12.28$) and the mean HRQOL score of adolescents who were identified as non-white ($M = 58.14, SD = 12.66$); $t(115) = -2.41, p = .018$, two-tailed). This means that the HRQOL of adolescents who were identified as white were higher (better health-related quality of life) than the HRQOL of adolescents who were identified as non-white.

SES with Youth A1c. The relationship between the family socioeconomic status (SES) of youth with T1D and the A1c results (A1c log) of the youth was investigated using Pearson product-moment correlation coefficient. The proxy of private versus public insurance was used to identify the SES of families. Families with private insurance were identified as having higher SES, and families with public insurance were identified as having lower SES. Preliminary analyses were performed to ensure no violation of the assumptions of normality, linearity and homoscedasticity. A small negative correlation was found between family SES and the youth A1c results, $r = -.163, n = 210, p = .018$. Those youth in families with higher SES (private insurance) had lower A1c results (better metabolic control) than those youth in families with lower SES (public insurance).

To test whether family SES status (private insurance versus public insurance) affected the A1c results of youth with T1D of different ages in a similar way, further analysis was conducted in which the data of youth was divided into preadolescent and adolescent age groups. A small positive correlation was found between the family SES of preadolescents and the preadolescents' A1c results, $r = .228, n = 93, p = .028$. Those preadolescents in families with higher SES (private insurance) had lower A1c results (better metabolic control) than those youth in families with

lower SES (public insurance). However, no correlation was found between the family SES of adolescents and the adolescent's A1c result, $r = .120$, $n = 117$, $p = .197$.

An independent samples t test was conducted to compare youth mean A1c results (A1c Log) based on family SES (public versus private insurance). There was a significant difference in the youth mean A1c results for those who had higher SES (private insurance) ($M = .937$, $SD = .073$) and those who had lower SES (public insurance) ($M = .965$, $SD = .086$); $t(208) = 2.34$, $p = .020$, two-tailed). Youth whose families had higher SES (private insurance) had significantly lower mean A1c results (better metabolic control), than youth whose families had lower SES (public insurance).

To test whether SES status (private insurance versus public insurance) of families affected the A1c results of youth with T1D of different ages in a similar way, further analysis was conducted in which the data of youth was divided into preadolescent and adolescent groups. No significant difference was found in the analysis of the mean A1c result of preadolescents who had higher family SES (private insurance) ($M = .928$, $SD = .062$) and the mean A1c result of preadolescents who had lower family SES (public insurance) ($M = .963$, $SD = .083$); $t(91) = -1.96$, $p = .06$, two-tailed); however, it approached significance at $p = .06$. There was also no significant difference found in the mean A1c results of adolescents with T1D who had higher family SES (private insurance) ($M = .944$, $SD = .081$) and the mean A1c results of adolescents with lower family SES ($M = .967$, $SD = .090$); $t(115) = -1.297$, $p = .197$, two-tailed). There was no significant difference found between the SES of the family of preadolescents or adolescents with T1D and their A1c results when analyzed separately.

SES and Youth HRQOL. The relationship between the family SES of youth with T1D (public insurance, private insurance) and the HRQOL of youth with T1D (measured using The

PedsQL™Diabetes survey) was investigated using Pearson product-moment correlation coefficient. Preliminary analyses were performed to ensure no violation of the assumptions of normality, linearity and homoscedasticity. No correlation was found between the family SES and youth HRQOL, $r = -.106$, $n = 210$, $p = .127$.

To test whether family SES status (private insurance versus public insurance) of families affected the HRQOL of youth with T1D of different ages in a similar way, further analysis was conducted in which the data of youth was divided into preadolescent and adolescent groups. There was no association found between the family SES and the HRQOL of either preadolescents or adolescents with T1D.

The HRQOL of youth with T1D was investigated to test for differences in the mean HRQOL score between youth whose families had higher SES (private insurance) and the mean HRQOL score of youth whose families had lower SES (public insurance). An independent samples t test was conducted to compare mean HRQOL of youth scores (measured using The PedsQL™Diabetes survey) based on family SES, represented by public versus private insurance. No significant difference was found in the HRQOL scores for youth who had higher family SES (private insurance) ($M = 66.99$, $SD = 12.09$) and youth who had lower family SES (public insurance) ($M = 63.99$, $SD = 13.73$); $t(208) = 1.53$, $p = .127$, two-tailed). There was also no significant difference found when the mean HRQOL scores of preadolescents and the mean HRQOL scores of adolescents were analyzed separately.

Although the mean HRQOL scores were higher (better HRQOL) in youth with higher family SES (private insurance) the difference in the mean HRQOL score of those youth and the mean HRQOL scores of youth whose parents had lower family SES (public insurance) were not found to be statistically significant in the current study.

Hypotheses 3

Youth with T1D with higher health-related quality of life will have parents with higher health-related quality of life.

Research Question 5

What is the association between youth with T1D health-related quality of life (HRQOL) and the HRQOL score of their parent?

Youth HRQOL with Parent HRQOL. The relationship between the HRQOL of youth with T1D (measured using The PedsQL™Diabetes survey) and the HRQOL of their parent (measured using the PedsQL™ Family Impact Module) was investigated using Pearson product-moment correlation coefficient. Preliminary analyses were performed to ensure no violation of the assumptions of normality, linearity and homoscedasticity. A small positive correlation was found between the youth and parent HRQOL score, $r = .214$, $n = 210$, $p = .002$. Youth with higher HRQOL scores (better HRQOL) had parents with higher HRQOL scores (better HRQOL).

To test whether the associations of HRQOL of youth of different ages were similarly associated, the HRQOL of preadolescents and adolescents were analyzed separately. A medium positive correlation was found between the HRQOL scores of preadolescents and the HRQOL scores of their parent, $r = .333$, $n = 93$, $p = .001$. However, no correlation was found between the HRQOL scores of adolescents and the HRQOL of their parent, $r = .125$, $n = 117$, $p = .181$.

Hypothesis 4

Youth with better metabolic control will have parents with higher health-related quality of life

Research Question 6

What is the association between the metabolic control of youth with T1D and parent's health-related quality of life (HRQOL)?

Youth A1c and Parent HRQOL. The relationship between the metabolic control of youth with T1D (measured by the A1c results) and the Parent HRQOL of youth with T1D (measured using the PedsQL™ Family Impact Module) was investigated using Pearson product-moment correlation coefficient. Preliminary analyses were performed to ensure no violation of the assumptions of normality, linearity and homoscedasticity. A1c results were skewed, so the results of the A1c were transformed into the variable A1c Log for the correlation calculations. No correlation was found between the youth A1c result and the Parent HRQOL, $r = -.122$, $n = 210$, $p = .078$.

To test whether the associations between A1c results of youth and the parent HRQOL was similarly associated with youth of different ages, further analysis was conducted in which the data of youth was divided into preadolescent and adolescent groups. No association was found between the A1c results of either preadolescents or adolescents with T1D and the parent HRQOL total score.

Research Question 7

Is youth's metabolic control (A1c result) associated with the psychosocial subscale scores of the parent's health-related quality of life (HRQOL)?

Youth A1c and subscales of Parent HRQOL. The relationship between the youth A1c results (A1c Log) and the Parent HRQOL survey subscales (measured using the PedsQL™ Family Impact Module) were investigated using Pearson product-moment correlation coefficient. Preliminary analyses were performed to ensure no violation of the assumptions of normality,

linearity and homoscedasticity. A1c results were skewed, so the results of the A1c were transformed into a new variable A1c Log for the correlation calculations. Data analyzed to measure the parent HRQOL was from the PedsQL™ Family Impact Module. The parent HRQOL total score was a combination of all the subscales. The six subscales in the scores of the PedsQL™ Family Impact Module were: Emotional Functioning, Social Functioning, Communication, Worry, Daily activities, and Family Relationships.

Youth A1c results had small negative associations with two subscales of the Parent HRQOL survey; the Parent Emotional Functioning subscale, and the Parent Family Relationships score. A small negative correlation was found between the A1c of youth and the Parents' Emotional Functioning subscale score of the HRQOL survey, $r = -.169$, $n = 210$, $p = .014$. There was also a small negative association found between the A1c of youth and the Parent Family Relationships score, $r = -.142$, $n = 210$, $p = .039$. Results for youth suggest that a higher Parent's Emotional Functioning score (better emotional functioning), is associated with a lower youth A1c result (better metabolic control) and a higher Parent Family relationship score (better family relationships) is associated with lower youth A1c results.

To test whether the associations between youth A1c results and Parent HRQOL psychosocial subscale scores (measured using the PedsQL™ Family Impact Module) were similarly associated with youth of different ages, further analysis was conducted. Data of youth was divided into preadolescent and adolescent groups. No associations were found between the A1c results of preadolescents and any of the subscales of the parent HRQOL Survey (measured using the PedsQL™ Family Impact Module).

Small negative associations were found between the A1c results of adolescents and two of the subscale scores of the parent HRQOL; Emotional Functioning subscale, and Social

Functioning (measured using the PedsQL™ Family Impact Module). A small negative association was found between the adolescent's A1c results and the parent HRQOL Emotional Functioning subscale score, $r = -.204$, $n = 117$, $p = .027$. A small negative association was also found between the adolescent A1c results and the parent HRQOL Social Functioning subscale score, $r = -.195$, $n = 117$, $p = .036$. Results for adolescents suggest that adolescent's lower A1c results (better metabolic control) were associated with a higher Parents' Emotional Functioning score (better emotional functioning). Additionally results suggest that adolescent's lower A1c results (better metabolic control) were associated with higher Parent Social Functioning score (better Social Functioning).

Hypothesis 5

Youth with T1D with higher health-related quality of life will be associated with better metabolic control.

Research Question 8

What is the association between the youth with T1D's health-related quality of life (HRQOL) and metabolic control (A1c result) of the youth with T1D?

Youth HRQOL and A1c. The relationship between the youth HRQOL with T1D (measured using The PedsQL™Diabetes survey) and the youth A1c result (A1c Log) was analyzed using Pearson product-moment correlation coefficient. Preliminary analyses were performed to ensure no violation of the assumptions of normality, linearity and homoscedasticity. Due to the skew of the A1c results, a transformed A1c Log result was used. A small negative correlation was found between the youth HRQOL and youth A1c result, $r = -$

.256, $n = 210$, $p < .001$. This means that higher youth HRQOL score (better health-related quality of life) was associated with lower youth A1c results (better metabolic control).

To test whether the associations between youth HRQOL was similarly associated with the youth's A1c results in youth of different ages, further analysis was conducted. Data of youth was divided into preadolescent and adolescents age groups. No association was found between the total score of the preadolescent HRQOL (measured using The PedsQL™Diabetes survey) and preadolescents metabolic control (A1c Log), $r = -.190$, $n = 93$, $p = .067$. However, there was a medium negative correlation between the adolescent HRQOL (measured using The PedsQL™Diabetes survey) and adolescents A1c results, $r = -.300$, $n = 117$, $p = .001$. Therefore, a higher adolescent HRQOL score (better HRQOL) was associated with a lower adolescent A1c result (better metabolic control).

Subscales of Preadolescent and Adolescent HRQOL and A1c. In order to determine if any of the subscale scores of the preadolescent HRQOL and the adolescent HRQOL surveys (measured using The PedsQL™Diabetes survey) were associated with their respective A1c results, an analysis was conducted using Pearson product-moment correlation coefficient. Preliminary analyses were performed to ensure no violation of the assumptions of normality, linearity and homoscedasticity. Due to the skew of the A1c results, a transformed A1c Log result was used. The youth HRQOL total score was a combination of all of the youth HRQOL subscales. The five subscales in The PedsQL™Diabetes survey were; About My Diabetes, Treatment –I, Treatment –II, Worry, and Communication. The subscales of the HRQOL survey were analyzed separately by the age of the youth.

No significant association was found between the preadolescent HRQOL (measured using The PedsQL™Diabetes survey) and the preadolescent A1c. However, a small negative

correlation was found with the preadolescent HRQOL Treatment-II subscale scores and the preadolescent's A1c, $r = -.235$, $n = 93$, $p = .023$. Higher scores in the preadolescent Treatment-II subscale (cares of diabetes were perceived less hard) were associated with lower preadolescent A1c results (better metabolic control).

The adolescent HRQOL total score and all of the subscale scores of the adolescent HRQOL, About My Diabetes, Treatment –I, Treatment –II, Worry, and Communication, were also negatively associated with the A1c results of the adolescents. Most notably, the Teen Treatment-I subscale of the Teen HRQOL survey had a medium negative correlation with the adolescent A1c score, $r = -.301$, $n = 117$, $p = .001$. Higher scores in all subscales of the adolescent HRQOL (better HRQOL) were associated with lower adolescent A1c results (better metabolic control). The highest association with A1c results of all the subscales was found with the Teen Treatment-I subscale (related to physical and emotional pain of diabetes).

Youth HRQOL and A1c Control Groups. In order to explore the youth HRQOL (measured using The PedsQL™Diabetes survey) of youth and the impact of levels of metabolic control of youth (measured by A1c Control Group variable), a one-way between – group analysis of variance (ANOVA) was conducted. The three A1c control group levels of metabolic control were: within goal range (< 7.5%); moderate control (7.5-8.5%); and poor control (> 8.5%). Youth A1c data at the three levels of metabolic control (within goal, moderate, and poor) were analyzed related to the youth's mean HRQOL score. There was a statistically significant difference at the $p < .05$ level for the three metabolic control groups. $F(2, 207) = 5.89$, $p = .003$. Post – hoc comparisons using the Tukey HSD test indicated that the mean HRQOL score for youth in within goal range (< 7.5%) ($M = 69.93$, $SD = 12.52$), was significantly different from the mean HRQOL score for youth in poor control (> 8.5%) ($M = 63.22$, $SD = 12.92$), $p = .012$.

The mean HRQOL score for youth in moderate control (7.5-8.5%) ($M = 68.40$, $SD = 11.20$), was also significantly different from the mean HRQOL score for youth in poor control ($> 8.5\%$) ($M = 63.22$, $SD = 12.92$), $p = .020$. However, no significant difference was found between the mean HRQOL score of youth in within goal range ($< 7.5\%$) ($M = 69.93$, $SD = 12.52$), and the mean HRQOL score of youth in moderate control (7.5-8.5%) ($M = 68.40$, $SD = 11.20$). (Table 9 & 10 p. 136). Please note that Figure 5 represents categorical means of HRQOL data based on the metabolic control groups identified above, the ANOVA output represents this as continuous, but these are discrete points.

Figure 5.

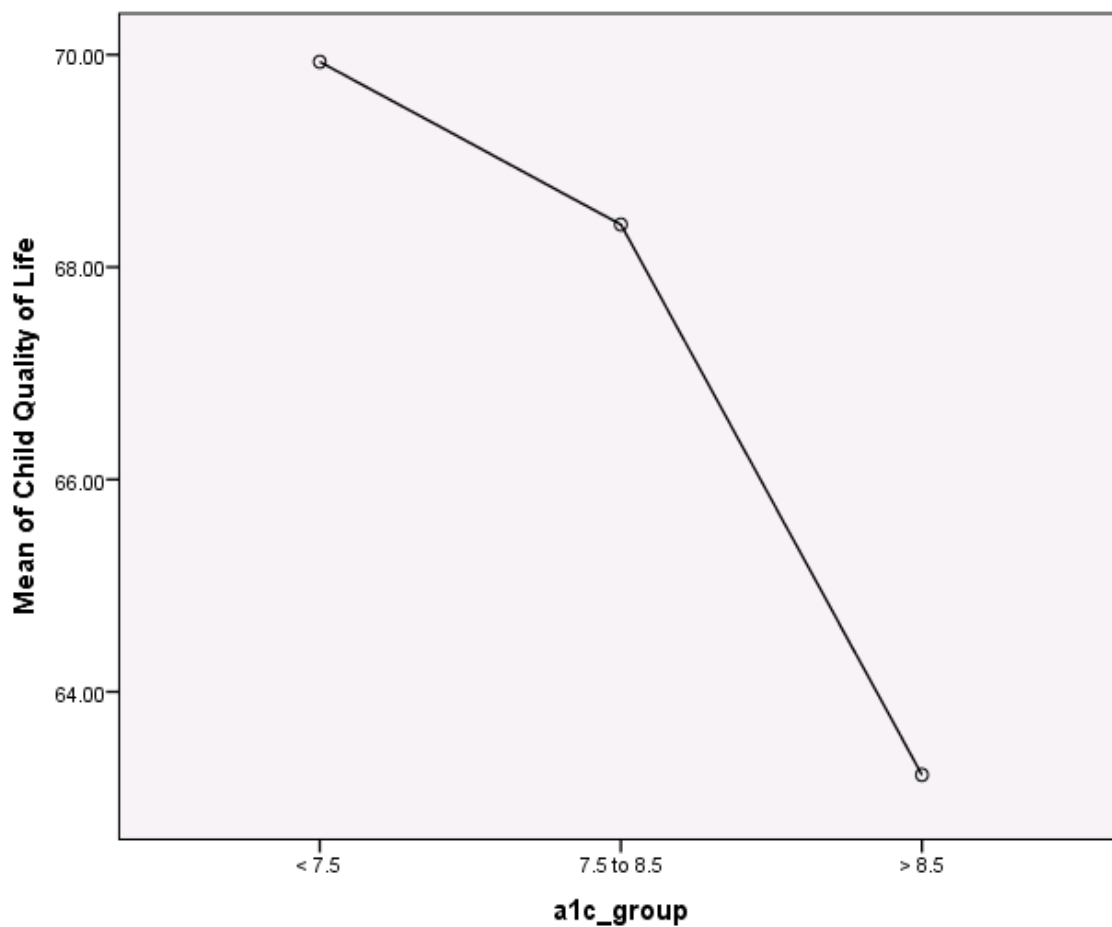


Figure 5. A1c Control Groups and HRQOL of Youth

Additional analysis of data

Regression analysis of youth variables associated with A1c. A standard regression analysis was used to assess what factors may be predictive of the metabolic control (measured by A1c result) of youth with T1D. Those independent factors which were significantly associated with the A1c results of youth T1D were included in each analysis. Those factors that were associated with the A1c results of youth were: Youth HRQOL score (measured using The PedsQL™Diabetes survey), ethnicity, family SES, and parent HRQOL (measured using the PedsQL™ Family Impact Module) Emotional Functioning subscale score of the Parent and Family Relationship subscale score. The dependent variable was metabolic control (measured by the A1c result). Preliminary analyses were performed to ensure no violation of the assumptions of normality, linearity and homoscedasticity. Due to the skew of the A1c results, a transformed A1c Log result was used for the analysis. The R Square in this model (using adjusted R square due to multiple variables) was .114, reflecting that 11% of the variability could be explained by this model, $n = 210$. The ANOVA was significant at $<.001$. A significant ANOVA test means it is likely that at least one of the variables would be significant in predicting the dependent variable. The variables that were significant predictors for the A1c of youth in this model were youth HRQOL score ($beta = -.194, p = .004$) and ethnicity ($beta = -.189, p = .006$). However, a test for outliers revealed that data from one of the youth parent dyads needed to be eliminated from the analysis, because it exceeded the critical value and distortions of parameter and statistical estimates could result (Osborne, J, & Overbay, A., 2004).

Excluding the youth/parent dyad outlier in the regression, the R Square in this model (using adjusted R square due to multiple variables) was .109, still reflecting that 11% of the

variability could be explained by this model, $n = 209$. The ANOVA was significant at $<.001$. A significant ANOVA test means it is likely that at least one of the variables would be significant in predicting the dependent variable. The variables that were significant predictors of metabolic control in this model were youth HRQOL score ($beta = -.195, p = .004$) and ethnicity ($beta = -.172, p = .012$), but there were no more outliers (Table 11, p. 137).

Power analysis. The primary study included data from 214 youth/parent dyads. Data from four youth/parent dyads were eliminated from the original dataset of 214 youth/parent dyads due to missing data identified in the data analysis plan. The resulting sample was data from 210 youth/parent dyads. The sample size needed for a 95% power level of the regression analysis of youth/parent dyads, based on 4 independent variables, to detect a .15 medium effect size at a .05 significance level was 129 youth/parent dyads to predict metabolic control. After data from one outlier parent youth was eliminated the sample size was 209 youth/parent dyads.

Standard regression with preadolescents. A standard regression analysis was used to assess what factors may be predictive of the metabolic control (measured by A1c result) of preadolescents with T1D. Independent factors that were significantly associated with the A1c result of preadolescents were HRQOL Treatment-II subscale (measured using The PedsQL™Diabetes survey), ethnicity, and family SES. The dependent variable was metabolic control (measured by the A1c result). Preliminary analyses were performed to ensure no violation of the assumptions of normality, linearity and homoscedasticity. Due to the skew of the A1c results, a transformed A1c Log result was used for the analysis. The R Square in this model (using adjusted R square due to multiple variables) was .186, reflecting that 19% of the variability could be explained by this model, $n = 93$. The ANOVA was significant, $p < .001$. A significant ANOVA test means it is likely that at least one of the variables would be significant

in predicting the dependent variable. The variable that was significant was ethnicity, ($beta = -.352, p < .001$). SES was not significant in this analysis, but close to significance at $p = .055$. However, the test for outliers revealed that there were five outliers. Therefore, the data from the five youth/parent dyad outliers were eliminated from the data set.

Excluding the outliers ($n = 5$), the R Square in this model (using adjusted R square due to multiple variables) dropped to .05, reflecting that only 5% of the variability could be explained by these factors, $n = 88$. The ANOVA continued to be significant, $p = .041$. A significant ANOVA test means it is likely that at least one of the variables would be significant in predicting the dependent variable. Ethnicity was no longer significant in this model, as the five outliers were all of the non-white preadolescents in the sample. Family SES was now the only significant predictor of the metabolic control of preadolescents, ($beta = .211, p = .049$) (Table 12, p. 137).

Standard regression with adolescents. Several regressions were tested using two different groups of regression factors for the adolescents. There were two variables that were equally associated with adolescent A1c results, the adolescent HRQOL total score and the adolescent HRQOL Teen Treatment-I subscale score. Two different regressions were run because when the regression was run using both the adolescent HRQOL score and Teen Treatment-I subscale score, none of the tested variables were predictive of the A1c result. Upon further analysis, the adolescent HRQOL total score and adolescent HRQOL Teen Treatment –I subscale factors did not uniquely contribute to the model when run together so were used separately to test the models of regression analyses with parent HRQOL Emotional Functioning and Social Functioning subscales.

Additional analysis was conducted after outliers were removed. Although there was greater association between the parent HRQOL Emotional Functioning subscale score and the adolescent A1c than the association between the parent HRQOL Social Functioning subscale and the adolescent A1c, the parent HRQOL Social Functioning subscale was a greater unique contributor. The standardized beta and the significance of the Parent Emotional Functioning subscale was ($beta = -.037, p = .744$) and the Parent Social Functioning subscale was ($beta = -.182, p = .112$). Together neither subscale was a significant contributor. The low standardized beta of the parent HRQOL Emotional Functioning subscale coupled with the higher standardized beta of the Parent Social Functioning subscale suggested that eliminating the parent HRQOL Emotional Function subscale might better support the model. A regression run using only the adolescent HRQOL Teen Treatment-I subscale and Parent Social Functioning subscale score, was the most significant model for predicting A1c results. The results of this regression were as follows.

A standard regression analysis for adolescents with T1D used the independent factors that were significantly associated with adolescents and A1c results were included in the analysis. These were the adolescents HRQOL Teen Treatment-I score (measured using The PedsQL™Diabetes survey), parent HRQOL Social Functioning subscale score (measured using the PedsQL™ Family Impact Module), and ethnicity. The dependent variable was metabolic control (measured by the A1c result). Preliminary analyses were performed to ensure no violation of the assumptions of normality, linearity, and homoscedasticity. Due to the skew of the A1c results, a transformed A1c Log result was used for the analysis. The R Square (using adjusted R square due to multiple variables) was .119, reflecting that 12% of the variability could be explained by this model, $n = 117$. The ANOVA was significant at $<.001$. A significant

ANOVA test means it is likely that at least one of the variables would be significant in predicting the dependent variable. In this model there were two variables that were significant. Adolescent HRQOL Treatment-I subscale ($beta = -.281, p = .002$) and Parent Social Functioning subscale ($beta = -.194, p = .029$). There were no outliers in this model (Table 13, p. 138).

Summary

The purpose of this study was to explore associations of the HRQOL of youth/parent dyads and the metabolic control of youth with T1D. Additionally, the study examined associations between the youth/parent dyad HRQOL and its psychosocial subscales with the metabolic control of youth with other individual, family, and diabetes specific factors such as age, gender, ethnicity, socioeconomic status, and use of technology. Regression analysis was conducted using the associated variables for youth/parent dyads and youth metabolic control. Regression analyses were also conducted using associated variables for preadolescents/parent dyads and adolescent/parent dyads and youth metabolic control separately.

Chapter 5: Discussion

A secondary analysis of the baseline data of an interventional study was conducted to investigate associations between youth/parent dyads' health-related quality of life (HRQOL) total scores and subscales and metabolic control of youth with type 1 diabetes (T1D). Youth HRQOL total scores and subscales were measured by The PedsQL™ Diabetes survey. Parent HRQOL total scores and subscales were measured by the PedsQL™ Family Impact Module. Youth metabolic control was measured using data from A1c results. Data from all youth/parent dyads (n =210) were analyzed in order to address the research questions. The purpose of this study was to explore associations between the HRQOL of youth/parent dyads and the metabolic control of youth with T1D. Additionally, the study examined associations between the youth/parent HRQOL survey and subscales with the metabolic control of youth and other individual, family, and diabetes-specific factors such as age, gender, ethnicity, socioeconomic status, and use of technology. A concept map was created to illustrate the expected outcomes of this analysis based on current literature (Figure 2, p. 116).

There were two significant results of this secondary analysis of data from 210 youth/parent dyads that supported the research questions. The first result was that youth HRQOL scores were significantly lower (lower HRQOL) if youth had poor metabolic control, defined in this study as A1c higher than 8.5%. Therefore, youth with T1D with poor metabolic control had significantly worse HRQOL. The second result was that youth HRQOL scores and the youth's ethnicity were predictive of their metabolic control as measured by A1c. Therefore, if the youth with T1D had lower HRQOL and were non-white their metabolic control was worse.

Subsequent analysis was conducted by age group of youth (preadolescent $n = 93$ and adolescent $n = 117$) to determine if developmental stage was an influential factor. Significant results of the data analysis of preadolescent youth/parent dyads were that family socioeconomic (SES) level was predictive of metabolic control. However, SES was only a predictor once data from outlier youth/parent dyads were eliminated. Importantly, and worth further investigation, the outlier youth/parent dyads in the preadolescent age group included all of the non-white youth ($n = 5$). No white youth from the preadolescent age group were outliers. This disparity suggests a particular vulnerability in ethnically diverse preadolescents with T1D no matter their family SES.

Significant results of the data analysis of adolescent youth/parent dyads were that a subscale of the adolescent HRQOL survey (Teen Treatment-I) and a subscale of the parent HRQOL survey (Social Functioning) were predictive of adolescent metabolic control. This result suggests that interventions that support the psychosocial health of both adolescents with T1D and their parents may improve adolescent metabolic control.

These results aligned with some of the relationships of variables proposed by the research questions and the original concept map: however, some relationships of variables were not significant in the current study. Other relationships between variables were more closely aligned with preadolescent youth aged eight to twelve or adolescent youth aged thirteen to sixteen. Therefore the original concept map was revised to better represent the findings of the current study (Figure 4, p. 118).

This chapter will review, interpret, and discuss results reported in Chapter 4. For each of the hypotheses and related questions, results will be compared and contrasted with existing literature on the topic. Those results that were significant when the preadolescent and adolescent

youth were analyzed separately will be discussed. The strengths and limitations of the study will be outlined. In conclusion, implications and recommendations for clinical, education, policy and research will be discussed.

Summary of Results

Table 8.5

Hypotheses and Research Questions

Hypothesis 1: There will be an association between diabetes treatment complexity (pump/continuous glucose sensor vs. injections), and youth with T1D's health-related quality of life and ability to meet metabolic treatment goals.

1. What is the association between diabetes treatment complexity (pump and/or continuous glucose monitor vs. injections) and metabolic control in youths with T1D?
 2. What is the association between diabetes treatment complexity (pump and/or continuous glucose monitor vs. injections) and health-related quality of life of youth with T1D?
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Hypothesis 2: There will be an association between gender, age, ethnicity and socioeconomic status and youth with T1D's health-related quality of life and ability to meet metabolic control goals in youth with T1D

3. What is the association between individual factors (youth age, gender) on metabolic control and health-related quality of life of youth with T1D?
 4. What is the association between family factors (ethnicity, family socioeconomic status) on metabolic control and health-related quality of life of youth with T1D?
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Hypothesis 3: Youth with T1D with higher health-related quality of life will have parents with higher health-related quality of life.

5. What is the association between youth with T1D health-related quality of life and the health-related quality of life of their parent?
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Hypothesis 4: Youth with better metabolic control will be associated with parents with higher health-related quality of life.

6. What is the association between the metabolic control of the youth with T1D and the parent's health-related quality of life?
 7. Is the youth's metabolic control associated with the psychosocial subscales of the parent's health-related quality of life survey?
-

Hypothesis 5: Youth with T1D with higher health-related quality of life will be associated with better metabolic control.

8. What is the association between the youth with T1D's health-related quality of life and metabolic control of the youth with T1D?
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Discussion of Findings

Hypothesis 1

The first finding related to hypothesis 1 is that no association was found between treatment complexity (the use of insulin pumps and/or CGM) and youth metabolic control. While this finding is supported by previous studies (Cherubini et al., 2014; Muller-Godeffroy et al., 2009; Valenzuela et al., 2006), there was some evidence that increased intensity of diabetes management (the use of more blood tests and insulin analogs) could improve metabolic control in youth over time (Dovic et al., 2014; Svoren et al., 2007). Adherence to care, testing blood sugars and injecting insulin boluses with meals and snacks were also shown to improve metabolic control (Hood, Peterson, Rohan, & Drotar, 2009; Ziegler et al., 2011). However, few studies were found in the literature that associated the use of insulin pumps or continuous glucose monitors (CGM) (the definition of treatment complexity for the current study) and improved metabolic control (Berg et al., 2014; Svoren et al., 2007). Although many families of youth with T1D believe that the use of technology would support better adherence to diabetes care, the use of insulin pumps and CGM devices has not been shown to improve adherence to diabetes care in youth (Burdick et al., 2004; Olinder et al., 2009; Secretariat, 2011).

The second finding related to Hypothesis 1 is that no association found between the use of insulin pumps or CGM and youth HRQOL. While this finding is supported by previous studies (Cherubini et al., 2014; Secretariat, 2011; Valenzuela et al., 2006), there has been some evidence that there may be an association between treatment complexity of youth with T1D and youth HRQOL (Muller-Godeffroy et al., 2009; Verchota, 2014).

Although technology use continues to increase, there has been little improvement in overall A1c results in youth with T1D over the last twenty years (Miller et al., 2015). No technology currently eliminates the need for manual intervention by the youth. It is possible that

technology has not evolved enough to significantly improve either youth metabolic control or youth HRQOL. Although insulin pumps and CGM give youth continuous access to both insulin and blood sugar data, youth continue to need to calculate the insulin doses based on blood sugar results and food ingested. Youth must also calibrate the CGM through finger poke blood sugar testing twice per day. Although continuous glucose monitors (CGM) that were integrated into the insulin pump improved the number of blood sugar results collected, it did not increase the number of insulin boluses delivered by youth or improve the youth's metabolic control (Neylon, O'Connell, Donath, & Cameron, 2014). This mirrored the results of previous work by Burdick et al. (2004), who found that youth who used pump technology to administer insulin boluses missed as many injections as youth who used syringes to administer insulin. These findings suggest that until technology is truly a closed-loop system, able to sense and respond to changes in blood sugar without any intervention on the part of the youth, its effect on overall control is limited.

Hypothesis 2

The first finding related to Hypothesis 2 is that no association was found between gender and age and metabolic control. However, there was an association found between ethnicity and socioeconomic status and metabolic control, as non-white youth had lower SES and higher A1c. While this finding about ethnicity is supported by previous European studies related to ethnicity and metabolic control (de Vries et al., 2013; Rosenbauer et al., 2012), there is some evidence that when ethnicity is controlled for, socioeconomic status is a predictor of metabolic control of youth (Springer et al, 2006). One study showed that non-white youth were more seriously ill at diagnosis of T1D, which puts them at greater risk for poor long-term metabolic control (deVries et al, 2013). In addition to ethnic disparities in access to healthcare, there are times when

healthcare providers intentionally or unintentionally deliver care differently based on a youth's ethnicity (Brosch, Bar-David, & Phelps, 2013).

The finding of the current study, that higher family SES was associated with better metabolic control was supported by a study by Springer et al. (2006). Springer et al. reported that family SES was more strongly associated with metabolic control than ethnicity, gender, age, and duration of diabetes. Changing insurance coverage plans, especially the presence of high deductibles, may impact access of care for youths. One recent study found that a higher percentage of youth diagnosed with T1D in Colorado were severely ill at diagnosis (Rewers, et al., 2015). This increase of severe illness at diagnosis was associated with an increase in deductibles that delayed care, especially in youth of lower family SES (Rewers, et al.). The severity of illness at diagnosis can have long-term impacts on the metabolic control of youth with T1D, as it decreases long-term endogenous insulin availability (de Vries et al., 2013). Therefore, if non-white youth are at risk of more severe illness at diagnosis and also come from a family with lower SES, non-white may be more at risk for long-term poor control than white youth from families with higher SES.

The second finding related to Hypothesis 2 is that while no association was found between gender, age, and SES and HRQOL, there was an association found between ethnicity and HRQOL. The results related to HRQOL and gender and age differed from previous studies (Hanberger, et al., 2009; Malakonaki, et al, 2011; Nardi, et al., 2008). No association was found with family SES and HRQOL in the current study; however, Hanberger (2009) found an association between family SES (using education of the mother as proxy for SES) and youth HRQOL. In the current study, youth who were identified as white had better HRQOL than youth

who were identified as non-white. No other diabetes studies were found in the literature that associated white ethnicity with higher HRQOL.

Hypothesis 3

The finding related to Hypothesis 3 was a small positive association between youth and parent health-related quality of life (HRQOL). When youth HRQOL was higher, their parent HRQOL was higher. The results of the current study are similar to results of other studies that found youth HRQOL was associated with parent HRQOL (Hanberger et al., 2009; Muller-Godeffroy et al., 2009). Assessment of the quality of life of youth with chronic illness and their parents, not just the control of their symptoms or disease process, is has been suggested as an important standard of care for children with chronic illness (de Wit et al., 2007; Malakonaki et al., 2011). Other researchers have suggested that the HRQOL of youth impacts the HRQOL of their parent, and that the HRQOL of the parent impacts the HRQOL of their youth (Varni, et al., 2009; Medrano, et al., 2013). Therefore, it may be important to consider both the HRQOL of the youth and the HRQOL of the youth's parent when developing interventions in order to support the best outcomes for families.

Hypothesis 4

The first finding related to Hypothesis 4 was that no association was found between youth metabolic control and parents HRQOL score. The second finding related to hypothesis 4 was that there were associations between youth metabolic control and two subscales of the Parent HRQOL survey. Youth with worse metabolic control had parents with lower scores in the Emotional Functioning subscale (anxious, sad, angry frustrated, helpless or hopeless) and Family Relationship subscale (communication, conflicts, decisions, solving problems, stress or tension).

Previous studies reported associations between youth metabolic control and negative healthcare outcomes (increased emergency room visits) and the psychosocial health of the parent (Butwicka et al., 2012; Butwicka et al., 2013; Clayton et al., 2013). Those studies suggested that better youth outcomes and lower costs might be achieved by supporting the psychosocial health of parents of youth with T1D. However, other studies found no correlations between the metabolic control of youth with T1D and the psychosocial health of their parents (Jaser, Linsky, & Grey, 2014; Jaser, Whittemore, Ambrosino, Lindemann, & Grey, 2008). There have also been studies that have explored family relationships (acceptance, involvement, critical parenting) and their impact on youth adherence and metabolic control. Metabolic control of youth with T1D may be predicted in part by problems in family relationships (King, Berg, Butner, Butler, & Wiebe, 2014; Lewin et al., 2006). The association between the youth A1c result and both the Parent Emotional Functioning subscale and the Parent Family Relationship subscale suggest that family therapy and family-centered interventions may support the improved metabolic outcomes of youth with T1D.

Hypothesis 5

The finding associated with Hypothesis 5 is that there is a negative association between youth HRQOL and metabolic control. Youth with better HRQOL had better metabolic control (lower A1c results). Youth with worse HRQOL had worse metabolic control (higher A1c results). An A1c result of greater than 8.5% was a critical parameter that predicted a significantly lower youth HRQOL than A1c results below 8.5%. HRQOL scores were significantly lower when A1c was greater than 8.5%. Changing the definition of poor metabolic control of youth to any A1c greater than 8.5%, the point where it may begin to impact their quality of life should be considered. Of note is that the mean A1c of the youth in the current

study was 8.95%, which was well above the 8.5% level. Many previous studies, across many countries, described poor metabolic control as an A1c greater than 9.0% (Campbell, et al., 2014; Maahs et al., 2014; Malik & Taplin, 2014; Miller et al., 2015; McKnight, et al., 2015). Since the final regression analysis suggested that the youth HRQOL score was predictive of A1c, the development of interventions to support improved youth HRQOL, might contribute to improving the A1c levels of youth, and thus the overall health and well-being of youth with T1D.

Additional Age-Based Analysis. A subsequent analysis was conducted to determine if developmental category was an influential factor in youth metabolic control. Youth data was divided into two developmental age groups: preadolescent youth aged eight to twelve and adolescent youth aged thirteen to sixteen. When the data were analyzed by developmental category, preadolescent and adolescent associations sometimes differed from total youth association. The differences of developmental age group results and the total youth results will be discussed in the following paragraphs.

For example, significant results of the multiple regression data analysis of preadolescent youth/parent dyads were that family socioeconomic (SES) level was predictive of metabolic control. Preadolescents with higher family SES had better metabolic control (had lower A1c results), whereas preadolescents with lower family SES had worse metabolic control (higher A1c results). However, SES was only a predictor once data from outlier youth/parent dyads were eliminated.

Importantly, and worth further investigation, was the finding that the outliers in the preadolescent age group that were eliminated in the final regression included all of the non-white youth (n = 5). No white youth from the preadolescent age group were outliers. A review of the non-white preadolescent/parent data found that non-white preadolescent/parent dyads had very

high A1c results (poor metabolic control) and/or very low HRQOL scores (lower HRQOL). The data from these non-white preadolescent/parent dyads could not be used in the final regression, but should be explored further as they differed so greatly from the white preadolescent/parent dyad data. Though the number of non-white preadolescents was small (n = 5) this disparity of worse metabolic control and/or worse HRQOL of non-white preadolescent/parent dyads suggested a particular vulnerability in health of non-white preadolescents with T1D and their families, no matter their SES.

A significant result of the multiple regression data analyses of adolescent/parent dyad data was that the most unique contributor variables to the outcome of metabolic control were one subscale of the adolescents HRQOL and one subscale of the parent HRQOL. The three variables that were associated with adolescent metabolic control were: 1) subscale Teen Treatment-I (cares hurt, feel embarrassed, argue with parents, hard to do everything) from the adolescent HRQOL survey; 2) subscale Social Functioning (isolated, no support, no time, no energy) from the parent HRQOL survey; and 3) ethnicity. These three variables were analyzed in a standard multiple regression. The two subscales, Teen Treatment-I and parent Social Functioning, were predictive of adolescent metabolic control, meaning that more problems related to adolescent treatment of diabetes and parent social functioning were predictive of worse adolescent metabolic control (See Table 14 for the list of statements in both of these subscales, p. 139). The finding that adolescent treatment of diabetes and parent social function was predictive of metabolic control suggests that interventions that support the psychosocial health of both adolescents with T1D and their parents may improve adolescent metabolic control.

Preadolescents whose families had lower SES had worse metabolic control. Preadolescents who were non-white also had worse metabolic control. While

adolescents who were non-white also had worse metabolic control, being non-white was not a predictor for lower metabolic control for adolescents in the regression analysis. For adolescents, their total HRQOL survey score was predictive of their metabolic control, when their HRQOL was lower their metabolic control was worse. The strongest model for factors that predicted the control of adolescents was a subscale of their HRQOL (Teen Treatment-I) and a subscale of their parent HRQOL (Social Functioning). Preadolescent and adolescent metabolic control was predicted by different factors. Therefore, the results of the current study suggests that the development of interventions need to be specific to those factors that predict the metabolic control of the specific age group in order to improve that age group's metabolic control.

Strengths of the study

A major strength of this secondary analysis is that the primary study was a Patient-Centered Research Institute (PCORI) grant funded study, which meant that the study went through a competitive process for funding that supported high research standards. An MD, PhD, academic researcher who is an Associate Professor in the Department of Pediatrics at the University of Wisconsin, Madison, led the primary study. The primary study was a collaboration between researchers at the Diabetes Center at the Children's Hospital of Wisconsin Diabetes Center and researchers at the American Family Children's Hospital Diabetes Center. This research collaboration was created in part to collect data from both rural and urban sites, and to expand the ethnic diversity of participants. Data for the primary study was collected following strict scientific protocols.

The exploration of the impact on youth A1c by psychosocial factors of parents was reviewed and approved by the primary investigator of the primary study for its unique contribution to the literature. The plan of the primary study did not include examining the

baseline data for factors that affect youth/parent HRQOL and youth metabolic control, so the current study adds to the impact of the primary study. This secondary analysis was conducted using baseline data that comprised the intake data for a yearlong longitudinal intervention study. The analysis for this study was conducted before the completion of the primary study. All data analysis was done in consultation with a PhD prepared statistician from the University of Wisconsin, Milwaukee College of Nursing.

The HRQOL data was collected from both youth and their parents. For all participants in the current analysis, the Cronbach's alpha scores, which were used to assess internal consistency and reliability, matched the Meyer, Gamst and Guarino (2013) criteria of 0.90 or better (outstanding), and middle 0.80's (very good). It has been suggested that the approach of routine and consistent assessment of HRQOL of youth and their parents supports a consumer-based health care system (Varni & Limbers, 2008). Upton et al. (2008) also suggested that both youth and parents must be included in the assessment of HRQOL as it is important to assess and understand the factors that impact of HRQOL in youth with T1D and their parents.

Data about youth HRQOL was gathered using The PedsQL™ Diabetes survey, a well-respected pediatric diabetes quality of life measurement tool shown to have high reliability and validity. In the current analysis, the Cronbach's alpha coefficient for preadolescents for the PedsQL™ Diabetes survey was 0.87. The Cronbach's alpha coefficient for adolescents for the PedsQL™ Diabetes survey was 0.91.

Research has shown that it is advantageous to use diabetes-specific tools when studying youth with T1D as diabetes specific tools have the potential to capture information that is specifically relevant to this vulnerable population. (de Wit et al., 2008). Data about parent HRQOL was gathered using the PedsQL™ Family Impact Module, another high reliability and

validity measure tested in many studies (Mano, Khan, Ladwig, & Weisman, 2011; Knez, Stevanovic, Vulić-Prtorić, Vlašić-Cicvarić, & Peršić, 2013; Medrano, Berlin, & Hobart Davies, 2013; Panepinto, Hoffmann, & Pajewski, 2009). The Cronbach's alpha coefficient for the total score for the Parent HRQOL survey, the PedsQL™ Family Impact Module, was 0.95.

The sample sizes for the regression analysis exceeded the needed sample sizes identified in the power analyses for the current study. The power analysis for the regression analyses of all youth in the current study supported a 95% power level for four independent variables, with a medium effect size of .15 and a significance level of .05, for a sample size of 129. The sample size of the current study was 209 (with one outlier removed).

Limitations of the study

A limitation of any secondary analysis is that the researcher's access to data is confined to the data that was collected to support the research questions of the primary analysis (Polit & Tatano, 2012). Investigators for the primary study selected all of the variables, subjects, and measurement tools. The data may not have included all of the confounders and data that may have been included if the study was specifically designed to answer the research questions posed in the secondary analysis (Hulley, Cummings, Browner, Grady, & Newman, 2013; Polit & Tatano, 2012). It was important for this nurse scientist to minimize the risk of using secondary data. Having direct access to the de-identified data, and having direct access to the primary study research team to resolve questions minimized risk. This researcher also had access and permission to analyze data quality, check for accuracy, test for usability, and determine appropriateness for addressing the proposed research questions (Conn et al., 2015; Dunn et al., 2015). Missing data was identified by this researcher in the dataset of the primary study and youth/parent dyads with missing data were eliminated from the analysis ($n = 4$).

There are several other potential limitations to this study. Sites were expanded to urban areas and there was purposive recruitment for ethnic diversity of youth, resulting in the percentage on non-white youth in the total sample matched the percentage on non-white youth in the state. However, the percentage of non-white preadolescent youth recruited for the study was below the state average. It is possible that this lack of ethnic diversity in preadolescents may have impacted the results for that age group. One of the exclusion criteria was speaking English, which may have reduced the ethnic diversity of participants. Because of the limited age range of youth from eight to sixteen in the primary study, the results of this study may not be generalized across all youth with T1D. Additionally, because of this study's cross-sectional design, only correlations, not causations, could be assessed. Finally, the study was conducted in one state in the Midwest; therefore the findings may not be generalizable nationally.

Implications and Recommendations

The results of this study have implications for clinical practice, education of the healthcare team, policy, and research.

Recommendations for Clinical Practice:

Health care providers working with youth with T1D and their families should be provided with evidence-based education. The following clinical recommendations are based on results from the current study:

1. **Use decreased health-related quality of life of youth with T1D as the indicator for poor metabolic control.** This study could support clinical practice in the care of youth with diabetes and their parents in several ways. This study found that the HRQOL of youth with diabetes declined when their metabolic control deteriorated to 8.5% or greater. This supports other studies that suggest that the assessment of HRQOL

should be a standard measure in the care of youth with T1D (de Wit et al., 2007; Ingerski, 2010; Malakonaki et al., 2011). It is possible that interventions tailored to support youth adherence and barriers to diabetes metabolic control may also support improvement in HRQOL of youth (Cox et al., 2014).

2. **Make screening for health-related quality of life more feasible in a clinical setting by using 5-question subscales to screen youth and parents for risks relevant to poor metabolic control.** Results of the current study suggested that for adolescents, the subscales of the HRQOL survey of the adolescents were correlated with their A1c, as were two subscales of the parent HRQOL survey tool. Lower scores in the Treatment-I subscale of the adolescents HRQOL survey together with lower scores in the Social Functioning scale of the parent HRQOL survey were predictive of worse metabolic control in adolescents with T1D. Results of this study would suggest that it might be efficient and effective to screen both adolescents and their parents with subscales of questions from the HRQOL survey, based on the youth developmental age, rather than administering the entire HRQOL tool.
3. **Develop personalized interventions for youth and parents based on data collected through HRQOL subscales.** In the current study, better HRQOL of preadolescents with T1D was associated with better HRQOL of the parents. This positive association of the HRQOL of preadolescents and their parents would suggest that interventions developed to support increased HRQOL of both youth and their parents in this age group could be beneficial to both groups. There was also a particular subscale of the HRQOL survey that was associated with the metabolic control of that age group. In particular, for preadolescents with T1D the Treatment II subscale (hard to do diabetes

cares) was negatively associated with metabolic control of preadolescents (See Table 15 for the list of Treatment II subscale questions, p. 140). This means that if the preadolescent score for Treatment II subscale was higher (less problems), their metabolic control was better (lower A1c). Interventions focused on coping with the diabetes cares of preadolescents may improve their A1c and subsequently improve their HRQOL. Targeted interventions that support improved HRQOL and metabolic control in youth with T1D and/or the HRQOL of their parents assessed through subscales in the HRQOL survey may support improved HRQOL and/or youth metabolic control.

4. **Develop interventions that minimize both clinical and psychosocial risks for both parents and youth with T1D.** New focus on the integration of both psychosocial and physical care may support the HRQOL and metabolic control of youth with T1D and their parents. Implementing psychosocial interventions like cognitive behavioral therapy for youth with T1D and their parents has been reported to improve depressive symptoms and metabolic control in youth with T1D (Ashraff, et al., 2013; Markowitz, et al., 2011). Strategies like cognitive behavioral therapy must be tested in pediatric healthcare environment to support Population Health initiatives, and reduce the economic burden of care of chronic illness.
5. **Conduct educational interventions for youth and parents in group settings that are relevant to the age of the youth with T1D.** The results of the current study suggest that adolescent metabolic control was predicted by the parent HRQOL Social Functioning subscale score. Adolescent metabolic control was worse (A1c was higher) if the parent Social functioning subscale scores were lower. Implementing

interventions that improve the social support of parents, such as group clinic visits that include parents or virtual web-based support groups for parents may help improve adolescent metabolic control and the HRQOL of their parents (Kime, McKenna, & Webster, 2013; Kohler, 1978; Kohler et al., 1982). Virtual support of parents through the internet may be especially important in rural areas (Merkel & Wright, 2012).

Education of Healthcare Team

Academic education and subspecialty training for health care providers working with youth with T1D and their families should be provided with evidence-based education that meets the following objectives:

1. **Increase awareness in healthcare professionals of the disparities of clinical outcomes in non-white youth with T1D.** It is important to educate healthcare providers through academic and professional training about the disparities between white and non-white youth in terms of their metabolic control and their HRQOL. Many healthcare providers are unaware of unintentional difference in their care delivery based on the ethnicity of the youth (Brosch, et al., 2013). Raising the awareness of this phenomenon during healthcare provider training could be the first step in reducing bias.
2. **Reduce unintentional differences in the care of non-white and/or youth with lower SES diagnosed with T1D which could affect their long-term health care outcomes.** It is more likely for non-white youth to be more seriously ill at diagnosis with T1D, which could impact their long-term metabolic control (deVries, et al., 2013). It is also more likely that all youth with lower SES are at risk to delay care due to insurance deductibles (Rewers, et al., 2015). Although T1D is a relatively common chronic illness of youth, the signs and symptoms of T1D are dismissed 70% of the time in initial contacts with

healthcare providers, especially with children less than two years old (Lokulo-Sodipe, et al., 2014). It must be emphasized in clinical training that 80% of children with T1D do not have first-degree family members with T1D (Parkkola, et al, 2013). Since the testing of urine glucose is not expensive, children presenting enuresis and/or frequent urination and/or weight loss should be standardly screened for T1D to support early intervention (Lokulo-Sodipe, et al.).

3. **Focus attention on health-related quality of life, not just control of disease.**

Researchers have suggested that monitoring health-related quality of life (HRQOL) of youth in clinical practice should become standard of care in youth with T1D (de Wit et al., 2007; Ingerski, 2010; Malakonaki et al., 2011). There has been some evidence in the literature that better metabolic control and HRQOL could be realized by focusing on both the physical and psychosocial aspects of self-management for youth with T1D and their families (Medrano et al., 2013). The results of the current study suggest that higher HRQOL of youth with T1D is a predictor of better youth metabolic control. The results of the current study also suggest that youth with T1D in poor metabolic control ($A1c > 8.5\%$) have significantly worse HRQOL. Therefore decreases in youth HRQOL or metabolic control could be important clinical indicators of the interventional needs of youth with T1D.

4. **Create family-centered interventions to support family function and metabolic outcomes of youth.**

Medrano, et al. (2013) suggested that the HRQOL of the youth both impacts and is impacted by the HRQOL of parents. Focusing on the support needs of parents may in turn support the achievement of metabolic control of the youth with T1D. Group interventions have been described in the literature as helpful for youth with

T1D and their parents (Loding et al., 2008; Plante & Lobato, 2008). Results of the current study suggest that group interventions to provide education and social support youth with T1D and their families should be tested in future research.

5. **Implement interventions that are developmentally appropriate for the best outcomes.** The current study suggests that the factors that impact metabolic control may depend on developmental level of youth with T1D. In the current study the factors that predicted the metabolic control of preadolescents and adolescents were different. Therefore, healthcare teams should consider developmentally specific interventions to support better metabolic control of youth with T1D (Markowitz, Garvey & Laffel, 2015).
6. **Deliver group-based education to provide information and social support for families of youth with T1D.** Educate health care providers about the indirect social benefits of group education that according to the results of the current study may support improved metabolic control of youth with T1D. Teach group related facilitation skills in order to optimize these types of interventions, as many healthcare providers have not had specific training related to group facilitation (London, 2009).

Policy

Policies for health care systems, public k12 schools, and access to care should be evidence-based education in order to meet the following objectives:

1. **Provide youth with T1D access to both clinical care and psychosocial services.**

Eighty percent of youth with T1D do not meet standards of metabolic control that support their long-term health (Chaing, 2014; Wood, 2013). These results are also supported by the results of the current study. Policies to support the targeted access to both clinical care and emotional health of youth with T1D may support their overall health outcomes.

The Mental Health Parity and Addiction Equity Act (MHPAEA) of 2008 required health insurers and group health plans to provide the same level of benefits for mental and/or substance use treatment and services that they do for medical/surgical care (SAMHSA, 2016). The Affordable Care Act further expanded the MHPAEA's requirements by ensuring that qualified plans offered on the Health Insurance Marketplace cover many behavioral health treatments and services. The need for mental health services for youth with T1D must continue to be protected in a changing political climate. The results of the current study suggest that the HRQOL of youth, which represents their perception of health and psychosocial functioning, is a predictor of their metabolic control; therefore access to both clinical and mental health services must be maintained to support the overall health of youth with T1D.

- 2. Increase resources such as nurses, psychologists, counselors, etc. to support K12 students with T1D to meet both their physical and emotional needs.** Results of the current study suggest that the mean A1c result of youth with T1D may reflect poor control (> 8.5%). Results of the current study also suggest that the HRQOL of youth with T1D is significantly lower when they have poor metabolic control. The presence of school nurses and psychologists to support the education, adherence, and emotional struggles of these youth should be recognized and funded. According to the National Association of School Nurses (NASN, 2014), 52 million of the nation's children attend school, and for many children in the United States, the school nurse is the sole provider of access to health care. Youth with T1D spend much of their day in the school setting, and would have greater access to services if provided at school. In the current healthcare climate, accountability to the health of the population versus payment for services models

are emerging as innovative ways to provide healthcare. Many population health initiatives test strategies to shift dollars to prevention and maintenance of health in the community versus treatment of illness in hospital settings. Focusing on providing care in venues like schools could support better access and better outcomes of youth with T1D and other chronic illnesses. Care in the school setting supports the idea of shifting care from high cost to high value, in which all care providers working at the top of their scopes of practice, and providing care where it is needed (AAFP, 2015).

3. **Create Alliances with Diabetes related charities and research organizations.** It is important to advocate for legislation to defend the rights of families of youth with T1D. Youth with T1D are sometimes denied access to daycare, education, jobs, and insurance coverage for supplies and physical and mental health services (ADA, 2014). Advocacy groups such as the American Diabetes Association (ADA), and the Juvenile Diabetes Research Foundation (JDRF) should join forces to support legislation provide access to physical and psychosocial care of youth with T1D in the school setting. One strategy to consider is that on issues of health policy, diabetes advocacy organizations, such as the ADA and JDRF share member mailing lists to allow members to opt in to calls to action to legislative action that aligns with topics of their shared interests.
4. **Ensure that all youth with T1D have access to insulin.** Diabetic ketoacidosis, which is caused by a lack of insulin, continues to be the primary cause of death of youth less than twenty-five years of age with T1D in the United States (Randall, et al., 2011). In the United States, some youth with T1D cannot afford to buy the supplies needed to support their diabetes care (Randall, et al.). Other youth with T1D have psychosocial issues that lead to non-adherence and are not receiving proper mental health services (Tucker, 2016).

Policy should be developed that mandates access to insulin and mental health services for all youth with T1D. A policy that mandated services to youth with T1D would not only save lives, but billions of dollars of cost for critical medical services of those youth with T1D (Randall, et al.). Globally, access to insulin is a problem as the primary cause of death for children in underdeveloped countries that develop T1D is lack of insulin (Katz & Laffel, 2015).

- 5. Advocate for insurance support of innovative designs of care that may positively impact youth and parent HRQOL and youth metabolic outcomes.** Over 80% of youth with T1D do not meet the clinical care goals that have been identified nationally and internationally. Therefore, other methods of delivering care and support for youth with T1D and their parents must be tested and supported to improve results (Chiang, 2014). There is evidence that delivering education to youth with T1D in a group versus individual setting that can be effective in meeting targeted developmental needs (Grey et al., 2009; Kime, McKenna, & Webster, 2013). Stellefson, et al. (2013) conducted a literature review related to delivering diabetes clinical care in group settings for adults with Type 2 diabetes (T2D), the researchers found that group clinical care for patients with T2D was an effective way to improve health outcomes as well as decrease costs. No recent literature was found that described group visits for the clinical care of youth with T1D. However, historically group visits have been a method used to provide effective outpatient clinical care for children that included educational and psychological support (Kohler, 1978; Kohler et al., 1982).

Research

Future research related to youth with T1D and their families could provide evidence for a) improved clinical practice and outcomes; b) accelerated development of educational curriculum and professional training that advances patient-centered and family-centered care; and c) create urgency for policy changes relevant to healthcare systems, ethnic disparity, schools, and access to care.

To expand the generalizability of the finding from this study, the study could be replicated to explore different factors related T1D based on age groups of youth, geographic locations, family configurations, ethnicity and socioeconomic status. Studies could be conducted to explore the following topics or questions:

1. **Conduct a study to determine if the critical indicator of decreased HRQOL is predictive at different A1c levels.** In the current study the HRQOL of youth with T1D with A1c results that were within goal range (< 7.5%) and moderate control (7.5 to 8.5%) were not significantly different. However, the youth with T1D had a HRQOL survey score that was significantly lower when the youth's A1c was greater than 8.5%. This study did not test to see if there was as difference of youth HRQOL at different levels of A1c test results, such as 8.6, 8.4, 8.3, etc. It might be helpful to test the association of different youth metabolic control results and HRQOL scores with a larger sample. Multi-site studies should be pursued to increase both the number of participants and support a more ethnically diverse study population.
2. **Conduct a subsequent study of the current study data targeting smaller age intervals of youth.** Additional analysis of the current data could be use as a hypothesis building study looking at smaller subsets age groups of youth, such as eight to ten year olds, eleven to thirteen year olds and fourteen to sixteen year olds. The current study

divided the participants into two age groups of youth, eight to twelve year olds and thirteen to sixteen year olds. In the current study, different factors were found to predict the metabolic control of these different developmental age groups. The current study did not test whether more specific age group categories, as outlined above, would show even more specific developmental differences. This should be explored further.

3. **Create a study that would test an intervention to support the social functioning of parents of adolescents with T1D and its impact on youth metabolic control.** A novel finding of the current study was that the impact of the social functioning of parents, which included isolation of parents, predicted decreased metabolic control of adolescents with T1D. There have been qualitative studies in which parents of children with chronic illness identify isolation as a difficulty of parenting a child with chronic illness (Cousino & Hazen, 2013; Kratz, Uding, Trahms, Villareale, & Kieckhefer, 2009; Woodgate, Atea, & Secco, 2008). Merkel and Wright (2012) in their evidence-based practice project found improvement of parent self-efficacy of diabetes self-management after the establishment of a web-based support and education group in a rural area. Further study is needed to test whether the metabolic control of youth with T1D improves when interventions to support the parents of those youth groups are implemented.
4. **Replicate the study with expanded age groups to include infant to emerging adult.** Only youth aged eight to sixteen with T1D were included in this study. This limits the generalizability and specificity of the results. As there were different factors that predicted the metabolic control of developmental age groups within the age range of eight to sixteen, it is likely that there are other factors that impact metabolic control of youth younger and older than that age range. Analyzing factors associated with HRQOL

and metabolic control of youth with T1D should be tested across all the age groups. This could lead to interventions more targeted and developmentally personalized for different age groups.

5. **Replicate this study with other chronic illnesses of youth.** Several qualitative studies of parents of chronically ill children have suggested that social isolation and lack of support were self-identified as barriers and issues for parents (Coffey, 2006; Curle, 2005; Kratz et al., 2009; Shilling et al., 2013; Woodgate et al., 2008). This suggests that social isolation of parents of children with chronic illness may not only be an issue related to the current study, or only for parents of youth with T1D. The impact of parent's HRQOL on clinical outcomes of those youth with chronic illness should be tested in future studies.
6. **Conduct a qualitative study related to the HRQOL and barriers to metabolic control of youth with T1D to identify additional factors to explore quantitatively.** Palinkas, et al. (2016) suggested that the implementation of evidence-based and other innovative practices and treatments is complicated. Therefore the use of both qualitative and quantitative methods to explore future questions in a complimentary way is beneficial. The results of the current study suggested that social isolation of parents was predictive of decreased metabolic control of adolescents with T1D. The identification of isolation as one of the difficult aspects of parenting a child with chronic illness was only found in qualitative literature by this researcher (Coffey, 2006; Curle, 2005; Kratz et al., 2009; Shilling et al., 2013; Woodgate et al., 2008). Additional qualitative data gathered from youth with T1D may inform future quantitative studies related to factors that may impact youth metabolic outcomes. Moreover, qualitative data gathered after quantitative results are analyzed, such as exploring the ethnic and

socioeconomic issues of non-white youth with T1D, might support better understanding of the quantitative findings of the current study.

Conclusion

Eighty-two percent of youth with Type 1 diabetes (T1D) in the current study had metabolic control that was higher than within goal range of A1c of less than 7.5%. Previous studies have reported that A1c results of youth with T1D greater than 7.5% increase the youth's risk for long-term and short-term complications related to T1D (DCCT/EDIC, 2009; Jacobson, Braffett, Cleary, Gubitosi-Klug, & Larkin, 2013). The original concept map created by this researcher to identify relationships of the variables studied, which was based on the literature, was revised based on the results of the current study.

Individual, family, and diabetes factors such as gender, age, and treatment complexity (use of insulin pump and/or continuous glucose monitor) were not associated with either youth health-related quality of life (HRQOL) or youth metabolic control in this study. Factors not associated with HRQOL or metabolic control were eliminated in the revised concept map. Family factors such as ethnicity and socioeconomic status (SES) were associated with youth metabolic control; however, only ethnicity was associated with youth HRQOL. In the total group of youth (n = 210), youth HRQOL was a predictor of youth metabolic control, which supports the initial concept map. Moreover, the result that an A1c result of greater than 8.5% (poor metabolic control) was a critical indicator of significantly decreased youth HRQOL expanded and strengthened the association of youth metabolic control and youth HRQOL. This additional association is represented in the revised concept map.

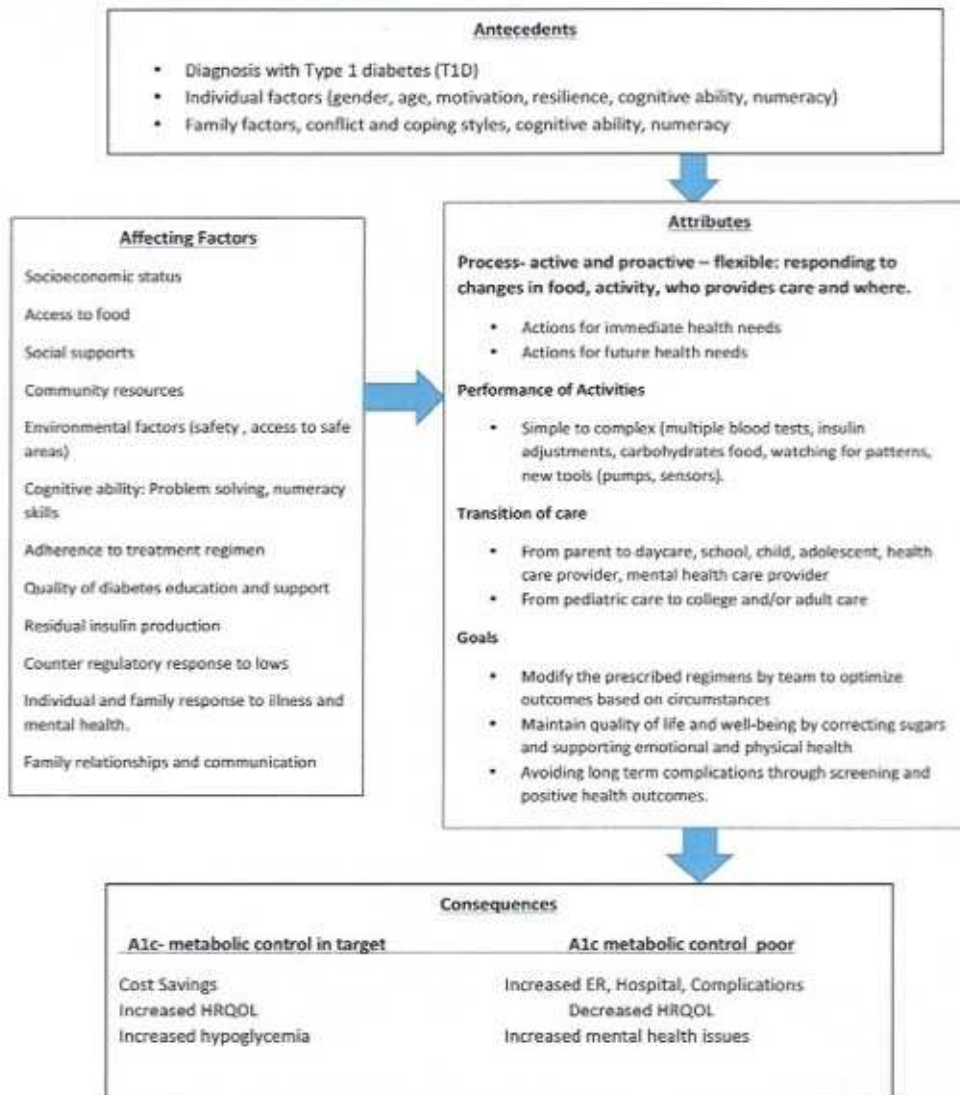
Preadolescent youth HRQOL was associated with their parents' HRQOL. However, neither preadolescent HRQOL nor their parents' HRQOL was associated with preadolescent metabolic control. Non-white ethnicity of preadolescent youth with T1D was predictive of poor metabolic control. Moreover, results of non-white preadolescents differed from the other data to the degree that all non-white ethnicity data represented outliers. Once those data from non-white youth/parent outliers were removed, family socioeconomic status (SES) became predictive of metabolic control. Preadolescents with lower family SES (represented by public insurance) had worse metabolic control than preadolescents with higher family SES. Non-white youth, and youth with lower family SES had worse metabolic control, which makes them more vulnerable to the health risks associated with T1D. It is not known why the metabolic control and HRQOL of non-white preadolescents differ so much from the metabolic control of white preadolescents. Additionally, it is not known why preadolescents with lower family SES have worse metabolic control than those with higher SES. Future research should explore the factors that might be impacting the health of both non-white preadolescents and preadolescents with lower family SES in order to develop interventions, education, and policy to improve the long-term health outcomes of preadolescents with T1D and their families.

Results of the current study supports other studies that reported that youth metabolic control may be associated with youth HRQOL and parent psychosocial health (Butwicka et al., 2012; Butwicka et al., 2013; Hanberger et al., 2009; Knez et al., 2013; Medrano et al., 2013). In adolescents with T1D, both the Parent HRQOL Emotional Functioning and Social Functioning subscales were associated with the adolescents' metabolic control. In adolescents with T1D, HRQOL was partially predictive of their metabolic control, as was their parent's HRQOL Social Functioning subscale score.

Care of youth with T1D and their families should be individualized and developmentally appropriate. Factors associated with HRQOL are not only different when preadolescents are compared with adolescents; there were factors associated with the HRQOL of parents of youth with T1D, like family SES, that were not associated with the HRQOL scores of youth. Policy should be created to support programs that advocate for non-white youth with T1D, and demand further study of ethnic disparity and vulnerability related to youth with T1D, as ethnicity was associated with worse metabolic control across all of the age groups of youth studied. Policy should also be created that protects youth with T1D from discrimination in schools, day care, employment, and insurance coverage. The results of this study suggest the importance of supporting the psychosocial health and quality of life of both youth with T1D and their parents in order to achieve the best outcomes of health and care. Focusing on improved psychosocial health and health-related quality of life of youth with T1D will support both their short-term and long-term health outcomes. Better short-term and long-term outcomes will in turn decrease the costs of care and management of youth with T1D over their lifetime. The results of this study suggest that the focus of healthcare for youth with T1D should not only be patient-centered but family-centered.

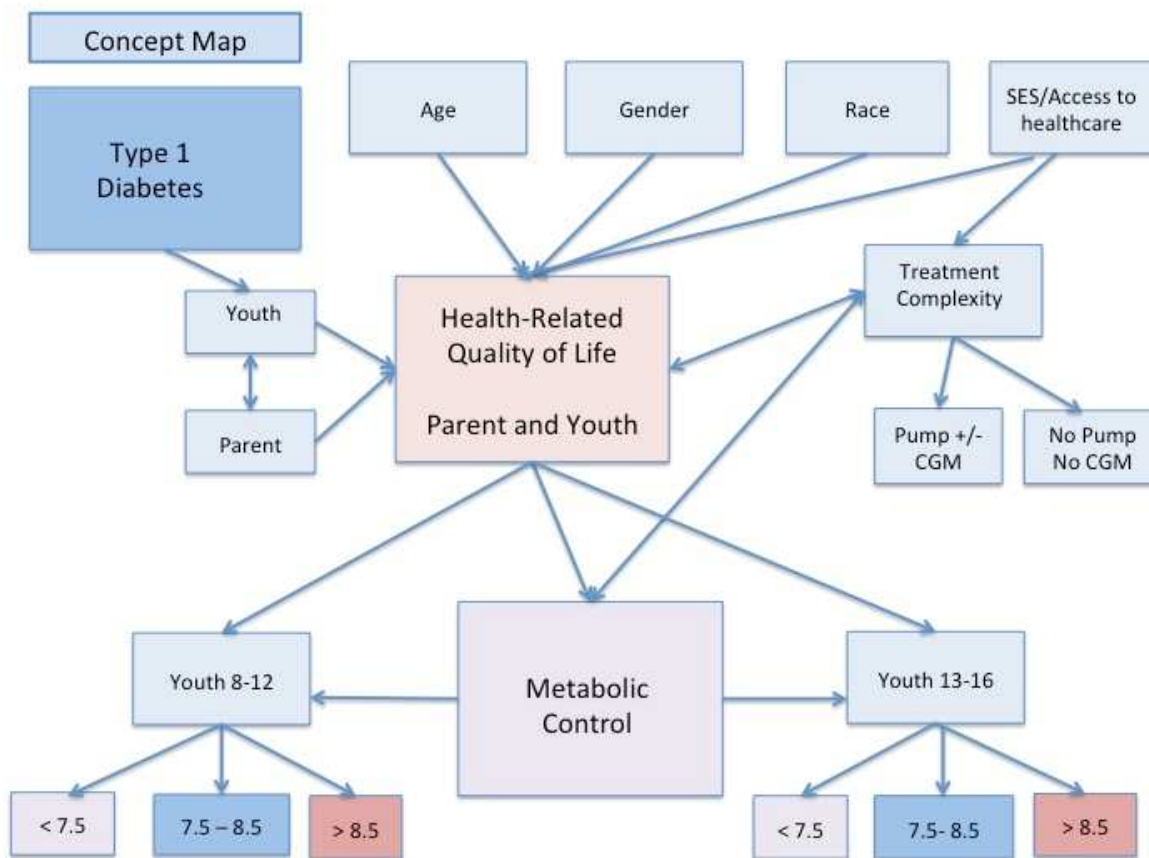
Figure 1.

Table 1: Concept Map of Self Management of Type 1 Diabetes in Children and Adolescents (modified from Schilling, Grey and Knaff (2002).



Adapted from the article by Schilling L.S., Grey, M. & Knaff K.A. (2002). The concept of self-management of type 1 diabetes in children and adolescents: an evolutionary concept analysis. *Journal of Advanced Nursing*, 37, 87-99

Figure 2.



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Figure 2. Concept Map for the Proposed Study

Figure 3.

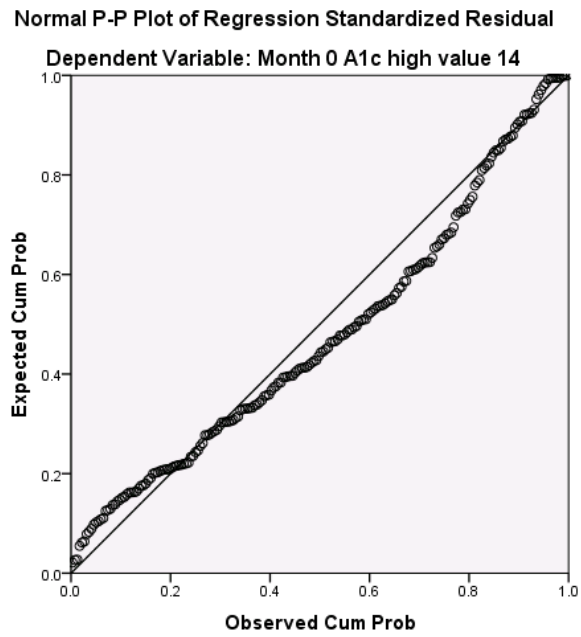


Figure 4. Normal P-Plot for A1c result 1

Figure 4.

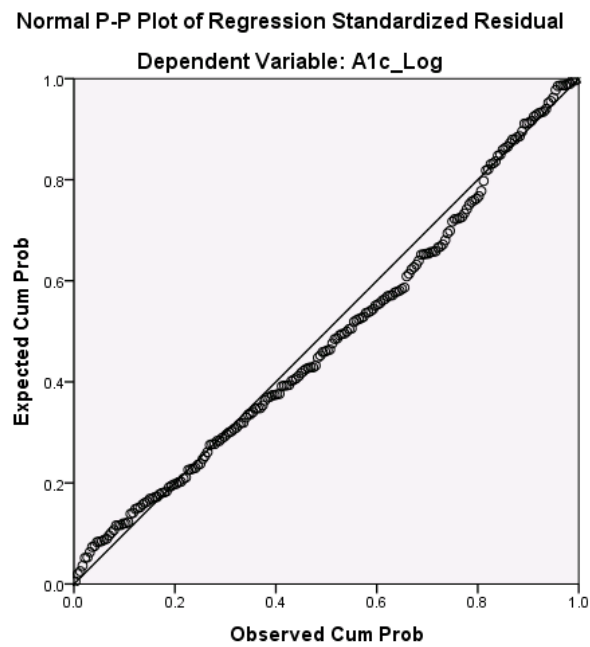


Figure 5. Normal P-Plot for A1c_Log 1

Figure 6

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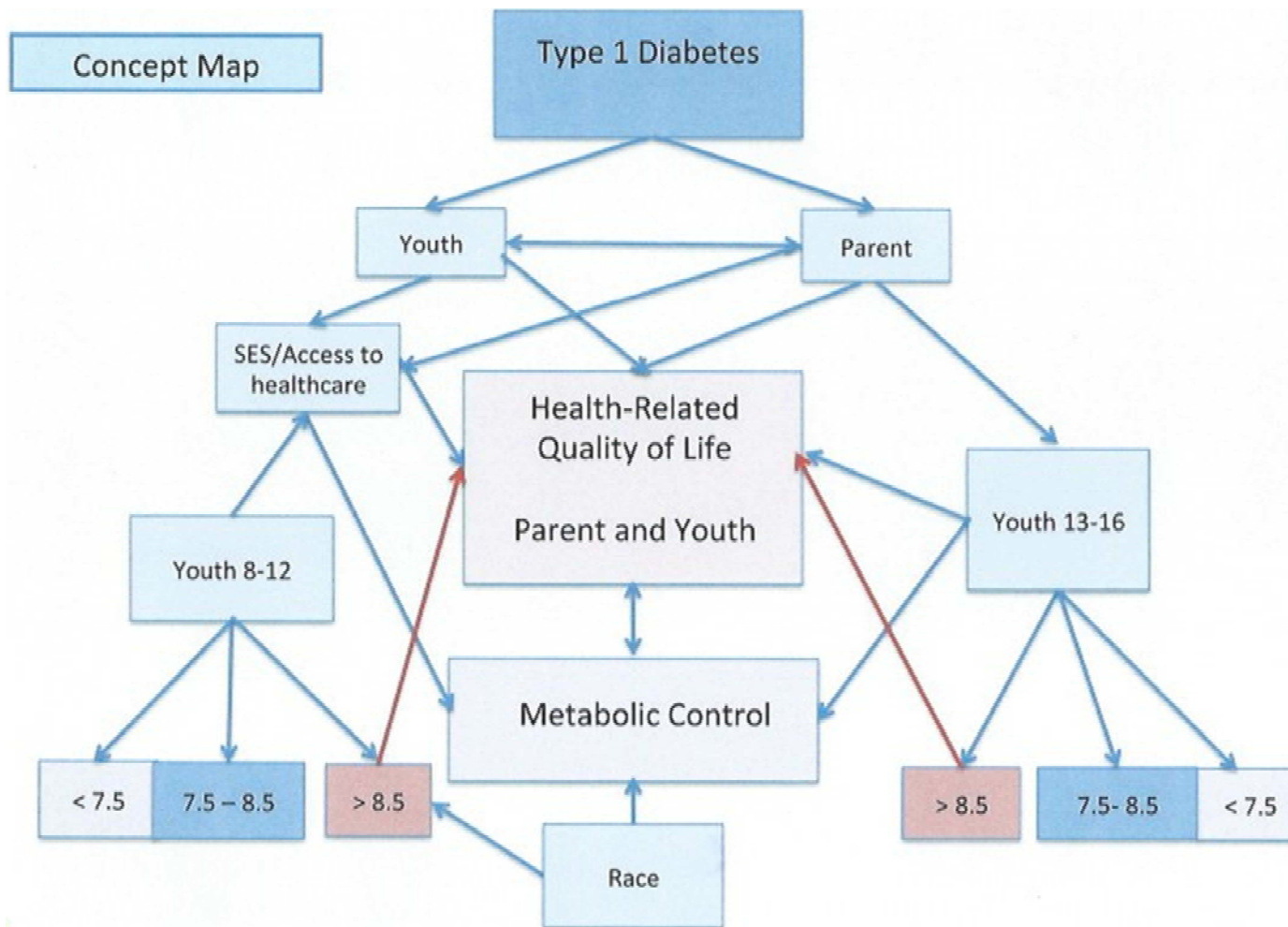


Figure 6. Revised Concept Map of Outcomes of this study.

Table 1

U.S. Preventive Services Task Force Levels of Evidence

I: Evidence obtained from at least one properly designed randomized, controlled trial or meta-analysis of randomized, controlled trials.

II-1: Evidence obtained from well-designed controlled trials without randomization.

II-2: Evidence obtained from well-designed cohort or case-control analytic studies, preferably from more than one center or research group.

II-3: Evidence from multiple time series with or without the intervention.

III: Opinions of respected authorities, based on clinical experience, descriptive studies or reports of expert committees

U.S. Preventive Services Task Force. (1996). Guide to clinical preventive services (2nd ed.). Baltimore: Williams and Wilkins

Table 2 Factors that impact HRQOL outcomes

Title of article Author Level of Evidence	Research Aim	Sample	Research Design	Results	Strengths/limitations
Cherubini, et al. (2014) Health-related quality of life and treatment preferences in adolescents with type 1 diabetes. The VIPKIDS study Level: II-2 Country: Italy	A determine whether the HRQOL of youth with type 1 diabetes is affected by different insulin treatment systems, and which features of HRQOL are impacted by the respective insulin treatment.	577 youth age 10-17 with T1D for at least 6 months on pump therapy (306) or MDI (271)	Population-based correlational, cross-sectional study in 14 centers in Italy who had been using pump therapy for 2 years. Used Insulin Delivery System Rating Scale (IDSRQ) and Diabetes Quality of Life for Youth (DQOLY)	Co-variables: age, gender, hours in physical activity, basal insulin doses, self-administration of insulin, and # visits to the center. Looking at MDI vs. Pump and HRQOL No significant difference in metabolic control, diabetes worries, social burden in the two groups. Pump had higher treatment satisfaction and perceived clinical efficacy and lower level of daily activity interference than MDI.	Strengths: 1. Multi-site 2. Number of participants 3. Quantile regression method 4. Dropped psychological measures that did not prove to be reliable or valid Limitations: 1. IDSRQ tool not able to be compared with other studies.
Hanberger, et al. (2009) Health-related quality of life in intensively treated young patients with type 1 diabetes Level: II-2 Country: Sweden	Hypothesis was that metabolic control, gender, age and socio-economic status predict HRQOL.	N= 400 youth with T1D (191 girls) and parents from two pediatric clinics.	Population-based Cross-sectional correlational. Database from 2 pediatric clinics. MDI and pump	Measure for HRQOL response rate 59.5% adolescents, 73% for 8-12 and 72.5% for parents. Good reliability and validity of measure. HRQOL correlated with better metabolic control and increased number of injections per day. Adolescent boys higher HRQOL than girls. Parents and youth rated general HRQOL better than Diabetes HRQOL. HRQOL of parents correlated with HRQOL with youth. Parents rate youth's HRQOL	Strength: 1. Number of patients and parents Weaknesses: 1. No control group 2. Parents mailed survey. 3. Unclear how youth got survey

				lower than youth do. Severe hypoglycemic decreased parent HRQOL In children 8-12, pump therapy had the highest impact.	
Ingerski, et al. (2010). Health-Related Quality of Life Across Pediatric Chronic Conditions Level: II-2 Country: USA	To compare health-related quality of life (HRQOL) across 8 pediatric chronic conditions, including 5 understudied populations, and examine convergence between youth self-report and parent-proxy report.	Meta-analysis of 589 patients and caregivers across 8 descriptive studies and conditions, including T1D.	Meta-analysis Descriptive statistics and frequencies were calculated for the total sample and each illness group. Exploratory analysis examined differences in HRQOL to previously published data for healthy youth.	Variables: age, gender, race, caregiver marital status. Chronically ill youth had lower HRQOL than healthy youth across all disease groups. Parent proxy numbers were lower across all subscales except for school functioning.	Strengths: 1. Comparison of HRQOL tool across chronic conditions. 2. Comparison of HRQOL parent proxy tool with youth tool. 3. Control group included for comparison. Limitations: 1. Variation across disease groups in regard to demographic and disease specific samples. 2. Differences in sample sizes across disease groups. 3. T1D group did not complete the physical functioning, which precluded inclusion of this condition.
Jacobson, et al (2013) The long-term effects of type 1 diabetes treatment and complications on health-related quality of life. Level:II-2 Country: USA	To examine the long-term effects of T1D diabetes Treatment, metabolic control and complications on HRQOL.	1,441 participants with T1D initially age 13-39 followed for 23.5 years	Population-based Longitudinal prospective study post RCT of DCCT, EDIC	Decrease in metabolic control, diabetes complications, and symptoms and development of psychiatric conditions led to decrease in HRQOL. There was also a sustained decrease in HRQOL over time, as well as an association between worsening metabolic control and severe hypoglycemic reactions. Intensive treatment does not increase or decrease HRQOL, but reduction of long-term symptomatic complications does produce increase HRQOL.	Strengths of this study: - long-term consistent follow up of large cohort - detailed prospective clinical and demographic information gathered in a high fidelity way - repeated measures of HRQOL Limitations: Participants in original RCT study were: - Self-selected to join the study and accept randomization to intensive vs. conventional therapy. - Excluded if they had psychosocial problems or limited support were excluded from the primary study.

					<ul style="list-style-type: none"> - High average SES and education, mostly Caucasian. - No control group.
<p>Malakonaki, et al. (2011) Health-related quality of life (HRQoL) of children with type 1 diabetes mellitus (T1DM): self and parental perceptions Level: II-1 Country: Greece</p>	<p>The aim of the study was to evaluate HRQOL in children and adolescents with T1D in Greece compared with healthy controls and to identify the effect of age, gender, age of onset of disease, and metabolic control on perceptions of HRQoL.</p>	<p>117 youth with T1D age 5-18, 53 male, parents 128 matched healthy control all youth on MDI regimen except one pump patient</p>	<p>Non-random, correlational population-based control trial using Generic HRQOL tool for both groups and Peds QL for those youth with T1D Parent used parent proxy report of the PedsQL</p>	<p>Variables: age, gender, age of onset, Hypo (<60) or Hyper >150) in one month, A1c, Youth with T1D lower physical HRQOL, poorer emotional, school, and total generic HRQOL compared to health controls. Social HRQOL not significant. Parents of youth with T1D measured youth HRQOL significantly lower in all areas than the youth. Variance: A1c, # high and low BG, age of onset and gender explained 24% of metabolic control.</p>	<p>Strengths: 1. Matched controls 2. Multi-site Limitations: 1. Convenience sample of population-based group.</p>
<p>Muller-Godeffroy, et al. (2009). Investigation of quality of life and family burden issues during insulin pump therapy in children with Type 1 diabetes mellitus—a large-scale multicentre pilot study Level: Country: Germany</p>	<p>To investigate psychosocial aspects of continuous subcutaneous insulin infusion (CSII) therapy in children with Type 1 diabetes and to identify relevant and sensitive measures.</p>	<p>38 youth with T1D, 8-11 and 76 youth 12-16 and parents, and 29 parents of youth 4-7. 6 months post pump therapy. Loss to follow up of youth was 23% and parents was 18%,</p>	<p>Multi-center prospective pre-/post cross-sectional study with youth with T1D in 18 German diabetes centers. 53 girls, 64 Boys</p>	<p>Variables: A1c, Diabetes QOL improved but general QOL did not. Parents reported reduced diabetes burden. Parents reported fewer concerns related to mealtime and fear of hypoglycemia.</p>	<p>Strengths: 1. Power analysis done to choose n 2. Although sample sizes in different age groups were small, most results were statistically significant Limitations: 1. Non-standard A1c (mathematically calculated) 2. No control group</p>
<p>Nardi, et al. (2008)</p>	<p>To evaluate self and parent reports on</p>	<p>70 youth with T1D > 1</p>	<p>Population based</p>	<p>Variables: A1c and disease duration**.</p>	<p>Strengths: 1. Control group</p>

Quality of life, psychological adjustment and metabolic control in youths with type 1 diabetes: a study with self- and parent-report questionnaires Level: II-1 Country: Italy	HQOL and psychological adjustment of youths with type 1 diabetes, in comparison to a general pediatric population, and identify relationships between disease duration, metabolic control and psychological parameters.	year and their parents control group 70 healthy, matched subjects.	Convenience sample cross-sectional study with control group	Adolescents showed worse HQOL and psychological disturbances. In this group for youth and parents higher A1c correlated positively with higher problem scores and lower HRQOL. ** significant only for parent reports correlated with psychological adjustment.	2. Matched parent and child information. 3. Included children in all age ranges. Limitations: 1. No power analysis to choose n. 2. Convenience sample
Reid, et al. (2013) Relations Between Quality of Life, Family Factors, Adherence, and Glycemic Control in Pediatric Patients With Type 1 Diabetes Mellitus Level: II-2 Country: USA	This study examined relations among diabetes-specific family factors, adherence to medical regimen, quality of life (QOL), and glycemic control in youth and adolescents with type 1 diabetes.	70 Youth with T1D age 9-18 and parents. 72% male	Cross-sectional correlational population based study of youth with parents using measures and interview data.	Family factors and QOL measures and interviews related to adherence. Variables: A2c, duration of T1D, hospitalizations, DKA, Clinic visits, missed clinic visits, calls to clinic, missed school days in last year. Improved AOL associated with improved adherence. PedsQOL Core module was only QOL measure, physical and psychosocial well-being associated with A1c and adherence.	Strengths: 1. Parents and youth HRQOL data. 2. Looked at sub-scale correlations and outcomes. 3. Included qualitative data. Limitations: 1. No control group
Sahin, et al. (2015) Assessment of Psychopathology, Quality of Life, and Parental Attitudes in Adolescents with Type 1 Diabetes Mellitus Level: II-1 Country: Turkey	The aim of the present study was to identify psychopathology, parental attitudes, perceptions of quality of life, and relationships between these factors in adolescents with T1D	50 youth with T1D > 6 mon.age 12-18 and their parents, 26 male. 50 healthy adolescent controls.	Population based cross-sectional correlational noon-random control study.	PedsQL scales used Children's Depression inventory Variables: Gender*, duration*, age, hospitalization*, Complications*. Diet: 32% good, 38% moderate, 30% poor compliance. 68% of patients had psychiatric disorders. 38% one disorder, 16% two disorders, and 10% 3 disorders.	Strengths: 1. Youth, parents and healthy controls were compared related to QOL. 2. Full psychiatric assessment done on youth with T1D. Limitations: 1. No full psychiatric assessment was done on health controls, unable to compare.

				Avg. depression scores and anxiety disorder scores of youth with T1D significantly higher than health youth, but not more frequent. *not significant	
Valenzuela et al. (2006) Insulin Pump Therapy and Health-Related Quality of Life in Children and Adolescents with Type 1 Diabetes Level: II-2 Country:USA	To compare the HRQOL of youths on injection regimens to those prescribed insulin pump therapy and examine factors related to HRQOL in youths with type 1 diabetes.	160 youth with T1D > 9 mon. and pump > 3 mon. age 5-7 years, 54% female, and parents	Population based multi-site cross-sectional study of youth and parents.	Variables: A1c* and regimen (pump vs. MDI)*, age*, duration*, family conflict*, child distress*, conduct problems*, parent distress* PedsQL- General and Diabetes Diabetes specific HQOL scores lower than general HQOL HRQOL is better predicted by measures of psychological adjustment than diabetes-specific clinical measures. 29% of variance predicted by child distress and family adjustment for both parent and child HRQOL. *no significant difference between MDI and pump	Strengths: 1. Youth and parents studied 2. Ethnically diverse 3. Multi-site Limitations: 1. No control group 2. Convenience sample

(Cherubini et al., 2014; Hanberger et al., 2009; Ingerski, 2010; Jacobson et al., 2013; Malakonaki et al., 2011; Muller-Godeffroy et al., 2009; Nardi et al., 2008; Reid et al., 2013; Sahin et al., 2015; Valenzuela et al., 2006)

Table 3 Factors that are associated with metabolic control

Title of article Author Country Level of Evidence	Research Aim	Sample	Research Design	Results	Strengths/limitations
Berg, et al. (2014) Self-Control as a Mediator of the Link Between Intelligence and HbA1c During Adolescence Level: II-2 Country: USA	The present study examined whether intelligence would be a resource for the maintenance of metabolic control across time and whether this effect was mediated through adolescents' greater self-control (regulation of cognitions, emotions, and behaviors).	252 early adolescents with T1D > 1 yr. 10-14 year old	Population-based longitudinal (2.5 year) prospective study of transition to adolescence with T1D, recruited from clinics that were part of a university/private partnership. Kaufman brief intelligence test (KBIT), Self control scale KBIT measured verbal and non-verbal intelligence-discriminant from academic achievement and psychological Brief self-control tool developed for college undergraduates.	Covariates: SES, pump or no pump, duration of diabetes* Higher SES and pump had lower A1c and was associated with higher intelligence and self control over cognition, emotion and behavior. self-control predicted less increase of A1c over time. Higher intelligence associated with better metabolic control through better self-control. * not significant	Strengths: 1. Standard A1c test 2. Multi-site 3. Number of participants 4. Longitudinal Limitations: 1. Self control scale validated for college students with 1 adolescent trial with Chronbach's alpha= 0.67 2. Convenience sample 3. No power analysis for n
Dovc, et al. (2014) Improved Metabolic Control in Pediatric Patients with Type 1 Diabetes: A Nationwide Prospective 12-Year Time Trends Analysis Level: II-2 Country: Slovenia	The aim of this study was to analyze temporal trends of metabolic control and possible factors influencing metabolic control, including treatment modality, in the Slovene pediatric T1D population over the last 12 years.	886 patients with T1D from 0 to 17.99 years at diagnosis with at least 1 year of follow up until 22.99 years old from 2000 to 2011.	Population-based longitudinal prospective study across 10 year period. Variables: gender, age, Year of measurement, treatment modality, BMI, Daily insulin dose, duration of T1D. Optimal A1c defined as <7.5% Sub- optimum> 7.5%	Δ from 2001- 2011 Decreased A1c from 9.26 to 7.75% (median) Age of diagnosis 12.68 to 7.53 yr. BMI increased * Daily insulin dose .76 to .7 u/kg. MDI or CSII (74%). 8 years in 2000 and .59 years in 2011.	Strengths: 1. Standard A1c test 2. Followed daily insulin dose which decreased 3. 4% attrition over 10 years 4. Standard education and team approach for all patients (including psychology). Limitations: 1. no control

			Poor A1c > 9.0%	* not significant	
Duke, et al. (2008) Glycemic Control in Youth with Type 1 Diabetes: Family Predictors and Mediators Level: Country: USA	This study examined predictive and mediated relationships among youth perception of critical parenting, Child Behavior Checklist Externalizing Subscale (CBCL) externalizing problem scores, adherence, and A1c in youth with T1D from low socioeconomic status families.	120 Caregiver/youth dyads with T1D	Population-based measures related to family functioning regarding diabetes management and structured adherence interviews.	Metabolic control significantly correlated with youth's age, duration of diabetes, and SES. Youth age correlated with critical parenting, guidance and control, and parent reported adherence. Duration of diabetes related to parent reported adherence. Combined measures predicted 44% of the variance in HbA1c. Adherence partially mediated critical parenting and HbA1c, while critical parenting and adherence mediated CBCL externalizing problem scores and HbA1c. CBCL externalizing problem scores did not mediate critical parenting and HbA1c.	Strengths: 1. Sample size 2. Measures had good internal consistency for this study in most measures and roles. 3. Parent and youth data Limitations: 1. Cross-sectional 2. Observational 3. Possible reporting bias 4. Low SES population-may not be generalizable 5. Older measures, some lower reliability scores for some scales
Gerstl, et al. (2007) Metabolic control as reflected by HbA1c in children, adolescents and young adults with type-1 diabetes mellitus: combined longitudinal analysis including 27,035 patients from 207	Aimed to obtain an estimate of the current level of metabolic control and to identify predictors in an unselected population of children and adolescents with T1D.	27,035 patients that represent 80% of children with T1D in Germany from 207 centers. 52% male Mean age 12.6 years.	Longitudinal prospective data de-identified from a national database between 1995 and 2005 Variables studied were age, gender, duration of diabetes, insulin regimen*, social status and HbA1c values.	A1c results overall: 1) 42% met goal < 7.5 2) 58% above goal 3) 23% poor or > 9% A1c significantly higher with: 1) longer duration of T1D 2) older age 3) Females	Strengths: 1. Sample size 2. Multi-center 3. Longitudinal Limitations: 1. Non-standard A1c method (mathematically standardized) 2. Observational

centers in Germany and Austria during the last decade Level: II-2 Country: Germany, Austria			*only variable not significant in the study.	Overall improvement over 10 years 1) 25-45% < 7.5 2) 75-65% > 7.5 3) 40-16% > 9.0	
Hood, et al. (2009) Association Between Adherence and Glycemic Control in Pediatric Type 1 Diabetes: A Meta-analysis Level: I Country: USA	To determine the magnitude of the adherence-glycemic control link in pediatric type 1 diabetes and evaluate its correlates.	21 studies 2492 youth with T1D	Meta-analysis of PubMed articles related to youth <19 with T1D and adherence factors and metabolic control.	As adherence increases, A1c decreases.	Strengths: 1. Sample size 2. Heterogeneity of sample. Limitations: 1. No report of SES or family structure. 2. No report of CT or pump therapy. 3. Heterogeneity of methods.
King, et al. (2013) Longitudinal Trajectories of Parental Involvement in Type 1 Diabetes and Adolescents' Adherence Level: II-2 Country: USA	To examine longitudinal trajectories of parental involvement and adolescent adherence to the Type 1 diabetes regimen, to determine whether changes in multiple facets of parental involvement over time predicted subsequent changes in adolescents' adherence, and to examine whether adolescent self-efficacy mediated the effect of parental involvement on adherence.	252 youth, median age 12.49 (10-14) years with T1D > 1 yr., 53.6% females and either their mother or mother and father.	Population-based prospective longitudinal study. 2.5 year long study with testing across 5 time points.	Measures: Adherence, Parental diabetes monitoring, Parental behavioral involvement, Self – efficacy. Using multilevel modeling, analyses indicated significant average declines over time in adherence and most indicators of parental involvement. Lagged multilevel models indicated that declines in mothers' and fathers' acceptance and diabetes monitoring predicted subsequent declines in adolescents' adherence.	Strengths: 1. Sample size 2. Parent/youth dyad or family 3. Longitudinal 4. Standard A1c method Limitations: 1. Observational

<p>Lewin, et al. (2006). The Relation Between Family Factors and Metabolic Control: The Role of Diabetes Adherence Level: II-2 Country: USA</p>	<p>To examine family factors as predictors of metabolic control in children with T1D and determine whether adherence behaviors mediate this relationship.</p>	<p>109 youth, 53 male, with T1D > 1 yr., age 8-18 and a parent (87% mothers). 78% white 10% black 7% Hispanic 3% native American 2% other 2 parent fam. - 73% 60% below avg. SES</p>	<p>Population based family dyads, convenience sample. 25 min. survey to test family functioning and adherence, metabolic control.</p>	<p>Four family functioning variables: parental warmth, critical and negativity, guidance and responsibility explained 34% of variance of A1c. Supported strong relationship between family factors and A1c. Adherence results explained sizable variance, together these explained 49% of variance in A1c.</p>	<p>Strengths: 1. Sample size 2. Both parent and child tested. 3. Large % of low SES 4. Use of multiple brief tools. 5. Standard A1c method Limitations: 1. Potential for report bias 2. Primarily low SES so less generalizable.</p>
<p>Olinder, Kernell, & Smide (2009) Missed bolus doses: devastating for metabolic control in CSII-treated adolescents with type 1 diabetes Level: Country: Sweden</p>	<p>To investigate the management of pump therapy in adolescents with T1D including their administration of bolus doses and to study relationships between insulin omission and metabolic control, and other factors that impact may impact metabolic control.</p>	<p>90 youths with T1D age 12-18 using insulin pumps to deliver their insulin doses. 34 males Duration of T1D 7.9 yr. =/- 3.8 Pump therapy 3.4 yr. =/- 1.9</p>	<p>Population based Cross-sectional study of first 90 patients of 195 between 12 and 18 who consented to the study and had used and insulin pump for more than 6 months.</p>	<p>38% of youth missed > 15% of insulin doses the previous day which causes significantly higher A1c results. These youth also took few boluses per day and checked their blood sugar less often. Multiple linear regression showed variance explained by frequency of bolus, blood sugar tests, adjusted for duration of T1D and age. HRQOL < for those who missed doses but not significant.</p>	<p>Strengths: 1. Sample size 2. Good reliability and validity of the measures, this sample tested. 3. Standard A1c method Limitations: 1. Self report 2. One day of parent/child dyad in survey.</p>
<p>Rausch, et al. (2012) Changes in Treatment Adherence and</p>	<p>To test models of unidirectional and bidirectional change</p>	<p>240 participants began and 225 11-14 year old youth</p>	<p>Multi-Site prospective longitudinal population based study</p>	<p>HbA1c increased from 8.2 to 8.6% (P < 0.001) and BGMF</p>	<p>Strengths: 1. Sample size 2. Multi-center (3 States)</p>

<p>Glycemic Control During the Transition to Adolescence in Type 1 Diabetes Level: II-2 Country: USA</p>	<p>between treatment adherence and glycemic control in youth with T1D.</p>	<p>with T1D finished the 2 year follow-up 46.2% male 13% Hispanic 68.4% received insulin via pump.</p>	<p>BGMF=Blood glucose monitoring frequency.</p>	<p>decreased from 4.9 to 4.5 checks per day ($P < 0.02$) during the 2-year period. Changes in the BGMF slope predicted changes in HbA1c. A change (increase) in HbA1c was associated with a change (decrease) in BGMF of 1.26 ($P < 0.001$) after controlling for covariates.</p>	<p>3. Longitudinal (2 years) 4. Standard A1c method Limitations: 1. Observational</p>
<p>Rosenbauer, et al. (2012) Improved Metabolic Control in Children and Adolescents With Type 1 Diabetes Level: II-2 Country: Germany, Austria</p>	<p>To investigate the temporal trend of metabolic control and potential predictors in German and Austrian children and adolescents with T1D.</p>	<p>30,708 patients from 305 centers, 211 pediatric centers Mean age 14.6 years =/- 3.7 years Mean age at onset 7.9=/- 4.0 years 52% male 12% ethnically diverse</p>	<p>Longitudinal prospective documentation through a database from between 1995 to 2009 Variables: age, sex, diabetes duration, migration background, BMI-SDS, and daily insulin dose were significant predictors of metabolic control CT=conventional treatment MDI= multi-dose treatment</p>	<p>This study showed a significant improvement in metabolic control in youth with T1D during the past decade and a decrease in hypoglycemic events. A1c results: <7.5% = 38.1% (goal) > 7.5% < 9.0% = 38.1% > 9.0% = 28.2% (poor) ▲ 38% CT to 7% CT ▲ 61% MDI to 78% ▲ 1% pump to 37% Significant results: older, female, duration, ethnicity, high BMI and higher daily insulin dose. CT had higher % > 9 % A1c- poor metabolic control</p>	<p>Strengths: 1. Sample size 2. Multi- site 3. Standard definitions 4. unit per kg. insulin dose 5. Identified improved Patient education as strength 6. Adjusted for co-founders in multiple regressions Limitations: 1. Non-standard A1c method (mathematically adjusted). 2. Observational</p>
<p>Springer, et al (2006)</p>	<p>To investigate the impact of factors that</p>	<p>455 patients < 18 , mean age 11.8, and</p>	<p>Population based cross-sectional study,</p>	<p>Low SES had a greater association</p>	<p>Strengths: 1. Number of patients</p>

<p>To investigate the impact of factors that might interfere with optimal glycemic control in youth with type 1 diabetes mellitus (T1DM) in the current era of intensive management, including the interplay of race/ethnicity and socioeconomic status (SES) on HbA1c levels. Level: Country: USA</p>	<p>might interfere with optimal glycemic control in youth with T1D in the current era of intensive management, including the interplay of race/ethnicity and socioeconomic status (SES) on HbA1c levels.</p>	<p>4.9 respectively with T1D for at least 6 months between Jan and Sept 2003.</p>	<p>Database review. Variables: Sex, age, race/ethnicity*, duration of diabetes, mode of insulin administration (pump vs injection), body mass index, SES, and HbA1c * not significant</p>	<p>with poor metabolic control than did race/ethnicity, which was not associated with differences in HbA1c level after controlling for SES. Significant difference: Gender, age, duration of T1D*, inj. Vs. pump, Lower SES *no significance when only youth with T1D >18 month studied.</p>	<p>2. Studied care given in a clinic setting. Weaknesses: 1. Outcome better for pumps, however there were exclusion criteria for use of pumps. 2. Avg. income and education higher than state and national averages so may not be generalizable.</p>
<p>Svoren, et al. (2007) Temporal Trends in the Treatment of Pediatric Type 1 Diabetes and Impact on Acute Outcomes Level: Country: USA</p>	<p>To evaluate temporal trends in pediatric T1D management and resultant effects on outcomes.</p>	<p>8-16 years old with T1D 1997: 299 patients 2002: 152 patients</p>	<p>Longitudinal cross-sectional study: 2 years each group, Variables: A1c, body mass index Z score (Z-BMI)*, and incidence rate (IR; per 100 patient-years) of hypoglycemia, hospitalizations*, and emergency room (ER) visits. * not significant</p>	<p>Significant improvement in metabolic control from cohort 1 to cohort 2 Significant differences: < severe hypoglycemia < ER visits > patients using analogs > patients using intensive therapy > blood sugar tests</p>	<p>Strengths: 1. Number of patients 2. Good inter-rater reliability of data extraction 3. Standardized A1c 4. Standard definitions Weaknesses: 1. Patient target number related to number of research assistants, not based on power analysis. 2. No LOS for hospital or cost analysis 3. One site</p>
<p>Viklund, Ortqvist (2014) Factors predicting glycaemic control in young persons with type 1 diabetes. II-2 Sweden</p>	<p>The aim of this study was to explore which health and HRQOL factors correlate and predict outcome in metabolic control in young persons with type 1 diabetes.</p>	<p>204 patients with T1D for at least 6 month ages 12-17</p>	<p>Cross-sectional population-based observational study. Convenience sample</p>	<p>Age had the strongest positive correlation with metabolic control. Age, physical health, social relations, problem solving, goal achievement, and object evaluation</p>	<p>Strengths: 1. Size of study 2. Multiple sites 3. Several factor measures Limitations: 1. No power analysis 2. 1 tool only had reliability /validity for adults and the other tools reliability</p>

				(object = diabetes), predicted 25% of the total variation in HbA1c. Did not find correlations with gender or diabetes duration in this study.	/validity was not documented.
Ziegler et al. (2011) Frequency of SMBG correlates with HbA1c and acute complications in children and adolescents with type 1 diabetes Level: II-2 Country: Germany/Austria	The aim of this study was to correlate the frequency of self-monitoring of blood glucose (SMBG) to the quality of metabolic control as measured by hemoglobin A1c, the frequency of hypoglycemia and ketoacidosis, and to see whether the associations between SMBG and these outcomes are influenced by the patient's age or treatment regime.	26,723- 85% of children in Germany/Austria. Children 0-18 52% male with T1D 233 centers in Germany and Austria	Population-based prospective Longitudinal data de-identified from a national database between 1995 and 2006. Variables: gender, age at visit, diabetes duration, therapy regime, body mass index (BMI: body weight in kilograms divided by square of height in meters), frequency of SMBG, HbA1c, rate of severe hypoglycemia, and diabetic ketoacidosis (DKA).	Less than 3 inj./day was sig. worse metabolic control. Adjusted for confounders, more frequent SMBG was significantly associated with better metabolic control up to 5 tests per day (> 5 no more improvement). On average, a drop of HbA1c (\pm SE) of 0.20% (\pm 0.007) for one additional SMBG per day ($p < 0.001$) could be observed.	Strengths: 1. Sample size 2. Multi- site 3. Standard definitions Limitations: 1. Non-standard A1c method 2. Observational

(Berg et al., 2014; Dovic et al., 2014; Duke et al., 2008; Gerstl et al., 2008; Hood et al., 2009; King et al., 2014; Lewin et al., 2006; Olinder et al., 2009; Rausch et al., 2012; Rosenbauer et al., 2012; Springer et al., 2006; Svoren et al., 2007; Viklund & Ortqvist, 2014; Ziegler et al., 2011)

Table 4*Variables used to perform the analyses to answer the questions of this study*

Concept to be studied	Unit of Analysis	Variable type	Measurement tool	Level of Measurement
Health-Related Quality of Life (HRQOL)	Youth/parent dyad	Dependent variable	PedsQL™Family Impact Module	Interval
		(Independent for regression analysis)	Diabetes PedsQL™scale	
Metabolic Control	Youth only	Dependent variable	POC Glycosylated hemoglobin/ A1c test result	Continuous
			A1c Control Groups: Within goal <7.5 Moderate 7.5-8.5 Poor > 8.5	Categorical
Gender	Youth only	Independent variable	Male/Female	Categorical
Age	Youth only	Independent variable	Age in years at start of study: Preadolescent 8-12 Adolescent 13-16	Categorical
Ethnicity	Youth only	Independent variable	White/Non-white	Categorical
Socioeconomic status (SES) Access to health care	Family	Independent variable	Health insurance as Proxy Public (lower SES) Private (higher SES)	Categorical
Treatment complexity Technology or No technology	Youth only	Independent variable	Insulin pump and/or Continuous glucose monitor (CGM)	Categorical
			Injections and finger poke blood sugar tests	

Table 5*Demographics of Participants and Context Variables*

Context Variables	N	%
Age		
preadolescents 8 – 12 years old	93	44.3
adolescents 13-16 years old	117	55.7
Gender		
male	106	50.5
female	104	49.5
Ethnicity		
white	192	91.4
non-white	18	8.6
Socioeconomic status		
private insurance	154	73.3
public insurance	56	26.7
Technology Use		
no technology	70	33.3
insulin pump +/- CGM	140	66.7
A1c Control Groups		
Within goal (< 7.5%)	39	18.6
Moderate (7.5-8.5%)	70	33.3
Poor (> 8.5%)	101	48.1

Notes: CGM = continuous glucose monitor

Table 6

Descriptive data for continuous variables used in the analyses

Variable	<i>N</i>	<i>Min.</i>	<i>Max</i>	<i>M</i>	<i>SD</i>
Youth HRQOL	210	23.33	93.75	66.19	12.59
Preadolescent HRQOL	93	23.33	93.75	66.55	12.65
Adolescent HRQOL	117	37.12	92.42	65.91	12.58
Parent HRQOL	210	26.72	98.28	64.71	16.66
Youth A1c Log	210	.76	1.15	.94	.08

Table 7

Comparison of A1c and A1c Log (transformed)

Variable	<i>N</i>	<i>Min.</i>	<i>Max</i>	<i>M</i>	<i>SD</i>
Youth A1c	210	5.70	14.00*	8.95	1.72
Preadolescent A1c	93	6.60	14.00*	8.77	1.52
Adolescent A1c	117	5.70	14.00*	9.09	1.86
Youth A1c Log	210	.76	1.15	.94	.08

*Note: measurement not valid greater than 14.0, so any number > 14.0 entered as 14.00

Table 9*One-Way Analysis of Variance Table for the Effects of A1c Control Group on HRQOL*

Variable	<i>df</i>	<i>SS</i>	<i>MS</i>	<i>F</i>	<i>p</i>
Between Groups	2	1781.03	890.51	5.88	.003
Within Groups	207	31327.65	151.34		
Total	209	33108.68			

Table 10*Comparisons of Within Goal, Moderate, and Poor control A1c groups*

(I) A1c Control Group	(J) A1c Control Groups	<i>MD(I-J)</i>	<i>SE</i>	<i>p</i>
Within goal <7.5	Moderate 7.5 to 8.5	1.53	2.46	.807
	Poor > 8.5	6.72*	2.31	.012
Moderate 7.5 to 8.5	Within goal <7.5	-1.53	2.46	.807
	Poor > 8.5	5.18*	1.91	.020
Poor > 8.5	Within goal < 7.5	-6.72*	2.31	.012
	Moderate 7.5 to 8.5	-5.18*	1.91	.020

* The mean difference (*MD*) is significant at the .05 level

Table 11*Regression Analysis Factors Predicting Youth A1c results*

Variable	<i>B</i>	<i>SE B</i>	β	<i>t</i>	<i>p</i>
Youth HRQOL	-.001	.000	-.195	-2.89	.004
Youth Ethnicity	-.049	.019	-.172	-2.56	.012
Youth SES	.015	.012	.088	1.31	.192
Parent HRQOL Emotional Functioning subscale	.000	.000	-.113	-1.68	.094

Note. Adjusted R² = .11 (N = 210, p < .001)

Table 12*Regression Analysis Factors Predicting Preadolescent A1c results*

Variable	<i>B</i>	<i>SE B</i>	β	<i>t</i>	<i>p</i>
SES	.030	.015	.211	1.99	.049
Preadolescent HRQOL Treatment-II subscale	-.001	.000	-.138	-1.31	.195

Note. Adjusted R² = .05 (N = 88, p = .041)

Table 13*Regression Analysis Factors Predicting Adolescent A1c results*

Variable	<i>B</i>	<i>SE B</i>	β	<i>t</i>	<i>p</i>
Adolescent HRQOL	-.001	.000	-.281	-3.14	.002
Treatment-I subscale					
Parent HRQOL Social	-.001	.000	-.194	-2.21	.029
Functioning subscale					
Ethnicity	-.029	.024	-.108	-1.21	.230

Note. Adjusted R² = .12 (N = 117, p = .001)

Table 14

HRQOL Statements that were Predictive of Adolescent A1c

Adolescent HRQOL Teen Treatment- I subscale

It hurts to get my finger pricked.

It hurts to get insulin shots.

I am embarrassed by my diabetes treatment.

My parents and I argue about my diabetes cares.

It is hard for me to do everything I need to do to care for my diabetes.

Parent HRQOL Social Functioning subscale

I feel isolated from others.

I have trouble getting support from others.

It is hard to find time for social activities.

I do not have enough energy for social activities.

Table 15

HRQOL Statements that associated with Preadolescent A1c

Preadolescent HRQOL Treatment- II subscale	It is hard for me to take blood glucose tests. It is hard for me to take insulin shots. It is hard for me to exercise or do sports It is hard for me to keep track of carbohydrates. It is hard for me to carry a fast-acting carbohydrate. It is hard for me to snack when I go low.
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Appendix

Description of the sample inclusion criteria for the primary study.

1. Youth included in the study are eight to sixteen years old, diagnosed with diabetes for greater than 12 months. Youth less than 8 years' old were excluded because of their limited ability to participate effectively in the tailored self-management session. Youth greater than 16 were likely to have future clinic appointment times affected by college and employment restrictions. The intervention groups were developmentally split between pre-teen (8-12 year olds) and teen (13-17 year olds). Content in the sessions was also tailored developmentally. The time period of greater than 12 months after diagnosis was chosen as the usual care of both clinics included self-management education that was normally completed by 12 months after diagnosis.
2. Children planning to continue care at the clinic for the next two years. This allowed the ability of families to complete all the testing and tailored intervention treatments.
3. English speaking . The PRISM tool used to identify the tailored group management interventions of the original study does not yet have reliability/validity data for non-English speaking families. It was also unlikely that enough non-English speaking families could have been recruited to facilitate tailored self-management group sessions for this population.

Data Management Plan of the primary study

The biostatistician and the PI worked with the Data Manager to implement the data management plan. All forms were kept in locked file cabinets. The Data Manager entered data into a password protected database. The data management plan included the following steps:

1. To ensure data accuracy, before presentation of the analysis files the Data Manager and the statistician cleaned the data using double data-entry or a two-person, cross-checking technique. As an additional safeguard, the frequency distributions of all variables will be checked before proceeding with the analysis.
2. Data was checked for sufficient variability in the dependent measures.
3. When 25% of the data was collected, the Data Manager checked patient criteria with the responding sample demographics for any problems/skew.
4. Beginning when 25% of the data was collected, data was checked to ensure that assumptions for planned statistical analyses were met.
5. To be included in the analysis, every case had a score on both the process and outcome variables. Thus, any case with missing outcome scores or 5% or more of the process scores will be excluded.
6. If problems arose, the statistical teams at the Medical College of Wisconsin, and the University of Wisconsin-Madison, the methodological experts and the PI had planned work together to make decisions about any needed modifications. The PI will keep a log by tracing the history and rationale for any needed modifications.

7. A template will be created for data entry including consistent header and rows. The form will contain drop-down choices to reduce human error, only, missing data will be coded as 9999, data set will be assessed for years at the beginning and end. The PI will keep a log for history and need for modifications.

Data Collection for the Primary Study

1. Research staff received extensive training related to recruitment of participants, eligibility criteria, obtaining consent and the research processes.
2. The research staff coordinated data collection. Time between visit components (e.g., meter and pump downloads, blood draws for routine tests, or provider encounter) was used for research staff to administer study instruments, as done successfully in preliminary pilot study.
3. Before families left the clinic, the research assistant checked data accuracy and completeness. Preliminary pilot studies suggested all items are completed by >95% of participants.
4. Assessments completed at Baseline, Session 1 (three month), Session 2 (six month), Session 3 (9 month), Session 4 (12 month), 6 month post intervention and 12 month post intervention were taken to the research office by research assistants immediately after each clinic session.
5. Range checks and consistency checks were programmed to occur at data entry.
6. Research assistants entered all data into Access databases that ultimately were merged to create analyzable datasets.
7. Final data resided in a Stata database with identifying information removed, but will be given in a format that can be used for SPSS analysis of the secondary study

Measurement:

1. Psychosocial health of the youth will be measured using the psychosocial health summary scores of the Diabetes PedsQL™ survey that is being administered in the original study. Diabetes Module scales (average $\alpha=0.71$) were acceptable for group comparisons. The Diabetes Module demonstrated inter-correlations with dimensions of generic and diabetes-specific QOL. Baseline data of this health-related quality of life (HRQOL) data was administered at baseline, 6 months, and will be administered at 12 months, 18 months and 24 months (one year after the interventions completed).
2. The PedsQL™ Family Impact Module measures parent self-reported emotional health as part of the quality of life data for parents. The Family Impact Module has subcategories of physical, emotional, social, and cognitive functioning, communication, and worry. The Module also measures parent-reported family daily activities and family relationships. The emotional subscale was shown to have an internal consistency alpha of .90 (Varni, et al, 2004). These Quality of Life measures were administered at baseline, 6 month, and will continue to be administered at 12, 18, and 24 months after the interventions.
3. Metabolic control was measured using the glycosylated hemoglobin (A1c). The A1c is the measure of choice for glycemic control. The A1c test provides an accurate estimate of patients' glycemic control for the last 90 days. A higher A1c means poor glycemic control (ADA, 2014; Chaing, et al., 2014; Reid, et al, 2013; Wood et al., 2013). A1c tests were gathered at baseline, 3, 6, 9, 12, 18, and 24 months (one year after the study interventions). The grant from the original study paid for the test to be completed at the host clinics to assure that the same process and assays would be used for the test, as there can be variability between laboratories. The baseline A1c data will be used in this secondary analysis.

4. Other variables that will be gathered from the primary baseline data.
 - a. Ethnicity. Literature suggests that the A1c outcomes of minority patients are statistically lower than those of white, non-Hispanic patients (Reid, et al., 2013).
 - b. Socioeconomic status through insurance status. Literature suggests that those youth/parent dyads with lower socio-economic status are more likely to have psychosocial health issues (Hassan, et al., 2006; Paniagua & Yamada, 2013).
 - c. Age of the youth.
 - d. Family structure. The parent or significant adult that is part of the study will be identified in the demographic data.

CURRICULUM VITAE

Joan Pennington Totka
Born in Milwaukee, Wisconsin

Education

University of Wisconsin – Madison, Madison, Wisconsin, Master’s of Science in Nursing,
Pediatrics and Education

University of Wisconsin – Milwaukee, Milwaukee, Wisconsin, Bachelor of Science in
Nursing

**Dissertation Title: TYPE 1 DIABETES: FACTORS THAT AFFECT YOUTH/PARENT
DYADS’ HEALTH RELATED QUALITY OF LIFE AND YOUTH METABOLIC CONTROL**

Research Experience

2013-2016

Lead of educational arm for PCORI grant funded research study, Family-Centered Tailoring
of Pediatric Diabetes Self-Management Resources, Principle Investigator Elizabeth Cox, MD,
University of Wisconsin, Madison. Multi-site study.

2010-2012 Nurse transition to practice research study at Children’s Hospital of Wisconsin.
Mixed methods study related to new nurse transition into practice.

Recent Honors and Awards

2016- Sigma Theta Tau Education award

2014- Julie Lathrop Nursing Research Award

Professional Affiliations

- Sigma Theta Tau Nursing Honor Society
- Midwest Nursing Research Society
- National Nursing Staff Development Organization
- Health Care Educator’s Association
- American Association of Diabetes Educators

Publications

Totka, J.P. Snethen, J.A., Cox, E.A. (2016). Group Education Research: Strategies to Ensure Fidelity.
(in review)

Ziebert, C., Klingbeil, C., Schmitt, C.A., Stonek, A.V., Totka, J.P., Stelter, A., & Schiffman, R.F. (2016).
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- Totka, J., Kachoyneanos, M. & Friedhoff, M., (1993) Pain management in children with diabetes, *Diabetes Educator*.

Presentations

- Poster: Totka, J.P., & Snethen, J.E. (2016) Type 1 Diabetes: Factors that Affect Youth/Parent Dyad's HRQOL and Metabolic Control, Pediatric Nurse Conference, Milwaukee, WI, November.
- Poster: Totka, J.P., & Snethen, J.E. (2014) Fidelity in Educational Intervention, Pediatric Nurse Conference, Milwaukee, WI, November.
- Totka, J., Stelter, A. (2013). *Implementing HeartCode® for Your Life Support Program* (Poster), Health Care Educator Association (HCEA), Annual meeting Cincinnati, Ohio, October.
- Klingbeil, C, Totka, J., (2013). *Infusing Professional Development into New Nurse Orientation: An Evidence Based Approach*, Association of Nursing Professional Development (ANPD)- formerly NNSDO, Annual meeting Dallas, Tx., July.
- Totka, J, Johnson, N., (2008). *The Multi-media approach: Essential Tools for Implementing EBP*. (Poster) 20th Annual Conference for Teachers of Nursing Practice, 1/8/2008 Madison, Wisconsin, USA.

- Totka, J, & Holz, R, (2008). Type 1 Diabetes in the Hospital: Stabilization and Maintenance of Care Nursing Grand Rounds, Children's Hospital of Wisconsin 2/13/2008, Wauwatosa, WI, USA
- Totka, (2008). What's New in Type 1 Diabetes research", Parkside Nursing Program's fundraiser for JDRF, Racine, Wisconsin. May, 2008.
- Totka, J, Johnson, T., (2008). Boundaries of Care in Pediatrics: Shall we dance? Pediatric Nursing Conference, 11/09/2008, Waukesha, Wisconsin, USA.
- Totka, J. & Johnson, N. (2007). Disseminating Evidence Based Practice on the Intranet. Registered Nursing Association of Ontario (RNAO) International Conference on Evidence-Based Practice, Markham, Canada, June 7, 2007.
- Johnson, N., Klingbeil, C., Totka, L., & Doyle, L. (2007). (poster) When not to go on-line: How to choose the appropriate educational strategy for nurses. University of Madison, Madison, Wisconsin: 19th Annual Conference on Nursing Education, January 8, 2007.
- Totka, J., Kirby, M., (2001). Type 2 Diabetes in Children. NWADE- Northeastern Wisconsin Diabetes Educator Association-September 6 & October 10, Appleton, WI
- Totka, J., (2001). Emerging trends in Pediatric Type 1 Diabetes. NPACE- National Nurse Practitioner Conference-Sept. 12, Milwaukee, WI
- Totka, J. (2001). (posters) Flexible insulin therapy in children and Pediatric screening for the use of the insulin pump. American Association of Diabetes Educators 28th Annual Meeting and Exhibition August 15-19, Louisville, KY
- Totka, J. (2000). Evaluating Case Management. Management of Type 1 Diabetes into the 21st Century - July 12 & 13, Vail, CO
- Totka, J., Chase, Peter (2000). Preventing DKA and Cerebral Edema. Management of Type 1 Diabetes into the 21st Century -July 12 & 13, Vail, CO
- Totka, J., Parton, E. (2000). Care and Advocacy for Children with Type 1 Diabetes in the School & What's New National School Nurse Conference June 29, Milwaukee, WI
- Totka, J. (2000). (poster) *Outcomes of the Development and Dissemination of a Pediatric DKA Guidelines* 2000 CDC Diabetes Translation Conference- April 18, New Orleans, LA