

RELATIONSHIPS BETWEEN QUALITY OF LIFE, FAMILY FACTORS, ADHERENCE,  
AND GLYCEMIC CONTROL IN PEDIATRIC PATIENTS WITH TYPE 1 DIABETES  
MELLITUS

By

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To Amy—You bring out the best in me. You motivate, inspire, and encourage. I am eternally grateful for your heart.

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## TABLE OF CONTENTS

	<u>page</u>
ACKNOWLEDGMENTS.....	4
LIST OF TABLES.....	7
LIST OF FIGURES.....	8
ABSTRACT .....	9
CHAPTER	
1 INTRODUCTION .....	11
Overview.....	11
Background and Significance .....	11
Prevalence of Type 1 Diabetes Mellitus .....	12
Treatment of Type 1 Diabetes .....	13
Adherence versus Glycemic Control .....	16
Diabetes-Specific Family Factors .....	18
Quality of Life .....	21
Adherence and Quality of Life .....	24
Specific Aims and Hypotheses .....	27
Specific Aim 1.....	27
Hypothesis 1 .....	27
Hypothesis 1a .....	27
Specific Aim 2.....	28
Hypothesis 2 .....	28
Specific Aim 3.....	28
Hypothesis 3 .....	28
Hypothesis 3a .....	29
Specific Aim 4.....	29
Hypothesis 4 .....	29
2 METHOD .....	30
Participants .....	30
Procedure .....	30
Measures .....	31
Measures Completed by the Pediatric T1D Patient.....	31
Measures Completed by the Parent/Primary Caregiver .....	32
Measures Completed by the Parent/Primary Caregiver and Pediatric T1D Patient.....	32
Statistical Analyses.....	35
3 RESULTS .....	39

Demographics of Participants .....	39
Relationships between Demographic Variables and Study Variables.....	39
Glycemic Control (A1c).....	39
Diabetes-Specific Family Factors .....	40
Quality of Life .....	41
Intercorrelations among Study Variables .....	41
Glycemic Control .....	41
Diabetes-Specific Family Factors .....	42
Quality of Life .....	43
Hypothesis Testing .....	43
Relationships between Quality of Life, Adherence, and Glycemic Control (Hypothesis 1) .....	43
Accounted Variance in Glycemic Control by the Model (Hypothesis 1a) .....	45
Relationship between Quality of Life and Behavioral Variables (Hypothesis 2).....	46
Quality of Life and Adherence.....	46
Quality of Life and Diabetes-Specific Family Factors.....	46
Relationship between Quality of Life and Biological Factors (Hypothesis 3) ....	47
Association between Glycemic Control and Ethnic Minority Status (Hypothesis 3a) .....	48
Child Self-Report versus Parent-Observed Report of Psychosocial Functioning (Hypothesis 4).....	48
 4 DISCUSSION .....	 56
Limitations.....	62
Implications and Future Directions.....	64
 LIST OF REFERENCES .....	 66
 BIOGRAPHICAL SKETCH.....	 71

## LIST OF TABLES

<u>Table</u>	<u>page</u>
3-1 Patient Demographic Data .....	49
3-2 Child Sample Diabetes-Specific Characteristics.....	50
3-3 Child-Reported Study Variables Correlation Matrix .....	51
3-4 Parent-Reported Study Variables Correlation Matrix.....	52
3-5 Multiple Regression Analysis with Parent-Report Measures Predicting A1c <sup>a</sup> .....	53
3-6 Quality of Life Means and Standard Deviations by Child Report and Parent Report.....	54

## LIST OF FIGURES

<u>Figure</u>	<u>page</u>
3-1 Mediation Model and Path Coefficients for Parent-Reported Quality of Life, Adherence, and A1c.....	55

Abstract of Dissertation Presented to the Graduate School  
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Type 1 diabetes is an endocrine condition typically diagnosed in childhood. In order to maintain satisfactory health status, patients with Type 1 diabetes are tasked with monitoring their caloric and carbohydrate intake, frequently monitoring their blood glucose level, and adjusting their insulin levels. The complexity of the recommended medical regimen can be particularly difficult to adhere to for youth and adolescents with Type 1 diabetes and their parents/caregivers. As a result, pediatric patients with this condition frequently experience health complications. Previous research has identified several behavioral, biological and psychosocial factors that appear to impact adherence to medical regimen as well as health status, referred to as glycemic control. This study examined predicted and mediated relationships among diabetes-specific family factors, adherence to medical regimen, quality of life, and glycemic control (health status) in youth and adolescents with Type 1 diabetes.

Patient and parent/caregiver dyads ( $n = 70$ ) completed a packet of measures assessing diabetes-specific family factors and quality of life. In addition, they were separately given a structured interview to assess medical regimen compliance. Health

status measures were accomplished by trained medical staff obtaining the patient's glycemic control as part of a routine pediatric endocrinologist visit. Statistical analyses were conducted using correlations and hierarchical regressions.

Combined measures accounted for 42% of the variance in glycemic control. Quality of life partially mediated adherence and glycemic control. Ethnic minority status was associated with poorer glycemic control than Caucasians. Limitations, implications, and future directions are discussed.

## CHAPTER 1 INTRODUCTION

### Overview

#### Background and Significance

Type 1 diabetes mellitus (T1D) is a chronic endocrine condition that is typically diagnosed in childhood or adolescence. The primary characteristic of this condition is an inability of the pancreas to produce insulin, a hormone necessary for the process of converting sugar, starches, and other foods into energy in the body. Youth and adolescents diagnosed with T1D, along with their families, are tasked by health care professionals with a challenging and restrictive treatment regimen, which they must follow for the remainder of their lives. As is the case with many other chronic illnesses, the lifelong presence of T1D in patients has led health professionals and researchers to examine the many facets of proper condition management. Medication regimen management in T1D can be particularly problematic, given the typically young age of onset combined with the regimen's complexity. Previous research has examined many variables that potentially influence T1D management in young patients including characteristics of the disease (e.g., symptom severity, complications, duration of disease), of the patient (e.g., disease education, psychosocial factors), and of the supporting family (e.g., parent-child conflict, family dynamics).

Although there has been a great deal of research in this area, as well as significant strides in subsequent treatment, providers and researchers continue to seek out the variables that are most effective in improving T1D management. This paper will review and synthesize the extant literature on T1D in pediatric patients. Specifically, it will examine the disease, its treatment, and evaluate previous research that has focused on

variables related to its management. The goal of this project is to integrate and further the empirical knowledge base by examining a model hypothesized to predict health status in pediatric populations with T1D.

### **Prevalence of Type 1 Diabetes Mellitus**

The American Diabetes Association (ADA) estimates that T1D affects 1 out of every 400-600 children in the United States, making it one of the most common chronic diseases of school-aged children (ADA, 2009). T1D has previously been referred to as juvenile diabetes due to its much younger typical onset in comparison to Type 2 Diabetes Mellitus (T2D; a.k.a. non-insulin dependent diabetes mellitus). However, with the advent of the obesity epidemic, younger and younger people have been diagnosed with T2D, thus necessitating a change in nomenclature to the current form, T1D, in order to avoid confusion. T1D is usually diagnosed in childhood, with a peak age of onset occurring in middle childhood. However, T1D can be diagnosed as late as middle adulthood. It results from autoimmune destruction of the pancreatic islet cells that produce insulin ( $\beta$ -cells). This destruction of cells leads to a cessation of insulin production by the pancreas. Without the production of insulin, the body is unable to regulate glucose metabolism and convert food into energy. Insulin also plays a significant role in physical growth, activity, brain function, and the body's ability to heal wounds. Despite significant advances in technology, the precise cause of T1D remains unknown. However, current research suggests that this condition is the result of a combination of a genetic predisposition and environmental factors (ADA, 2010; Silverstein et al., 2005; Wysocki et al., 2003).

## **Treatment of Type 1 Diabetes**

Since there is no cure for T1D at present, patients are faced with a complex treatment regimen in order to best manage their condition. The core component of this regimen is the administration of subcutaneous insulin to compensate for the patient's inability to produce insulin on their own. This insulin administration is executed either with the use of syringes or via an external insulin pump. The dosage of insulin required is a continuous variable that is dependent on many factors. In order to know how much insulin to administer, the patient must monitor their blood glucose level several times throughout the day. This is typically accomplished by pricking one's finger with a lancet in order to place a small amount of blood on a blood glucose meter strip. This strip is then inserted into a blood glucose meter which provides accurate information about blood glucose levels. Additionally, the patient must monitor his/her food intake and physical activity, as both of these can impact blood glucose levels.

Regarding blood glucose levels, normal amounts range between 80-120mg/dl. The goal of "tight control" of the T1D treatment regimen is to maintain a blood glucose level within this range. The A1c is a blood test of glycosylated hemoglobin which measures the patient's relative blood glucose functioning over a 2–3 month period. This is commonly referred to as glycemic control (a.k.a. metabolic control). In the context of diabetes research and outcomes, glycemic control represents a patient's health status. Quantitatively, desirable A1c levels are those under 6.5%, which would be classified as good glycemic control (ADA, 2010). Given the multiple contributors to proper maintenance of blood glucose levels (i.e., insulin administration, blood glucose testing, food intake monitoring, exercise monitoring), it is not surprising that maintaining "good" glycemic control in terms of A1c levels for patients with T1D may present obstacles.

Repeated deviations from normal A1c can result in both short-term and long-term complications for the T1D patient. In the short-term, patients can develop conditions such as hypoglycemia, seizures, and diabetic ketoacidosis (DKA). DKA is a potentially life-threatening condition that is the result of an absolute shortage of insulin. In terms of long-term complications, conditions such as nephropathy, neuropathy, and retinopathy can result from repeated hyperglycemia.

Despite the presence of numerous, potentially life-threatening complications, adherence to treatment regimens remains a significant problem for pediatric T1D patients. This is not surprising in light of epidemiological research indicating that as many as 50% of pediatric patients are non-adherent to their medical regimen (Rapoff, 1999; Matsui, 1997). Pediatric T1D patients appear to accurately reflect this lack of adherence. A 9-year follow-up study of T1D youth reported that 45% of the adolescents in their study were in some way non-adherent to their treatment regimen (Kovacs et al., 1992). Adherence issues vary across the different aspects of the T1D treatment regimen. Regarding insulin, research has suggested that 10% of patients report administering the wrong dose, 20% report administering an injection at the wrong time, and 19% report difficulty adhering to physician recommendations regarding adjustments to their insulin dose (Delamater et al., 1998). Despite the high prevalence of errors in insulin administration, most patients do report that they regularly take their insulin. Insulin administration does not appear to be the domain of T1D regimens with the highest rate of adherence problems. Blood glucose monitoring, for example, presents a higher rate of adherence problems such that 31% of pediatric patients do not adhere to recommendations about timing and frequency. Further, 48% of pediatric T1D patients

do not adhere to recommended eating habits, as reported by their parents (Delamater et al., 1998). As shown by research, many different areas of T1D treatment regimen present frequent barriers to adherence in youth and adolescents with this disease.

In an effort to combat the problems related to adherence in T1D treatment regimens, the Diabetes Control and Complications Trial (DCCT; 1994; 1993) sought to identify the relationships between regimen adherence, glycemic control, and long-term diabetes-related complications. Findings from this groundbreaking 10-year study continue to guide common approaches to T1D treatment regimens today. Participants in this study were randomized into two treatment groups: conventional therapy and intensive therapy. Conventional therapy consisted of 1–2 daily injections combined with daily monitoring of blood glucose levels. Further, participants in the conventional therapy group did not make adjustments to their insulin dosages based upon food intake or blood glucose levels. In contrast, the intensive therapy group participants were required to administer 3 or more insulin injections per day or use an insulin pump. Additionally, they checked their blood glucose levels a minimum of 4 times per day. Participants in the intensive therapy group also made insulin dosage adjustments dependent on blood glucose levels, physical activity, and food intake.

Findings from this large-scale study indicated that participants in the intensive therapy group not only were better able to achieve glycemic control, but they also experienced a delayed onset and slower progression of diabetes-related medical complications. Specifically, risks of retinopathy, neuropathy, and nephropathy were reduced in the intensive therapy group by rates of 50% or higher. These findings further emphasized the importance of well-maintained glycemic control in terms of impacting

long-term health. Implications from the DCCT study resulted in sweeping changes in the realm of “standard care” of patients with T1D. Since the study, intensive insulin therapy is frequently recommended for patients in order to better achieve and maintain good glycemic control, as well as to reduce the risk of subsequent diabetes-related complications. The DCCT suggested that the majority of patients with diabetes, including youth, should utilize an intensive insulin regimen to optimally treat their condition. Although the DCCT reported that patients on an intensive insulin regimen are at a two to three-fold risk for hypoglycemic episodes, they reported that the risk-benefit ratio still indicated that this regimen is the treatment of choice due to the improved glycemic control.

Patients on an intensive regimen typically administer 4–6 daily insulin injections, using a combination of long-acting and short-acting insulin. Carbohydrates from each meal must be counted and taken into consideration regarding insulin dosage. It is recommended that patients using this treatment check their blood glucose levels 4 or more times daily, particularly before and after meals. There are many young children and adolescents who find that being prescribed an intensive regimen is neither desirable nor easy to follow. As such, parental involvement is vital to the success of treatment.

### **Adherence versus Glycemic Control**

Thus far, much has been said about the relationship between adherence and glycemic control in T1D regimen management. The term “adherence” has previously been defined as the “extent to which a patient’s behavior coincides with medical or health advice” (Haynes, 1979). Given that the goal of treatment regimens is to improve health status (A1c), it would seem as though adherence to one’s treatment regimen

would be virtually perfectly correlated with glycemic control (health status). However, although the two are related, the relationship is not perfect. Most studies of adherence in patients with T1D fail to document high correlations between reports of adherence and glycemic control (Harris et al., 2000; Johnson, 1994; Johnson, 1993; Johnson et al., 1992; La Greca, 1990). One possible explanation for this discrepancy may result from problems with measuring the construct of adherence. For example, if a patient's prescribed medical regimen is not effective, even perfect adherence is not expected to result in good glycemic control. Nevertheless, researchers believe that adherence is a significant predictor of HbA1c. Glasgow and colleagues (1987) suggested that the relationship between adherence and glycemic control is not always straight-forward, and that adherence must be examined in the context of other factors. Research has identified such factors including regimen characteristics (i.e., intensive vs. conventional), disease characteristics (e.g., duration, age of onset, related complications, etc.), and family variables (Rapoff, 1999; LaGreca & Schuman, 1995).

Additionally, it has been suggested that biological variables such as being a member of an ethnic minority can negatively influence glycemic control. A multi-site study by Chalew and colleagues (2000) inferred that being African-American was predictive of poorer glycemic control, although their analysis did not control for socioeconomic variables. Work by Petitti and associates (2009) produced similar findings with regard to glycemic control in ethnic minority youth with T1D, this time controlling for factors such as family income, family structure, and parental education. These findings certainly warrant further investigation in this domain.

## **Diabetes-Specific Family Factors**

A great deal of research has indicated that diabetes-specific family factors mediate the relationship between adherence and glycemic control in youth and adolescents with type 1 diabetes (Duke et al., 2008; Lewin et al., 2006; Anderson et al., 2002). Knowing the important role that family factors play in relationship to adherence, it is important to identify the specific factors (positive and negative) in order to better develop effective interventions to improve adherence. As with most parent-child relationships, parental involvement plays a key role. However, it is necessary for parents to be more than simply non-negative. It is vital that they exert some level of positive, supportive involvement in their child's regimen.

Research by Anderson and associates (1997) examined the relationship between blood glucose monitoring and adherence. Their study was conducted in the context of parental involvement in this task. Results from the study indicated that a higher frequency of blood glucose monitoring was associated with better adherence and glycemic control. Interestingly, factors contributing to these findings were not limited to the frequency of monitoring, but also included parent-child agreement on monitoring, as well as parental support and involvement in monitoring. Positive and supportive parenting behaviors, such as those of this study, intuitively seem to be helpful in increasing adherence and subsequently glycemic control. Conversely, negative parenting behaviors seem counterproductive. As illustrated by Lewin and colleagues (2006), poor adherence was associated with several negative family processes including criticism and lack of warmth and support. This point is further supported by research from Duke and associates (2008) that identified parental nagging about diabetes-specific behaviors as a strong predictor of poor adherence.

Diabetes-specific family factors have been continually shown to impact adherence to T1D regimens in youth. Hauser and colleagues (1990) conducted a four-year longitudinal study examining medical regimen adherence in youth and adolescents with type 1 diabetes. Their study of over 300 participants indicated that the strongest predictor of long-term adherence was family conflict as perceived by the child. Similar findings have been shown in research by Miller-Johnson and associates (1994) examining parent-child relationships as they pertain to regimen management in type 1 diabetes. Their findings indicated that a negative parent-child relationship was predictive of both poor adherence and poor glycemic control. Duke and colleagues (2008) noted that both negative diabetes-specific family behaviors (i.e., nagging about regimen) as well as child externalizing behaviors were both indicative of poorer adherence. Further illustrating the impact of family factors, Lewin and associates (2006) examined 100 youth and adolescents with type 1 diabetes. Their results showed a significant impact from negative family processes (i.e., criticizing, lack of warmth & support) on subsequently lower adherence and glycemic control. In their model, family factors predicted 50% of the variance in glycemic control.

Due to the abundance of literature supporting the importance of diabetes-specific family factors as it pertains to adherence and glycemic control in type 1 diabetes, many researchers have developed measures to assess family factors in an effort to identify and treat those that may preclude adherence. Most of the commonly used measures are self-report measures given to both parent and child. Although designed with different areas of particular focus, most are assessing some level of family conflict. The Diabetes Family Conflict Scale (DFCS; Hood, et al., 2007) is one of the most commonly

used diabetes-specific family conflict measures. It was designed to evaluate the level of diabetes-specific support that the adolescent receives from his/her family. Factor analyses showed that all of the items in this measure load on either direct (e.g., blood glucose monitoring) or indirect (e.g., discussing diabetes with friends) diabetes-specific tasks. Analyses indicated that direct diabetes-specific tasks are predictive of both adherence and glycemic control. Further, the indirect tasks were shown to be related to mood and quality of life. This measure could be beneficial in identifying the level of family conflict in order to assess what method of treatment would achieve optimal outcomes. Another family factor often assessed is social support. As demonstrated in research from Miller-Johnson and associates (1994), positive parent-child relationships are predictive of better adherence and glycemic control. It is feasible to propose that social support is an important part of this relationship. With this in mind, the Diabetes Social Support Questionnaire-Family Version (DSSQ-F; La Greca, et al., 2002) was developed as a self-report measure to assess the level of diabetes-specific support that the child receives from his/her family. Analyses of this measure indicate that the strongest predictor of adherence is parental support of the child's diabetes. Another example of a commonly utilized measure of family factors in youth with type 1 diabetes is the Diabetes Family Behavior Checklist (DFBC; Schafer et al., 1986). Analysis of the DFBC shows that responses load onto either positive or negative family support factors. Both factors are predictive of adherence and glycemic control in respective directions. Although there are many other well-established measures of family functioning, these were used to highlight the importance of assessing any and all family factors that may be contributing to problems with adherence. Further, the analyses of these measures

emphasizes the robust relationships between diabetes-specific family factors and both adherence and glycemic control.

### **Quality of Life**

The biopsychosocial model proposes that physical and psychological factors combine to produce health outcomes (Engel, 1977). With this in mind, physicians are increasingly encouraged to treat the “whole” patient, using a holistic approach to clinical treatment. The application of this multi-dimensional approach to health outcomes is frequently referred to as “Quality of Life.” Research on health-related quality of life (QOL) has increased over the past two decades. Going beyond mortality and morbidity, QOL measures typically focus on broad domains of functioning, such as social, physical, academic, and psychological well-being.

As with most chronic medical conditions, the presence of T1D is bound to have some negative effect on the patient’s QOL. Due to the developmental, social, and cognitive changes that are universally experienced in childhood through adolescence, we see a particularly dramatic fluctuation in QOL, regardless of health. With this in mind, Varni and colleagues (2007) sought to examine the impact of numerous chronic conditions on youth and adolescents’ quality of life and compare them to healthy controls. Their research involved over 2,000 youth and adolescents with health conditions including: diabetes (type 1 and 2), cancer, end-stage renal disease, cardiac disease, asthma, juvenile rheumatoid arthritis, obesity, and cerebral palsy. They also included a cohort of youth with no chronic health conditions. Their findings shed a great deal of light on the impact of many diseases and subsequent quality of life. All of the disease groups in their study reported significantly lower overall quality of life (both self-report and parent-proxy) than the healthy control group. However, youth and

adolescents in the diabetes group appear to be the least affected of the disease groups included in the study. Specifically, the diabetes group was the only disease group that did not significantly differ from the control group on subscales of social and school functioning. Breaking the group into specific types of diabetes, the authors showed that youth and adolescents with T2D showed significantly lower levels of overall quality of life, social functioning and academic functioning than those with T1D. Parents of the children with T2D also reported significantly lower levels for their children in the same domains in comparison to parents of children with T1D. This could partially be attributed to the fact that those children with T2D were more likely to be overweight or obese than those with T1D. To further illustrate this as a possible explanation, the children in the obesity group in this study performed significantly lower across quality of life measures than the diabetes group.

Like many psychosocial factors, quality of life is a continuous variable. Elements that contribute to increases or decreases in quality of life change naturally as a result of developmental changes that occur from youth to adulthood. Patients with diabetes are no different in this context. The factors that affect quality of life in youth versus adolescents have both similarities and differences. In young children with diabetes, the primary source of responsibility for disease-specific regimen typically involves the child's parent or guardian. As youth develop into adolescence, there is usually some level of transition of primary responsibility for disease-specific regimen components from the parent(s) to the adolescent (Anderson & Laffel, 1997). Thus, throughout childhood and adolescence, there is typically a strong component of family factors involved. As shown in several research studies (e.g., Duke et al., 2008; Lewin et al., 2006), diabetes-

specific family factors mediate the relationship between adherence and glycemic control. Since both glycemic control and adherence have been shown to be related to quality of life in numerous studies (e.g., Wagner et al., 2005; Hoey et al., 2001; Hesketh et al., 2004; Vanelli et al., 2003), it seems logical to posit that some key factors impacting quality of life in both youth and adolescents include family factors, adherence, and glycemic control.

One factor influencing quality of life in patients with diabetes appears in adolescence and seems to persist through adulthood. Beginning in adolescence, we see that females with diabetes report lower levels of quality of life than their male counterparts. This point is further illustrated in research by the SEARCH for Diabetes in Youth Study Group (Naughton et al., 2008), which examined health-related quality of life in youth and adolescents with type 1 and 2 diabetes. Their findings showed a general drop in quality of life across sex in adolescence when compared to youth, which appears to be a relatively universal phenomenon independent of disease (Varni et al., 2007). However, the SEARCH group also showed an age by sex interaction such that female adolescents reported significantly lower quality of life than their male counterparts. This apparent “gender gap” appears to remain into adulthood in terms of diabetes. When Wexler and colleagues (2006) identified correlates of health-related quality of life in adults with T2D, being female was among the factors that predicted lower quality of life.

As seen in previous research, having diabetes naturally impacts quality of life to an extent, although the effect appears to be relatively low in comparison to some other chronic disease groups. This relationship is strengthened by many contributing factors,

including diabetes-specific family factors, adherence, glycemic control, sex, perceived burden, and diabetes-specific complications. These factors may have a stronger or weaker impact on quality of life as the patient progresses from childhood through adolescence into adulthood. Beginning in adolescence, females with T1D appear to be at more risk for lower quality of life, which may make them more at risk for other associated factors such as poor adherence and glycemic control. Given the relationship between quality of life and many health outcome factors, it would behoove clinicians to utilize interventions that take quality of life into consideration when treating a person with diabetes, regardless of age.

### **Adherence and Quality of Life**

There has been a growing amount of research in pediatric psychology focusing on medical adherence and potential contributing factors to non-adherence or poor adherence. This increase in focus is due in part to epidemiologic research indicating that as much as 50% of pediatric patients are non-adherent to their medical regimen (Rapoff, 1999; Matsui, 1997). With this in mind, much of the research has focused on identifying predictors of adherence in this population. Quality of life has been thought to be associated with adherence.

In a study examining children and adolescents with T1D, Wagner and associates (2005) sought to identify correlates of quality of life. Their findings indicated that lower age (pre-adolescence), better glycemic control, and an intensive insulin regimen were all associated with better quality of life. Of importance in these findings is the correlation between good glycemic control and quality of life, as adherence has also been shown to be associated with glycemic control. Research by Laffel and colleagues (2003) also focused on quality of life in youth with type 1 diabetes. Interestingly, their

results showed a negative relationship between diabetes-specific family conflict as perceived by the child and the child's self-reported quality of life. A great deal of research has shown that diabetes-specific family factors mediate the relationship between adherence and glycemic control in youth and adolescents with type 1 diabetes (e.g., Duke et al., 2008; Lewin et al., 2006). Thus, evidence that quality of life is associated with diabetes-specific conflict, a family factor, begins to develop a clearer picture of the relationship between quality of life and both adherence and glycemic control as it pertains to this disease population.

In a larger scale study, researchers from the Hviore Study Group on Childhood Diabetes (Hoey et al., 2001) sought to examine the relationship between glycemic control and quality of life in adolescents with type 1 diabetes. They expanded the scope of their study to include participants from 11 countries across Europe, North America, and Asia. The results of their study suggested that the relationship between glycemic control and quality of life appears to be somewhat universal and unaffected by cultural and ethnic differences. Participants in their study showed a gradual decrease in both quality of life and glycemic control when comparing younger adolescents to older ones. Although some of this reduction in quality of life is seen across adolescents regardless of disease (Varni et al., 2007), researchers also attribute part of this apparent drop to difficulties related to the transfer of disease-specific regimen behaviors as the child transitions into young adulthood (Anderson & Laffel, 1997). Another interesting finding from the Hviore Group showed that female adolescents report increased worry, lower life satisfaction, and worse physical health at an earlier age in adolescence than their

male counterparts, although both show a gradual decrease when compared to younger patients.

Naturally, whenever the discussion focuses on pediatric medical regimen adherence, it is important to discuss the involvement of their parents. The research is fairly clear that positive involvement by the parents is important, although over-involvement has sometimes been shown to be counter-productive. Graue and colleagues (2005) conducted a study examining the effect that parents may have on their child's glycemic control and their quality of life. As would be expected, their findings indicated that factors improving both glycemic control and quality of life include: parent-child cohesion on disease-specific tasks, parental support of disease-specific behaviors, and a positive level of involvement. Their results also showed that both over-involvement and negative support behaviors tend to have a negative effect on both glycemic control and quality of life. Research from Vanelli and colleagues (2003) produced similar results, suggesting that good glycemic control is associated with good quality of life. Further, they showed that parent-child conflict predicted both poorer glycemic control and quality of life.

There has been extensive research on pediatric T1D patients involving some combination of the variables discussed (i.e., QOL, adherence, family factors, glycemic control, and demographic information). However, the relationship between all of these variables simultaneously has not been adequately investigated. It is with this in mind that the current study was proposed. Based upon the existing research, the current study aimed to examine all of the aforementioned variables and hypothesized a contribution to the literature by creating a model that accounts for a greater total amount

of explained variance in glycemic control. With this information, more effective interventions can be developed in order to improve patient health status.

### **Specific Aims and Hypotheses**

The current study proposed to investigate the relationships of child, parent, and family level variables on adherence, quality of life, and glycemic control in pediatric T1D patients. Long-term goals of this area of research are to develop more effective interventions designed to improve overall QOL, adherence, and health status specifically for this patient population.

#### **Specific Aim 1**

The first aim of the proposed study is to investigate the relationship between adherence, quality of life, and glycemic control in youth and adolescents with T1D.

#### **Hypothesis 1**

Based on research indicating a positive relationship between quality of life and both adherence and glycemic control (Wagner et al., 2005; Laffel et al., 2003; Vanelli et al., 2003), it is expected that quality of life will mediate the relationship between adherence and glycemic control. For the current study, two regression models were conducted using the separate parent and child reports of adherence (DSMP) and quality of life (*PedsQL* Core) scores. This was done in order to accurately portray these domains as assessed by the patients and their caregivers.

#### **Hypothesis 1a**

Based on previous research suggesting that adherence and family factors have accounted for as much as 40% of the variance in glycemic control (Duke et al., 2008), it is expected that the addition of quality of life to this model will explain at least 45% of the variance in glycemic control.

## **Specific Aim 2**

The second aim of the proposed study is to investigate the relationship between quality of life and other behavioral factors in youth and adolescents with T1D.

## **Hypothesis 2**

Given the extant research in this area (Duke et al., 2008; Graue et al., 2005), it is expected that the associations between behavioral factors (adherence, diabetes-specific family factors) and quality of life outcome measures (*PedsQL* Core and Diabetes modules) will be statistically significant.

## **Specific Aim 3**

The third aim of this study is to investigate the relationship between quality of life and biological factors (i.e., age, sex, race, and diabetes-related complications) in pediatric T1D patients.

## **Hypothesis 3**

Given the research suggesting that QOL (as measured in the current sample by the separate child and parent-report *PedsQL* Core and Diabetes modules) in young patients with T1D is negatively impacted by both increasing adolescent age and being female (Naughton et al., 2008; Varni et al., 2007; Hoey et al., 2001), it is expected that there will be significant negative correlations between quality of life and both age and being female. Based on research examining QOL and diabetes-specific complications (Huang et al., 2007; Wexler et al., 2007) it is expected that there will be a negative relationship between QOL and number of diabetes-specific complications.

### **Hypothesis 3a**

Based on previous research indicating poorer glycemic control in ethnic minorities (Petitti et al., 2009; Chalew et al., 2000), it is expected that ethnic minority status will be negatively associated with glycemic control.

### **Specific Aim 4**

The fourth aim of the proposed study is to compare patient self-reports and parent-observed reports on the measures of QOL in pediatric T1D patients.

### **Hypothesis 4**

Given that parents of chronically ill children tend to rate their child's physical and psychosocial functioning as lower than the child's report (Guyatt et al., 1997), it is expected that parent-observed reports on the PedsQL Core and Diabetes modules will rate child's psychosocial functioning more poorly than the child's self-report in this domain.

## CHAPTER 2 METHOD

### **Participants**

Participants were 70 youth with T1D and their parent(s)/caregiver recruited from the outpatient Pediatric Endocrinology Clinic at the University of Florida in Gainesville, Florida. Our original goal was 100 youth/parent dyads. For reasons that are unknown, patient populations were sparser than had previously been seen at these clinics. Thus, recruitment was slow over the 12 months in which it occurred prior to the current analyses. Inclusion criteria for study participation were 1) patient age 8-18, 2) diagnosed with T1D for at least six months, 3) living with and accompanied by their primary caregiver, 4) no other chronic medical conditions, 5) no diagnosis of mental retardation or psychotic disorder (child or caregiver), and 6) ability to read, write, and understand English (child and caregiver). Regarding demographics, it was expected that our sample population would be similar to distributions noted in recent census results for Alachua County, Florida. These statistics suggested that our sample will likely be overwhelming Caucasian (~65–70%), with smaller populations of African Americans (~20–25%), Hispanic/Latino (~5–10%), and other ethnic minorities.

### **Procedure**

Participants and their primary caregivers were recruited during their regular visits to the Pediatric Endocrinology Clinic. Clinic nurses identified patients who met inclusion criteria. Upon receiving this information from clinic nurses, trained members of the research team approached patients and their primary caregivers to explain the study. Qualifying participants received a \$10 gift card at the completion of their involvement. The research staff obtained a signed informed consent from the legal guardian of all

participants in the study. Assent from participating children was obtained when possible. The pediatric patients and their primary caregivers were separately interviewed about T1D regimen adherence and independently completed subsequent questionnaires. It was expected that total completion time for participation in the study would be approximately 30–45 minutes. Research team members were available throughout the testing process in order to provide clarification when needed. In order to obtain measurement of glycemic control (A1c), pediatric endocrinology nurses obtained finger-stick blood samples as part of the patients' routine care at the clinic.

## **Measures**

### **Measures Completed by the Pediatric T1D Patient**

**Diabetes-specific family factors.** The *Diabetes Family Behavior Scale* (DFBS; Waller et al., 1986) was used to assess T1D-specific family functioning. This 60-item self-report measure contains three subscales (warmth/caring, guidance/control, and problem solving) that assess the child's perceptions of family support in the context of T1D self-management tasks. From a psychometric standpoint, the DFBS has shown good internal consistency ( $\alpha = 0.82$ ), as well as good test-retest reliability for the warmth/caring and guidance/control subscales ( $\alpha = 0.79$  and  $0.83$ , respectively) (Waller et al., 1986). Previous research has indicated that, while the warmth/caring and guidance/control subscales are associated with glycemic control ( $r = .36$  and  $.50$ , respectively), there exists only a weak correlation between glycemic control and the problem solving subscale. As such, this subscale was not used in the current study.

**Glycemic control.** Glycemic control is a biological marker of health status in patients with diabetes. Currently, the measure of choice for glycemic control is the glycosylated hemoglobin (A1c) test. The A1c provides an accurate estimate of the

patient's glycemic control over the past two to three months. Higher A1c values are indicative of poorer glycemic control. For patients with T1D, the ADA suggests that optimal figures representing good glycemic control are those values of A1c less than 6.5% (ADA, 2010). In the current study, pediatric T1D patients had an A1c test done during their visit to the Pediatric Endocrinology Clinic as part of routine care. Patients routinely have their blood drawn and A1c checked as part of their regularly scheduled appointments. Blood samples were analyzed by trained, qualified, and experienced technicians from the Pediatric Endocrinology Team using a Bayer DCA 2000+. For this study, blood samples were analyzed by trained members of the Pediatric Endocrinology Team.

#### **Measures Completed by the Parent/Primary Caregiver**

**Demographics.** The parent/primary caregiver was asked to complete a standard demographic information form that solicited information including age (of child and caregiver), sex (of child and caregiver), education, income, duration of T1D, and family structure (e.g., one-parent, two-parent, grandparent, etc.).

#### **Measures Completed by the Parent/Primary Caregiver and Pediatric T1D Patient**

**Diabetes-specific family factors.** The *Diabetes Family Behavior Checklist* (DFBC; Schafer et al., 1986) (parent and child versions) was used to assess family functioning with regard to pediatric T1D treatment regimen. It is a 16-item self-report measure containing both a positive/supportive and a negative/unsupportive scale. Higher scores indicate more negative diabetes-specific family factors. Research on this measure has indicated that the 7-item negative/unsupportive scale is most strongly associated with T1D adherence and glycemic control (Lewin et al., 2006; Shafer et al.,

1986). Therefore, the current study only utilized the 7 negative/unsupportive items for analyses.

The *Diabetes Family Conflict Survey* (DFCS; Hood et al., 2007) was used as an additional measure of family functioning in the context of the patient's T1D treatment regimen. It is a 19-item self-report measure (child and caregiver versions) that includes questions related to diet, insulin, blood glucose testing, and school. Rates of internal consistency for this measure were acceptable, ranging from  $\alpha = .81$  (caregiver report of diabetes-specific conflict) to  $\alpha = .85$  (youth patient report of diabetes-specific conflict) (Hood et al., 2007).

**Quality of life.** The *PedsQL™ Pediatric Quality of Life Inventory-Core* module (Child Self-Report and Parent Report Versions) (*PedsQL™*; Varni et al., 1999) were used to assess pediatric QOL. The *PedsQL* version used in this study includes the core module, measuring generic QOL in the last month with separate versions for children 8–12 years of age and teens 13–18 years of age. The parent version of the core module also measures generic QOL of the child, with separate versions for parents to answer for their 8–12 year old child or for their 13–18 year old teen. Both versions of this 23-item module assesses four scales (Physical-8 items, Emotional-5 items, Social-5 items, and School-5 items) which generate three summary scores: (1) Total Scale Score-23 items, (2) Physical Health Summary Score-8 items, and (3) Psychosocial Health Summary Score-15 items. On the Child Self-Report version, all items are statements to which the child is asked to rate their agreement on a 5-item Likert scale ranging from “Never” to “Almost Always,” and include statements such as “It is hard to pay attention in class,” and “I worry about what will happen to me.” The statements on the Parent

Report version are slightly modified from the Child Self-Report version and ask the parent/guardian to rate how much of a problem their child has had in each of the measured domains in the past month in their opinion. Cronbach's  $\alpha$  values for reliability on both versions for the Total Scale Score (Child Self-Report  $\alpha = 0.88$ ; Parent Report  $\alpha = 0.90$ ), Physical Health Summary Score (Child Self-Report  $\alpha = 0.80$ ; Parent Report  $\alpha = 0.88$ ), and Psychosocial Health Summary Scale (Child Self-Report  $\alpha = 0.83$ ; Parent Report  $\alpha = 0.88$ ) are all within acceptable limits for group comparisons. In terms of validity, the *PedsQL* differentiates not only between healthy children and acutely or chronically ill children but also between levels of disease severity within a given medical condition. Higher scores on the *PedsQL* indicate better quality of life.

The *PedsQL™ Pediatric Quality of Life Inventory-Diabetes* module (Varni et al., 2003) was given to both child and parent to assess diabetes-specific QOL. It is a 28-item, self-report measure that assesses functioning on five scales (Diabetes Symptoms, Treatment Barriers, Treatment Adherence, Worry, Communication). The Diabetes module was found to have satisfactory internal consistency reliability (Child Self-Report  $\alpha = .71$ ; Parent Report  $\alpha = .77$ ) and was able to distinguish healthy controls from patients with diabetes.

**Adherence.** The *Diabetes Self-Management Profile* (DSMP; Harris et al., 2000) was used to assess T1D regimen adherence. This structured interview consists of 23 questions in the domains of insulin administration/dose adjustment, blood glucose monitoring, exercise, diet, and management of hypoglycemia. This measure assesses adherence in each of these domains over the past three months. The DSMP interview was administered separately to pediatric patients with T1D and their respective

parent/caregiver by trained members of the research team. Completion of the interview is typically accomplished in approximately fifteen minutes. Responses are coded on scales ranging from either 0 to 1 or 0 to 4, with higher ratings indicating better regimen adherence. The combined ratings are summed to create a total adherence score, which can range from 0 – 79. Previous psychometric research on the DSMP has shown satisfactory to good internal consistency ( $\alpha = 0.76$ ) and inter-observer agreement (94%) (Harris et al., 2000). Higher scores on the DSMP indicate better adherence.

In order to be properly trained to administer the DSMP, research team members were required to complete a series of trainings. They were first given background materials on diabetes in order to educate them on the disease. The DSMP was reviewed with them and scoring was demonstrated. Team members were then required to observe and score mock interviews, and to practice until able to meet specific criteria. Once in the Pediatric Endocrinology Clinic, they were required to independently score observed clinic interviews until such time that there was a minimum of 90% inter-rater reliability. When this level of agreement was attained, the team member was allowed to conduct live interviews, with the first two being supervised to ensure continuity. Throughout the data collection phase, all team members were checked 3 times per year for reliability. For a subset of the current sample, inter-rater reliability was 93%.

### **Statistical Analyses**

All data processing and statistical analyses were conducted using the statistical software package, PASW Statistics 18.0.0 by SPSS.

Parallel analyses were conducted on the child-report measures and the parent-report measures. Analyses were conducted on both child and parent-report versions in order to accurately assess the domains measured. Although our desire was to trust in

the accuracy of child self-report on psychosocial measures, there is research to suggest that chronically ill children are more susceptible to social desirability response bias than their parents (Logan et al., 2008). Thus, parent-report versions were separately analyzed as an additional source of information. Previous research suggests that parent-reported psychosocial measures of chronically ill children are a reliable and accurate method of assessment (Le Coq et al., 2000). Preliminary analyses were conducted to test for relationships between independent and dependent variables for purposes of control in subsequent analyses. To identify significant relationships between respective continuous factors, a correlation matrix was computed. Dichotomous variables were compared using independent-samples *t*-tests. This also eliminated demographic items that were not significantly related to study measures in subsequent analyses. Descriptive statistics were obtained, including mean age, sex ratio, and mean duration of disease. In addition, these statistics identified variables that may have influenced results through skewness or kurtosis. As correlational analyses were conducted, the criterion value for significance was adjusted according to the number of comparisons in order to avoid any family-wise errors.

In order to examine the relationships between variables for purposes of control, regression analyses were used with glycemic control (A1c) as the dependent variable. Separate regressions were conducted using child and parent-report versions of study measures. Independent variables were comprised of demographic information, diabetes-specific family factors, adherence, and QOL. The possible presence of mediation effects was tested using hierarchical linear regression in accordance with Baron and Kenny's (1986) guidelines: 1) the predictor should be significantly associated

with the outcome variable, 2) the predictor should be significantly associated with the mediator, 3) the mediator should be associated with the outcome variable, and 4) the addition of the mediator to the full model should significantly reduce the relationship between the predictor variable and the outcome variable. Standardized coefficients were calculated to examine changes in path coefficients with the addition of the mediator to the model. Sobel's Z-Scores were calculated to assess significance of changes in path coefficients (Sobel, 1988). Additionally, Pearson's correlations were conducted on the proposed factors to examine any possible relationships between them. For the regressions, only those variables from each block that were shown to be statistically significantly related to the dependent variable (glycemic control) were included. There were not a sufficient amount of significant correlations between study variables when examining the child-report versions to justify a regression analysis. However, the parent-report versions of study variables were correlated to a necessary degree to conduct regression analyses. The parent-report hierarchical regression was conducted as follows: Block 1-Significant Demographics (Race); Block 2-Significant Family Factors (DFBC); Block 3-Adherence (DSMP); Block 4-Quality of Life (*PedsQL* Core module). It was expected that this full model would account for at least 45% of the variance in glycemic control (Hypothesis 1a)

To examine the relationship between patient self-report and their respective parent-observed reports, independent-samples *t*-tests were conducted comparing the *PedsQL* Child and Parent Proxy versions. Since multiple statistical analyses were conducted on the same data, a modified Bonferroni correction factor was implemented

to control for any family-wise error and the resulting criterion level of significance was reduced accordingly.

## CHAPTER 3 RESULTS

### **Demographics of Participants**

A total of 70 child/parent dyads were enrolled in this study. The participants in this study were predominantly Caucasian (75.0%), with 18.8% identifying themselves as African-American, 1.6% as Hispanic, and 4.7% as other ethnicities. This sample was similar in ethnic diversity to what was expected when compared to the demographic makeup of Alachua County, Florida. Children in the current study ranged in age from 9 to 18 ( $M = 13.72$ ,  $SD = 2.56$ ), with parents/caregivers ages 24 to 68 ( $M = 43.84$ ,  $SD = 9.46$ ). The pediatric patients in this study were 59.4% male and 40.6% female. Caregivers who participated in this study self-identified as 56.7% mothers, 25.4% fathers, 9% grandparents, 3% step-fathers, and 6% other. The sex distribution of the caregivers was 67.8% female and 32.2% male. Detailed descriptive statistics are shown in Table 3-1.

### **Relationships between Demographic Variables and Study Variables**

#### **Glycemic Control (A1c)**

Correlational analyses and independent-samples *t*-tests were conducted to identify significant relationships between demographic variables (e.g., age, race, sex, number of adults in the home) and the independent variable, glycemic control (A1c). A Pearson's *r* correlation matrix was conducted comparing all of the continuous demographic variables (i.e., number of children in the home, years since diagnosis, number of missed school days in the past year, and number of phone calls to the endocrinologist in the past month). A total of five demographic comparisons were run in this manner, necessitating a modified Bonferroni adjustment to avoid family-wise errors. Since five

comparisons were run, the criterion for statistical significance was reduced to  $p = .01$  (.05/5). None of the aforementioned continuous demographic variables were significantly associated with glycemic control.

The number of episodes of diabetic ketoacidosis was significantly associated with glycemic control ( $r(42) = .509, p = .001$ ). It is intuitive that fewer episodes of DKA, a potential consequence of poor glycemic control, would be associated with better glycemic control, with which the findings in the current sample were consistent. The medical nature of DKA as well as the high, yet intuitive, correlation with glycemic control precludes this variable from being included as a variable in regression analyses.

Independent-samples  $t$ -tests were conducted comparing the dichotomous demographic variables to glycemic control. Initially, sex was the only dichotomous demographic variable. However, several other demographic variables (i.e., marital status, race, relationship to child, with whom the child resides, level of parental education, household income, age of the child, and number of endocrinologist appointments in the past year) were collapsed into dichotomous variables due to the low frequency of some responses as well as for clarification. A total of nine  $t$ -tests were conducted, resulting in a criterion for significance reduced to  $p = .006$ . None of the demographic variables were significantly associated with glycemic control at this criterion. However, a  $t$ -test comparing Caucasians to all other races suggested a trend toward significant differences on A1c levels ( $t(62) = 2.56, p = .013$ ).

### **Diabetes-Specific Family Factors**

Multiple correlations were run to examine any significant relationships between the demographic variables and our measures of diabetes-specific family factors and adherence. Separate correlations were run using the child and parent-reported

versions of these measures when applicable. However, following necessary adjustments to the criterion level for significance, no significant relationships were identified between demographic variables and these study measures. A trend toward significance was seen in the *t*-test comparing child-reported adherence between households with or without both parents ( $t(66) = -2.39, p = .02$ ). A trend was also seen comparing parent-reported adherence to whether or not their child is a teenager ( $t(54) = 2.45, p = .018$ ).

### **Quality of Life**

Relationships between quality of life and demographic variables were assessed in the hypothesis testing section of this paper, as this is our third hypothesis. All demographic variables demonstrating significant relationships with the dependent variable were controlled for in subsequent analyses.

## **Intercorrelations among Study Variables**

### **Glycemic Control**

Correlational analyses were conducted to identify study variables that were significantly associated with the dependent variable (A1c) for subsequent analyses. Separate analyses were again conducted using the child and parent-reported versions of study variables.

Analyses of the child-reported versions of study variables involved six comparisons, therefore the criterion for significance was reduced to  $p = .008$ . Analyses demonstrated significant relationships between our dependent variable of glycemic control (A1c) and the child-reported *Diabetes Family Behavior Checklist* (DFBC;  $r(68) = .348, p = .004$ ), a measure of diabetes-specific family conflict (family factors). Glycemic control was significantly associated with our child-reported measure of adherence to the

medical regimen, the *Diabetes Self-Management Profile* (DSMP;  $r(68) = -.403, p = .001$ ). Neither child-reported version of the *PedsQL* (Core and Diabetes modules) was significantly associated with glycemic control.

Correlational analyses comparing the parent-reported versions of study measures to the dependent variable of glycemic control involved four comparisons. Thus, the criterion for significance was reduced to  $p = .013$ . Results showed a significant relationship between glycemic control and parent-reported diabetes-specific family conflict on the DFBC ( $r(68) = .297, p = .012$ ). A significant negative relationship was exhibited between glycemic control and parent-reported adherence on the DSMP ( $r(65) = -.386, p = .001$ ). An additional negative correlation was shown between glycemic control and parent-reported quality of life as measured on the *PedsQL* Core module ( $r(56) = -.457, p = .001$ ). The parent-reported version of the *PedsQL* Diabetes module score was not significantly associated with glycemic control in the current sample at our adjusted criteria ( $r(56) = -.270, p = .044$ ), although a trend towards significance was demonstrated.

### **Diabetes-Specific Family Factors**

In addition to the aforementioned correlations with the dependent variable of glycemic control, several significant associations were found between the parent-reported diabetes-specific family factor measure (DFBC) and other independent variables after adjusting for the number of comparisons on the same data. Scores from the parent-reported version of the DFBC were negatively associated with parent-reported adherence to medical regimen (DSMP;  $r(67) = -.354, p = .003$ ), overall quality of life (*PedsQL* Core;  $r(55) = -.401, p = .002$ ), and diabetes-specific quality of life (*PedsQL* Diabetes;  $r(55) = -.488, p < .001$ ). No significant relationships were shown

between child-reported measures of diabetes-specific family factors and other test variables.

### **Quality of Life**

Significant relationships between the various quality of life outcome measures and other independent variables are addressed below as this was our second hypothesis. A comprehensive description of all correlations between child-reported study variables is presented on Table 3-3. A correlation matrix of parent-reported study variables is shown on Table 3-4.

## **Hypothesis Testing**

### **Relationships between Quality of Life, Adherence, and Glycemic Control (Hypothesis 1)**

To examine the hypothesis that quality of life will mediate the relationship between adherence and glycemic control, Baron and Kenny's (1986) steps for mediation were conducted. Parallel regressions were conducted using the child-reported and parent-reported versions of the measures.

Examining the child-report versions of the measures, a regression was conducted using adherence (DSMP) as a predictor of glycemic control (A1c). This analysis showed that adherence was significantly correlated with glycemic control ( $r(67) = -.403, p = .001$ ), thus satisfying the first requirement of mediation. The path coefficient (c) was computed to be  $-.081, SE = .022$ . The second step of Baron and Kenny's test of mediation requires a significant relationship between the initial variable (adherence) and the mediator variable (quality of life). Separate regressions were subsequently conducted using the *PedsQL* Core module and the *PedsQL* Diabetes module as the dependent variable and adherence (DSMP) as the independent variable.

No significant correlation was demonstrated between child-reported adherence and the *PedsQL* Core module ( $r(55) = .214, p = .113$ ). Therefore, the second requirement of mediation was not met with the *PedsQL* Core module as the measure of quality of life. Utilizing the *PedsQL* Diabetes module as a measure of quality of life also produced a non-significant correlation with the DSMP ( $r(54) = .164, p = .231$ ). Since the second requirement for mediation was not met using the child-reported versions, no additional mediation analyses were run using these versions.

Mediation analyses were conducted on the parent-reported versions of the current measures. The first step of the mediation process, demonstrating a relationship between the initial variable (adherence) and the outcome variable (A1c), showed a significant relationship ( $r(67) = -.386, p = .001$ ). The path coefficient (c) was  $-.069, SE = .02$ . Since the parent-report *PedsQL* Core module was the only quality of life measure significantly associated with the dependent variable (A1c) at the adjusted level of significance, it was used in the second step of the mediation process. Results indicated that there was a significant relationship between the parent-reported versions of the *PedsQL* Core module and DSMP ( $r(56) = .389, p = .003$ ), satisfying the second step of mediation. The path coefficient (a) between adherence and quality of life was  $.534, SE = .177$ . The third step in this mediation process requires showing that the mediator (quality of life) has an effect on the outcome variable (A1c) while controlling for the initial variable (adherence). A regression was run using A1c as the dependent variable and both parent-reported adherence (DSMP) and quality of life (*PedsQL* Core total score) as predictors. Analyses showed that, after controlling for adherence, quality of life had a significant negative relationship with glycemic control ( $r(56) = -.457, p = .011$ ).

Additionally, the path coefficient (b) between quality of life and glycemic control was  $-.053$ ,  $SE = .016$ . These findings met the requirements of the third step. The final step of Baron and Kenny's mediation testing examines whether partial or complete mediation is occurring. The path coefficient (c') between adherence and glycemic control was  $-.041$ ,  $SE = .022$ . Since the subtraction of c' from c ( $-.069 - (-.041) = -.028$ ) does not equal zero, partial mediation was demonstrated. To test the significance of the indirect effect of adherence on glycemic control via quality of life, a Sobel's Z-statistic test was run. For this sample, Sobel's  $Z = -2.23$ ,  $SE = .013$ ,  $p = .026$ . Thus, in this sample, quality of life significantly mediated the effect of adherence on glycemic control, which supports our first hypothesis. The mediation model is shown in Table 3-5.

#### **Accounted Variance in Glycemic Control by the Model (Hypothesis 1a)**

To examine the hypothesis that the current model (demographic variables, family factors, adherence, and quality of life) would account for at least 45% of the variance in glycemic control, a hierarchical multiple linear regression analysis was conducted using parent-report versions of the study measures. Since race was the only demographic variable previously identified as trending toward a significant association with the dependent variable (A1c), it was the only variable entered into the first block of the equation. The DFBC score was entered in the second block to represent diabetes-specific family factors, as it was significantly correlated with glycemic control in the current sample. The parent-report DSMP score, our study measure of adherence to medical regimen, was entered into the third block. It was also significantly associated with glycemic control. The parent-report *PedsQL* Core module score, which was significantly correlated with glycemic control, was entered into the fourth block as our measure of quality of life. The overall model accounted for approximately 41.6% of the

variance in glycemic control in the current sample ( $r^2 = .416$ ;  $F(4,44) = 7.12$ ,  $p < .001$ ).

In order to account for any multicollinearity between study variable, the variance inflation factor (VIF) was calculated during the regression. VIF values in the current regression were much less than 10 (maximum VIF = 1.397), which signified no potential problems with multicollinearity in the current model. Although this model accounted for a significant portion of the variance, it did not meet our expectations and thus Hypothesis 1a was not supported. The regression model is shown in Table 3-6.

### **Relationship between Quality of Life and Behavioral Variables (Hypothesis 2)**

In order to test our second hypothesis that quality of life outcome measures would be significantly related to other behavioral factors relevant to diabetes (i.e., adherence to medical regimen and diabetes-specific family factors), Pearson's  $r$  correlations were conducted on these continuous variables. Separate comparisons were conducted using child and parent-report versions of measures when applicable.

#### **Quality of Life and Adherence**

The child-report *PedsQL* Core and Diabetes modules were not significantly associated with any of the other child-report study measures. However, the parent-report *PedsQL* Core was significantly associated with our parent-report measure of regimen adherence (DSMP;  $r(55) = .389$ ,  $p = .003$ ). The parent-report *PedsQL* Diabetes module was also significantly associated with parent-reported adherence in this sample ( $r(55) = .494$ ,  $p < .001$ ).

#### **Quality of Life and Diabetes-Specific Family Factors**

Correlational analyses identified multiple significant relationships between parent-reported quality of life measures and the parent-report measure of diabetes-specific family conflict in the current study. The parent-report *PedsQL* Core was significantly

negatively associated with our parent-report measure of diabetes-specific family conflict (DFBC;  $r(55) = -.401, p = .002$ ). The parent-report *PedsQL* Diabetes module was also significantly associated with the parent-reported DFBC ( $r(55) = -.488, p < .001$ ).

Overall, significant correlations were identified in the current sample between parent-observed quality of life and both adherence and diabetes-specific family factors, lending support to our second hypothesis.

### **Relationship between Quality of Life and Biological Factors (Hypothesis 3)**

Independent-samples *t*-tests were run to compare the dichotomous biological variables to the quality of life measures used in this study with a Bonferroni-corrected criterion for significance of  $p = .005$ . Once again, separate analyses were conducted using the child and parent-report versions of the quality of life measures. No significant relationships were demonstrated between either version of the *PedsQL* modules and whether or not the child was a teenager. The number of episodes of diabetic ketoacidosis (DKA) in the past year was negatively associated with the child-report *PedsQL* Core score ( $r(42) = -.436, p = .004$ ). There were no significant relationships demonstrated between the parent-report quality of life measures and number of DKA episodes. Analyses in the current study did not identify any differences between sexes on either child or parent-reported measures of quality of life.

Overall, significant negative correlations were identified between child-reported quality of life and the number of diabetes-specific complications in the current sample. No quality of life differences by sex or age were identified in the current study. Thus, our third hypothesis is only partially supported.

### **Association between Glycemic Control and Ethnic Minority Status (Hypothesis 3a)**

As previously mentioned, an independent-samples *t*-test comparing Caucasians to all other races suggested a trend toward significant differences on A1c levels after adjusting the criterion for significance ( $t(62) = 2.56, p = .013$ ). Post-hoc analyses in the current study showed that Caucasian children had significantly lower A1c levels ( $M = 8.90, SD = 2.05$ ) than African American children ( $M = 10.33, SD = 2.17; t(58) = -2.14, p = .036$ ). Together, these findings add support to our hypothesis that there is an association between being an ethnic minority and having poorer glycemic control.

### **Child Self-Report versus Parent-Observed Report of Psychosocial Functioning (Hypothesis 4)**

Independent-samples *t*-tests were conducted to examine the relationship between patient self-report and their respective parent-observed reports on the *PedsQL* Core and Diabetes modules. Multiple comparisons were conducted on the same data; necessitating a modified Bonferroni correction to avoid family-wise error. This was accomplished by dividing the standard level for significance, .05, by the number of comparisons, which was eight. Therefore, for these analyses values for significance were set at  $p = .006$ . Statistical analyses indicated that parents rated their child's functioning significantly lower than the patient self-report on the *PedsQL* Core total score ( $t(111) = 3.76, p < .001$ ) and the *PedsQL* Diabetes module score ( $t(110) = 4.07, p < .001$ ). Several subscales were also significantly different. These results support our fourth hypothesis. Means and standard deviations for *PedsQL* total scores and subscale scores by parents and patients are shown in Table 3-7.

Table 3-1. Patient Demographic Data

	<u>N</u>	<u>Valid%</u>	<u>M</u>	<u>SD</u>	<u>Range</u>
Child					
Age	57		13.72	2.56	9–18
12 or Younger	21	38.9			
13 or Older	33	61.1			
Sex ( <i>n</i> = 69)					
Male	41	59.4			
Female	28	40.6			
Race/Ethnicity ( <i>n</i> = 64)					
Caucasian	48	75.0			
African-American	12	18.8			
Hispanic	1	1.6			
Other	3	4.7			
Parent/Guardian					
Relationship to child ( <i>n</i> = 67)					
Mother	38	56.7			
Father	17	25.4			
Grandparent	6	9.0			
Step-Father	2	3.0			
Other	4	6.0			
Marital Status ( <i>n</i> = 55)					
Single/Never Married	13	23.6			
Married/Remarried	32	58.2			
Separated/Divorced	9	16.4			
Widowed	1	1.8			
Annual family income ( <i>n</i> = 54)					
Below \$9,999	11	20.4			
\$10,000–\$19,999	11	20.4			
\$20,000–\$39,999	13	24.1			
\$40,000–\$59,999	7	13.0			
\$60,000–\$79,999	7	13.0			
\$80,000 and above	5	9.3			
Number of Children in Home ( <i>n</i> = 54)					
One	18	33.3			
Two	17	31.5			
Three	16	29.6			
Four	1	1.9			
Five	1	1.9			
Eight	1	1.9			

Table 3-2. Child Sample Diabetes-Specific Characteristics

	<u>M</u>	<u>SD</u>	<u>Range</u>
Years Since Diagnosis ( <i>n</i> = 30)	5.44	4.31	.88–15.00
A1c Level Today ( <i>n</i> = 69)	9.27	2.15	5.40–14.00
Number of Hospitalizations ( <i>n</i> = 54)	0.87	0.99	0–6
Number of Episodes of Diabetic Ketoacidosis (DKA) ( <i>n</i> = 42)	0.86	1.37	0–5
Number of Endocrinologist Appointments in Past Year ( <i>n</i> = 50)	4.00	2.31	1–12
Number of Missed Endocrinologist Appointments in Past Year ( <i>n</i> = 51)	0.43	0.76	0–3
Average Number of Times Called Endocrinologist in One Month ( <i>n</i> = 50)	0.74	0.88	0–4
Number of Missed Days of School in Past Year ( <i>n</i> = 52)	7.83	10.08	0–55

Table 3-3. Child-Reported Study Variables Correlation Matrix

	A1c	DFBC	DFCS	DFBS	DSMP	<i>PedsQL</i> Core	<i>PedsQL</i> Diabetes
A1c							
DFBC	.348**						
DFCS	-.047	.004					
DFBS	-.116	-.101	.009				
DSMP	-.403**	-.189	.159	-.021			
<i>PedsQL</i> Core	-.224	-.154	.124	-.037	.214		
<i>PedsQL</i> Diabetes	-.196	-.057	.016	-.019	.164	.676**	

\*  $p < .05$

\*\*  $p < .01$

Table 3-4. Parent-Reported Study Variables Correlation Matrix

	A1c	DFBC	DSMP	<i>PedsQL</i> Core	<i>PedsQL</i> Diabetes
A1c					
DFBC	.297*				
DSMP	-.386**	-.354**			
<i>PedsQL</i> Core	-.457**	-.401**	.389**		
<i>PedsQL</i> Diabetes	-.270*	-.488**	.494**	.777**	

\*  $p < .05$

\*\*  $p < .01$

Table 3-5. Multiple Regression Analysis with Parent-Report Measures Predicting A1c<sup>a</sup>

Step	Variables(s)	$R^2$	$\Delta R^2$	$F$	$\beta$
1	Demographics Race	.117	.117	5.73*	.354**
2	Family Factors DFBC	.156	.038	3.87*	-.018
3	Adherence DSMP	.276	.120	5.20**	-.217
4	Quality of Life <i>PedsQL</i> Core Score	.416	.140	7.12***	-.425**

<sup>a</sup> All standardized regression coefficients ( $\beta$ ) are from the final block of the regression.

\*  $p < .05$

\*\*  $p < .01$

\*\*\*  $p < .001$

Table 3-6. Quality of Life Means and Standard Deviations by Child Report and Parent Report

PedsQL Scale	Child Report ( <i>n</i> = 57)		Parent Report ( <i>n</i> = 56)	
	<u>M</u>	<u>SD</u>	<u>M</u>	<u>SD</u>
Total Scale Score	82.61***	11.23	72.00***	18.05
Psychosocial Health Summary Score	79.74**	12.75	69.85**	18.77
Physical Health Summary Score	88.02**	11.20	77.26**	22.09
Diabetes Module Total Summary Score	75.52***	10.20	66.44***	13.24
Diabetes Symptoms Summary Score	65.40*	14.29	58.08*	16.43
Diabetes Treatment Summary Score	85.28***	10.45	74.10***	14.28
Diabetes Worry Summary Score	71.58	21.37	66.07	25.07
Diabetes Communication Summary Score	80.80*	20.84	70.98*	28.52

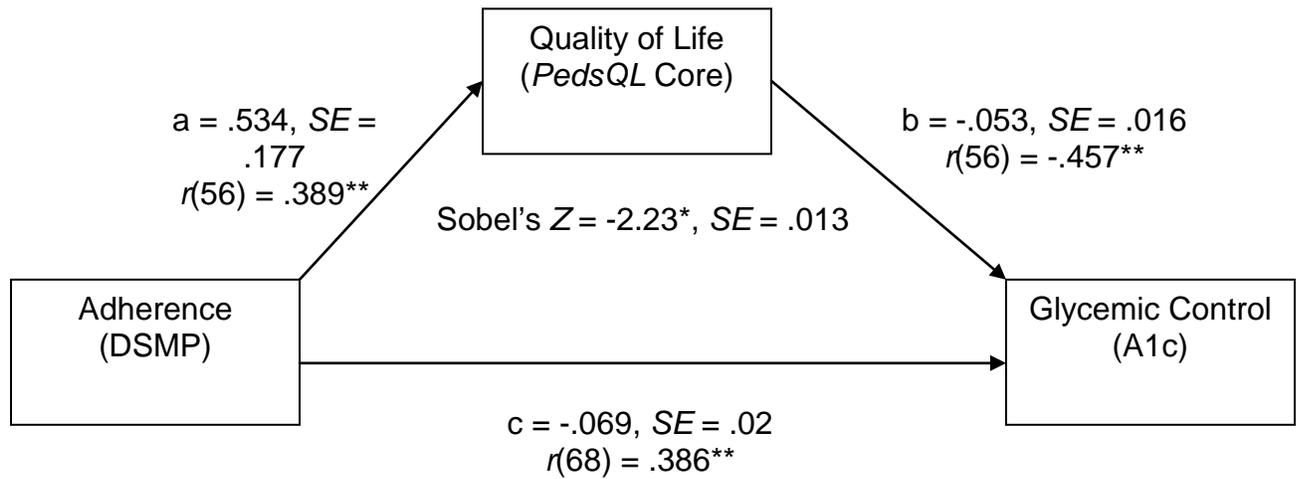
Values are significantly different at:

\*  $p < .05$

\*\*  $p < .01$

\*\*\*  $p < .001$

Figure 3-1. Mediation Model and Path Coefficients for Parent-Reported Quality of Life, Adherence, and A1c



\*  $p < .05$   
\*\*  $p < .01$

## CHAPTER 4 DISCUSSION

The goal of the current study was to examine the relationships between diabetes-specific family factors, adherence to medical regimen, quality of life, and glycemic control. This study is unique in that it is one of the first studies to incorporate all of these independent variables in an examination of the psychosocial factors that influence glycemic control in youth and adolescents with Type 1 diabetes. Given the complexity of a typical T1D medical regimen, combined with the serious potential complications associated with poor glycemic control, it is extremely important to examine factors that may predict better disease management in this population.

This study found that, in the current sample population, quality of life partially mediated the relationship between adherence to medical regimen and glycemic control. A portion of adherence accounted for a change in quality of life, which in turn accounted for a change in glycemic control above and beyond the change in glycemic control explained by adherence. This is an important finding because although intuitively we would expect there to be a perfect relationship between adherence and glycemic control, this is not the case in reality. Therefore, there must exist other elements beyond adherence that influence glycemic control. Previous research identified some diabetes-specific family factors as mediators of glycemic control (Duke et al., 2008; Lewin et al., 2006; Anderson et al., 2002). Quality of life has been shown to be significantly associated with glycemic control in multiple studies (Grau et al., 2005; Vanelli et al., 2005; Wagner et al., 2005; Hoey et al., 2001). Prior to the current study, there has been no published research attempting to show that quality of life mediates the relationship between adherence and glycemic control. By identifying quality of life

as a mediator of the relationship between adherence and glycemic control, we further clarified the need for quality of life to be taken into consideration with regard to interventions in this area.

However, despite the findings of our mediation model, the explanation of this relationship is not entirely clear. It appears from our model that quality of life mediates the relationship between adherence and glycemic control; however, this is not a certainty. What can be said with certainty is that the three constructs are heavily interrelated. When discussing the involvement of adherence and quality of life in this model, the inevitable “chicken or egg” quandary presents itself. Is it plausible that poor quality of life unrelated to diabetes results in youth with T1D being less motivated and concerned with their complex medical regimen, thereby resulting in poor adherence and poor glycemic control? Is it possible that poor adherence due to unexplained factors leads to poor glycemic control which then result in poor quality of life? Is it plausible that the possibility of poor glycemic control spurns poorer adherence and quality of life? At this point, a final understanding of these possibilities remains unknown.

The question could likely be asked—why is quality of life important in patients with Type 1 diabetes? Given the complexity, inconvenience, and discomfort of an intensive diabetes regimen, psychosocial variables such as quality of life are the factors that can likely influence motivation and adherence. As Richard Rubin (2000) stated in his editorial, poor quality of life may contribute to a “to hell with it!” attitude which could lead to poor self-care, poor adherence, and ultimately poor diabetes health status. Intangible factors such as quality of life appear to make a difference with regard to

adherence. This is particularly important during periods in which adherence could be more difficult such as when feeling ill, tired, or angry.

Similar to results from previous research, the current study showed that negative diabetes-specific parenting as reported by both the child and parent (e.g., nagging about diet, criticizing for poor exercise) had a significant negative association with glycemic control such that increased diabetes-specific family conflict was associated with increased A1c values or decreased/poorer glycemic control. Both child and parent-reported adherence also demonstrated a significant negative relationship with glycemic control (better adherence associated with lower A1c or better glycemic control). Parent-reported quality of life had a similar negative correlation with glycemic control, although child-report versions did not. This negative relationship suggested that increased (better) quality of life was associated with decreased (better) glycemic control. Child-reported quality of life was significantly negatively associated with the number of episodes of diabetic ketoacidosis. This relationship is rather intuitive, as it would be expected that children with a high number of DKA episodes would likely report lower quality of life.

The results in our sample with respect to quality of life, adherence, diabetes-specific family factors, and glycemic control essentially mirror the relationships between these variables as shown in previous research. In the current sample, the parent-reported versions of the study variables produced more meaningful relationships than the child-report versions. One possible explanation for this occurrence is that since the study measures were predominantly face-valid, it is possible that the children in our study were more susceptible to social desirability response bias than their parents,

subsequently portraying themselves in a more positive light. This possibility is supported by research showing that chronically ill youth are more vulnerable to this response bias than their parents, particularly when self-reporting psychosocial problems (Logan et al., 2008).

The fact that this study revealed a mediation effect of quality of life on glycemic control through adherence could be used to tailor future interventions. There has been some research (Hirsch, 2000; Rubin, et al., 1993) suggesting that brief interventions aimed at improving diabetes-specific coping skills and self-management have resulted in improved some aspects of quality of life (i.e., empowerment, emotional well-being, diabetes self-efficacy). Knowing that quality of life partially mediates the relationship between adherence and glycemic control further emphasizes the need for interventions that target quality of life in addition to other factors.

The findings of the current study were inconsistent with a majority of current research in two respects. There was not a difference by sex or age on child or parent-report measures of quality of life in the current sample. The interpretation of this finding that seemed most plausible to us was that this was likely to be a reflection of the relatively small sample size.

This study included measures assessing diabetes-specific family factors, as these have previously been shown to account for variance in glycemic control (Duke et al., 2008). In the current sample, the only family factors measure that was significantly predictive of glycemic control was both the child and parent-reported versions *Diabetes Family Behavior Checklist* (DFBC). The items on this measure assess negative and unsupportive diabetes-specific behaviors. The child version asks the child to rate how

often their primary caregiver engages in these behaviors, while the parent version asks the parent to self-rate their own behavior. The fact that both versions of this measure were so strongly predictive of glycemic control is very telling of the impact of negative diabetes-specific behavior. Given that this measure has consistently been shown to be predictive of glycemic control, it stresses the importance of interventions for the parents/guardians of children with diabetes to teach the importance of positive diabetes-specific behaviors as well as the health consequences of negative behaviors.

Findings from the current study with regard to the effect of race on glycemic control appear to suggest a possible racial disparity with regard to health status. Previous research (Petitti et al., 2009; Chalew et al., 2000) has shown that racial/ethnic minorities, particularly African-Americans, have poorer glycemic control than Caucasians even after controlling for other variables such as parent income, family structure, parent education, form of insurance, and duration of diabetes. However, recent research has suggested that there is a disparity in the accuracy of A1c test results in African-American children (Kamps et al., 2010). Specifically, this research suggested that African-American children with higher A1c levels than Caucasian children often have similar mean blood glucose levels. The authors opined that A1c levels alone are not an accurate reflection of health status in African-American patients with diabetes. Had this information been validated and replicated prior to this study, we might have included an additional measure of health status, such as mean blood glucose level, so that we could control for any inaccuracies on our assessment of health status. Although it is possible that the African-American children in our population may have had higher A1c levels due to psychosocial or socioeconomic reasons, the findings

of Kamps and colleagues suggest the possibility that the interpretation of a difference in health status is merely an inaccurate measuring mechanism. If this is true in the case of youth with Type 1 Diabetes, African American ethnic status may not be associated with poorer glycemic control. Kamps and colleagues commented on the misinterpretations of A1c levels in African-American patients with diabetes as potentially harmful consequences. However, findings from a single study would need significant replication prior to accepting them. In light of the Kamps study, further research on racial differences in diabetes is warranted.

Previous research in pediatric literature suggests that parent-reports of their chronically ill child's functioning are variable in their accuracy (Guyatt et al., 1997). Consistent with our hypothesis, parents in the current sample reported significantly lower general and diabetes-specific quality of life than their children self-reported. This reporting gap across the various quality of life domains is noteworthy for clinicians when inquiring about a patient's functioning. This difference in observed functioning of the pediatric Type 1 diabetes population extends knowledge of similar parent/patient gaps in other chronically ill child populations. Although this data does not imply that parent report or child report of the child's quality of life is more accurate per se, it once again highlights differences in perception of well-being, among other factors, between a child and their parent. Given other findings of different answers to the same questions from children and their parents (e.g., adherence, negative diabetes-specific behaviors) once they have been differentiated, it may have implications for possible changes in health care provider behavior. Although further research is needed to clarify this issue, it is possible that more accurate health care information with regard to day-to-day

responsibilities, such as adherence, might be obtained by discussing these topics separately with both parties. This may particularly relevant for questions to which socially desirable responses may be more likely.

Overall, the findings from this study supported the majority of our hypotheses. In conducting this study, we sought to better understand the relationships among some of the factors that have been useful in understanding differences in glycemic control. It is our hope that our study will contribute to improved psychosocial interventions for improving glycemic control in the pediatric T1D patient.

### **Limitations**

We need to highlight some of the limitations of the current study. While the use of self-report questionnaires is common in psychological research, the data they provide are subjective in nature. However, it is also important to state that many of the domains assessed in the current study would be impossible or impractical to objectively measure, making subjective self-report measures necessary. The impact of social desirability needs to be taken into consideration. By examining both the patient self-report and parent-observed versions of measures in the current study, some of these limitations have been addressed.

Over the twelve months of recruitment, enrollment in the current study was slower than previous studies of similar design conducted at the same pediatric endocrinology clinics. This contributed to the relatively small sample size in the current study. Regardless of the reason(s) for this slow rate of enrollment (e.g., fewer clinics due to economic constraints, reduced patient attendance at clinics due to financial problems), the small sample size places limitations on the scope of our investigation as well as any generalizability of conclusions. Participants in the current sample were recruited from

the catchment areas for our clinic. A larger and more diverse sample would provide for a larger variety of patient attributes that might further clarify predictors of glycemic control in pediatric T1D patients. Sample size limits the study's power, as do Bonferroni corrections to avoid family-wise errors on multiple correlations of the same data. It is possible that further group differences were not identified due to these limitations. Despite the sample size, quality of life was shown to partially mediate the relationship between adherence and glycemic control. Given the pattern of results seen in the current sample, it seems plausible that stronger conclusion could be drawn from a larger sample.

Missing data can be a particular problem confronting clinical research. This was true for demographic data in the current study. The study would have benefitted from improved procedures to ensure that all questions had been answered in the study packets prior to terminating the interview process. Such procedures could have increase the amount of useable data for the number of participants enrolled in the study. This would have further improved power in analyses already affected by sample size.

The cross-sectional design of the study in nature did not allow for more helpful information that could have been obtained through a longitudinal design. For example, many of the variables examined in this study likely fluctuate over time. A longitudinal study with repeated measure within participant could have demonstrated how quality of life, adherence, A1c, and other variables change over time. Additionally, findings of a mediation model that remain valid in a longitudinal study can allow causal relationships to be identified. A longitudinal study would enhance confidence in conclusions about

quality of life mediating the relationship between adherence and glycemic control, as well as numerous other significant correlations that were identified.

The current study may have been strengthened by utilizing other methods of assessing diabetes regimen adherence in addition to the DSMP. The interview format of the DSMP may contribute to socially desirable responses for participants. Separating parents and their children during their respective adherence interviews and emphasizing the importance of being honest in their answers rather than concerned with giving the “right” answer were procedures used in the current study to address some aspects of social desirability. Information about the complexity of diabetes treatment regimens did not allow the use of objective measures of adherence used in some other pediatric disease populations (e.g., pill counts, prescription records). The DSMP has been well-validated and used in numerous studies. The high degree of validation of the DSMP through repeated use in clinical research provides greater confidence in the measure despite concerns related to the self-report nature of this adherence measure.

The use of only the A1c for health status in Type 1 diabetes may be considered another limitation, although it is not a subjective, self-report measure. However, the A1c is considered the gold-standard in diabetes research and is universally used as it was in the current study.

### **Implications and Future Directions**

The current study identified an original finding in the partial mediation by quality of life in the relationship between adherence and glycemic control in youth and adolescents with Type 1 diabetes. Additionally, we replicated the findings of previous studies indicating that adolescent patients with T1D are at higher risk for lower quality of life than pre-adolescent patients with T1D. A larger, longitudinal study with multiple

assessment points would likely clarify the magnitude of quality of life's involvement in the relationship between adherence and glycemic control. As previously discussed, the "chicken or the egg" paradox remains with regard to the constructs of adherence, glycemic control, and quality of life. Further research on the findings of the current study with a larger and more diverse population is warranted. Extensions of this research as well as research on other psychosocial factors may contribute to the development of more effective and accurate interventions aimed at stabilizing glycemic control. Given the large overlap between some of these study variables, an intervention aimed at improving one domain would likely result in improvement in others.

The findings from the current study suggest the value in identifying factors that impact quality of life when developing interventions to improve adherence and, ultimately, glycemic control in youth and adolescents with T1D. The current study accounted for roughly 42% of the variance in glycemic control. Further exploratory studies should seek to detect additional factors, whether psychosocial, biological, or otherwise, that influence glycemic control in youth with T1D. Additionally, future research clarifying the relationships between any predictive variables would be vital with regard to the development of interventions. The better understanding of the factors impacting glycemic control, the more effective interventions that can be developed to improve the physical and emotional well-being of youth with T1D as they cope with this chronic condition over the course of their lives.

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