EXECUTIVE FUNCTIONING, PARENTING STRESS, AND FAMILY FACTORS AS PREDICTORS OF DIABETES MANAGEMENT IN PEDIATRIC PATIENTS WITH TYPE 1 DIABETES USING INTENSIVE INSULIN REGIMENS

By

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To the children with diabetes and their families who willingly gave their time to participate in this project. Their participation has provided invaluable information in the ongoing quest to improve pediatric diabetes management. However, my work in this field is always conducted with the hope that this research will one day become obsolete when diabetes becomes a *curable* rather than a *chronic* condition.

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LIST OF ABBREVIATIONS

A1c	Hemoglobin A1c (metabolic control)
ADA	American Diabetes Association
BRIEF	Behavior Rating Inventory of Executive Functioning
BRIEF-GEC	BRIEF Global Executive Index (composite BRIEF score)
CSII	Continuous subcutaneous insulin infusion (insulin pump)
DCCT	Diabetes Control and Complications Trial
DFBC	Diabetes Family Behavior Checklist
DFBS	Diabetes Family Behavior Scale
DFRQ	Diabetes Family Responsibility Questionnaire
DKA	Diabetes ketoacidosis
DSMP	Diabetes Self Management Profile (adherence interview)
DSMP-R	DSMP-Revised (intensive insulin questions added to adherence interview)
MDI	Multiple daily injections (intensive insulin regimen)
PIP	Pediatric Inventory for Parents (pediatric parenting stress measure)
PIP-D	PIP-Difficulty index score
PIP-F	PIP-Frequency index score
T1DM	Type 1 Diabetes Mellitus

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The care of youth with type 1 diabetes mellitus (T1DM) has become increasingly complex as a result of longitudinal studies suggesting the importance of good metabolic control in decreasing the rates of diabetes-related complications. Today, youth with TIDM are more frequently prescribed intensive insulin regimens (i.e., multiple daily injections or insulin pump therapy) which require a great deal of planning, organization, and problem-solving to execute correctly. There has been a paucity of research on factors that may impact pediatric patients' diabetes management when using intensive regimens. The purpose of the current study was to examine a variety of child, parent, and family factors hypothesized to impact diabetes adherence and metabolic control in pediatric patients with T1DM. Specifically, child executive functioning, pediatric parenting stress, and diabetes-specific family factors were evaluated as predictors of diabetes management in pediatric patients using intensive regimens.

Seventy-two youth with T1DM and their caregivers participated in the study, which entailed completing self-report questionnaires, an adherence interview, and measurement of metabolic control. Results suggested that diabetes adherence mediates the relation between both pediatric parenting stress and diabetes-specific family factors and metabolic control. Although

adherence mediates the relation between child executive functioning and metabolic control in youth reporting relatively better adherence, this finding was not supported in youth reporting relatively worse adherence. The role of executive functioning in metabolic control was found to be moderated by child-reported adherence. Regression models including all study variables predicted large proportions of the variance in metabolic control, although there were differences based on child-reported adherence. Findings from this study will provide preliminary information about characteristics that predict outcome for youth with T1DM using intensive regimens. Future directions include continued study of these variables as well as development of interventions to help promote adherence to intensive T1DM regimens.

CHAPTER 1
INTRODUCTION

Overview

Type 1 diabetes mellitus (T1DM) is a chronic condition typically diagnosed in childhood or adolescence. Pediatric patients diagnosed with this condition and their families face the lifelong challenge of managing the condition with a complex and time-consuming treatment regimen. Due to the chronic nature of T1DM, health professionals and researchers have a continuing interest in examining variables affecting the management of this condition. Past research has explored a variety of disease characteristics (e.g., severity, time since diagnosis), patient characteristics (e.g., self-efficacy, disease knowledge), and family characteristics (e.g., family conflict, parental support) hypothesized to influence the management of T1DM in pediatric patients. Despite the wealth of research in this area, health professionals and researchers alike continue to search for empirical answers to help patients with T1DM manage their condition more effectively. This paper will discuss the extant literature on T1DM in pediatric populations including the nature and treatment of T1DM and past research focusing on variables related to the management of this condition. Based upon a survey of previous research findings, the goal of this proposal is to integrate and extend the empirical knowledge base by investigating a model hypothesized to predict diabetes management in pediatric populations.

Background and Significance

Prevalence of Type 1 Diabetes Mellitus

In the United States, T1DM mellitus occurs in approximately 1 in 600 children, making it a common pediatric chronic condition (LaPorte, Matsushima, & Chang, 1995). In the past, T1DM was referred to as childhood diabetes, juvenile-onset diabetes, or insulin-dependent diabetes. Although T1DM is typically diagnosed in children and adolescents, with the peak age

of onset in middle childhood, diagnosis can be made as late as middle adulthood. T1DM results from the autoimmune destruction of the pancreatic islet cells that produce insulin (β-cells), which eventually leads to the inability to produce insulin. Insulin is a hormone, which regulates glucose metabolism and plays a vital role in growth, activity, wound healing, and brain function. Without insulin, energy from food cannot be converted into a usable form. Although the exact pathogenesis is unknown, T1DM is thought to result from a combination of genetic predisposition and environmental factors, which serve as catalysts (American Diabetes Association [ADA], 2005; Wysocki, Greco, & Buckloh, 2003b).

Treatment of T1DM

Currently, there is no cure for T1DM; however, patients can manage the condition with a complex treatment regimen involving several components. First and foremost, patients with T1DM are required to administer subcutaneous insulin in order to survive and maintain their blood glucose level. Insulin administration may occur via syringes or an external insulin pump. However, the administration of exogenous insulin is inexact and patients must also monitor their blood glucose levels. Patients typically monitor their blood glucose several times daily by pricking their finger with a lancet and using a blood glucose meter. Patients must also coordinate their food intake and physical activity, because these factors can significantly influence blood glucose levels.

The goal of T1DM treatment is maintaining blood glucose levels within the normal range (80-120 mg/dl). In patients with T1DM, health status is measured in terms of metabolic control, which is the degree to which a patient's blood glucose levels approximate the normal range. Metabolic control is typically quantified with a blood test known as the A1c test. This biological assay represents the average blood glucose level over the previous 6 to 8 weeks. For patients with T1DM, A1c values under 7.0% are considered good metabolic control (ADA, 2005). Given

that patients must carefully monitor and balance the four components of the diabetes treatment regimen (insulin administration, blood glucose testing, food intake, and exercise), the goal of good metabolic control is difficult to achieve and blood glucose levels often deviate from the target range. These deviations from normal blood glucose levels place patients with T1DM at-risk for short-term complications such as hypoglycemia, seizures, and diabetic ketoacidosis (DKA). Furthermore, long-term hyperglycemia can result in severe medical complications such as nephropathy, neuropathy, and retinopathy (ADA, 2005).

Despite the danger of complications, many pediatric patients with T1DM do not display adequate adherence to their physician-recommended treatment regimens. Past research has found that pediatric patients show differing rates of adherence to the various treatment components for T1DM. For example, although most patients report taking their insulin injections, 10% report administering the wrong dose, 20% report giving the injection at the incorrect time, and 19% report having difficulty adhering to their physician's recommendations about adjusting their insulin dose (Kovacs, Goldston, Obrosky, & Iyengar, 1992). For other diabetes treatment components, patients typically report higher rates of nonadherence. In terms of blood glucose testing, 31% of pediatric patients do not adhere to the recommended timing or frequency of this treatment regimen. According to parent report, 48% of adolescents with T1DM do not adhere to the recommended eating practices. Moreover, a 9-year follow-up study of newly diagnosed patients found that 45% of adolescents with T1DM patients were nonadherent with their treatment regimen (Kovacs, et al., 1992). Overall, adherence to the diabetes treatment regimen is a significantly problematic for many pediatric patients with T1DM.

The Diabetes Control and Complications Trial

In recent years, the relationship between treatment adherence, metabolic control, and long-term T1DM-related complications has been empirically supported through a landmark 10-year

study, the Diabetes Control and Complications Trial (DCCT Research Team, 1993). In this study, individuals with T1DM were randomized into two groups: the conventional therapy group and the intensive therapy group. Patients in the conventional therapy group were prescribed one to two daily injections and daily monitoring of blood glucose levels. Most notably, conventional therapy patients did not adjust their insulin doses based upon their food intake or blood glucose levels. Patients in the intensive therapy group administered three or more injections daily or used an insulin pump and performed at least four daily blood glucose tests. This more intensive regimen also required that patients make insulin dosage adjustments based upon their blood glucose levels, diet, and exercise. Results of this study demonstrated that individuals in the intensive therapy group were able to achieve better metabolic control, as measured by a lower A1c test result. These patients also experienced a delayed onset and slower progression of diabetes-related complications. For example, in the intensive therapy group, the risk of retinopathy was reduced by 76%, the risk of nephropathy was reduced by 50%, and the risk of neuropathy was reduced by 60%. These findings highlighted the importance of tight metabolic control. For example, of patients in "good" control (A1c values $\leq$ 6.87) 90% were free of retinopathy. However, among patients with "poor" metabolic control (HgbA1c $\geq$ 9.49) 57% developed retinopathy. The DCCT (1993) findings have resulted in widespread changes in the standards of medical care of patients with T1DM. In recent years, physicians typically recommend intensive therapy in order to help patients achieve better metabolic control and lessen the risk of diabetes-related complications.

Intensive diabetes treatment regimens

Multiple daily injections (MDI) and continuous subcutaneous insulin infusion (CSII) via an insulin pump are intensive methods of T1DM management that allow patients to achieve improved metabolic control compared to traditional methods of T1DM management (DCCT,

1993). Patients using MDI are typically prescribed 4-6 daily insulin injections, which include the use of long-acting and short-acting insulin. In order to calculate their dose of short-acting insulin, MDI patients typically determine the amount of carbohydrates consumed at each meal or snack. For these patients, frequent blood glucose monitoring ($\geq$ 4 times daily) is essential, particularly before and after meals. Furthermore, the adjustment of insulin dosages, diet, and exercise based upon blood glucose levels is also a core component of successful disease management (Geffken & Winter, 2001).

Similarly, in CSII blood glucose testing, carbohydrate counting, and insulin dosage adjustments are crucial treatment components. However, CSII patients receive insulin through an insulin pump instead of administering insulin injections. An insulin pump is an external device that administers insulin throughout the day via a catheter. Patients receive basal insulin (i.e., small amounts throughout the day) and bolus insulin for high blood glucose levels and food intake. Thus, CSII functions in much the same way as a pancreas does in an individual without T1DM, except CSII involves considerable conscious organization, planning, and flexibility by the individual with diabetes or their caretakers. Other important considerations for insulin pump patients include site changes, which typically occur every 2-3 days, and the mechanical functioning of the pump, which is monitored by patients through alarms and messages displayed on the insulin pump (Boland et al., 1999). The effectiveness of insulin pump therapy in the management of T1DM has been well documented. A recent meta-analysis conducted by Weissberg-Benchell and colleagues (2003) indicated that insulin pump patients demonstrate significantly improved metabolic control compared to patients using conventional therapy. Advantages of CSII include fewer severe hypoglycemic episodes at night, more predictable insulin absorption, greater meal flexibility, and the possibility of improved metabolic control.

Difficulties associated with CSII in the past, such as insulin pump malfunctions and site infections, have decreased with newer, more sophisticated technologies (Boland et al., 1999).

Following the landmark DCCT (1993) findings, intensive T1DM treatment regimens have become much more popular with patients and physicians alike. Although combined estimates of intensive therapy (MDI and CSII) are not available, in 1998 one physician noted, "DCCT-style intensive therapy is the standard of care" (Lorenz, 1998 p. 2021). Due to tracking methods (e.g., records of insulin pump manufacturers), CSII usage is more thoroughly documented than MDI usage. Estimates show that during the past 10 years the rate of CSII usage has increased dramatically, from an estimated 15,000 patients using CSII in the United States in 1993 to over 81,000 patients by the year 2000 (Bode et al., 2002). In 2002, data from insulin pump sales suggested that more than 200,000 patients worldwide were using CSII, with close to half of those patients in the United States (Pickup, Mattock, & Keen, 2002). Estimates of CSII usage in pediatric patients have found that 25% of young people with T1DM in the United States are currently using an insulin pump to manage their condition (White et al., 2001). Although the true level of CSII and MDI usage is unknown, both data based and anecdotal evidence suggests that the popularity of intensive forms of T1DM management is increasing exponentially (Boland et al., 1999).

Who benefits from intensive diabetes treatment?

To date, few empirical investigations have focused on predictors of success in patients with T1DM using intensive therapy. This is an important issue to consider given the significant financial costs and the close medical supervision required for patients using intensive regimens. In reference to this issue, the DCCT (1993) researchers noted that

> Intensive therapy was successfully carried out in the present trial by an expert team of diabetologists, nurses, dietitians, and behavioral specialists, and the time, effort, and cost required were considerable. Because the resources needed are not widely available, new

> strategies are needed to adapt methods of intensive treatment for use in the general community at less cost and effort. Meanwhile, the health care system should provide the support necessary to make intensive therapy available to those patients who will benefit (p. 981).

As implied by the DCCT research group, many clinicians, researchers, and health care administrators have advocated for the sparing use of intensive therapies due to the significant financial costs (Kanakis, Watts, & Leichter, 2002; Pickup, et al., 2002; Wredling, Adamson, & Lins, 1994). Given the rise of managed care and high costs of health care, issues such as "cost containment and the need for the most appropriate use of expensive technology" have been brought to the forefront of medical care (Pickup, et al., 2002, p. 593). In fact, CSII usage in countries other than the United States, such as the United Kingdom, has not increased as dramatically, largely due to the financial burden this type of treatment would place on government sponsored health care resources (Wredling, et al., 1994). The intensive treatment provided during the DCCT, which included more frequent clinic visits, increased blood glucose monitoring, and diabetes education, is estimated to have cost more than $4,000 per year, per patient (Lorenz, 1998). In particular, CSII can impose a serious financial burden on patients and the health care system. For example, one estimate suggests that while the supplies and insulin required for syringe-injected insulin treatment costs up to $1,496 per year, CSII costs up to $4,234 annually. This estimate does not include the initial costs of CSII, which typically range from $5,000-$5,500 (Kanakis, et al., 2002). It is also important to consider the extensive demands placed upon medical providers when patients use more intensive treatment regimens. There are significant deficiencies in the availability of specialized diabetes medical teams, which should include endocrinologists, diabetes trained nurses, diabetes educators, nutritionists, and psychologists. In order to be appropriately managed, patients with T1DM using intensive therapies should have access to these types of professionals (Lorenz, 1998). In sum, the financial

aspects of intensive treatment for T1DM dictates the need for research identifying which patients may benefit most from this type of costly treatment.

Currently, many medical professionals and researchers make judgments about which patients are best suited for intensive treatment regimens based solely on clinical experience. For example, in the DCCT (1993), patients were not included in the intensive treatment group if they were considered "too unstable or unmotivated to follow through on the rigorous demands" of intensive treatment (Anderson, 2003, p. 2204). From a clinical standpoint, some medical professionals have asserted that patients who frequently monitor their blood glucose levels or maintain records of their daily T1DM activities will be successful candidates for CSII therapy (Bode et al., 2002). Others have theorized that patient characteristics such as high family involvement and the absence of psychopathology such as eating disorders may also be related to treatment success with intensive regimens (Boland, Ahern, & Grey, 1998). Additional recommendations regarding patient characteristic important to assess when beginning CSII have ranged from high video game scores to high patient motivation to improve their metabolic control (Wredling, et al., 1994). Conversely, other health care providers recommend lenient requirements for patients initiating CSII therapy stating, "no adherence tests or qualifying tasks must be completed before CSII is begun, although older children and adolescents must express an interest in pump therapy" (Bode et al., 2002, p. 75). Hypotheses regarding factors predictive of successful outcome in intensive T1DM regimens need to be evaluated empirically.

Although research has demonstrated that positive medical outcomes are associated with intensive T1DM therapy, research related to psychosocial factors related to this type of treatment are relatively scarce. Weissberg-Benchell and colleagues (2003) found that only 16 out of 52 studies comparing patients using CSII to those using conventional insulin therapy reported data on psychosocial variables (e.g., depression, anxiety, responsibility taking, self-efficacy, quality

of life, locus of control, self-esteem). Due to inconsistencies in measurement, synthesizing the data in this area is difficult. In general, findings suggest that there are few, if any, negative psychosocial outcomes experienced by insulin pump patients compared to patients using more conventional treatment. (Weissberg-Benchell et al., 2003). In children and adolescents, there is some evidence to suggest that age mediates the relationship between intensive diabetes regimens and psychosocial outcomes. Madsen, Roisman, and Collins (2002) found that for young adolescents (aged 13 to 15) initiation of intensive insulin therapy was associated with increased school dissatisfaction but no increases in psychological distress. However, with older adolescents (aged 16 to 18) the initiation of intensive treatment was associated with small elevations in general psychological distress. These findings indicate that close attention should be paid to the psychological consequences of intensive diabetes treatment regimens, especially in older adolescents.

An interesting study conducted by Wysocki and colleagues (2003a) compared outcomes in youth with T1DM randomly assigned to either intensive insulin therapy or usual care, in order to identify patient characteristics predictive of success with intensive regimens. The authors examined the construct of self-management competence, which is a composite of the patients' diabetes knowledge, treatment adherence, and quality of interactions with health care providers. Surprisingly, results showed that patients randomized to the intensive care group obtained similar improvements in metabolic control, regardless of their level of self-management competence. The authors conclude that given their results, patients should not be denied access to intensive treatment regimens based upon variables such as diabetes knowledge, adherence, or their interactions with health care providers. However, they note that patients with low self-management competence may succeed with intensive treatment due to the increased support provided by medical professionals (e.g., monthly clinic visits, weekly telephone contact with a

diabetes nurse, access to psychological and nutritional services) (Wysocki, et al., 2003b). Despite these surprising results, it is important to consider how well these treatment effects can be maintained over time. Anderson (2003) points out those patients with low self-management competence may experience deterioration in metabolic control when the increased support (typically present only in funded research settings) is no longer available. A similar regression in metabolic control was seen in intensive therapy DCCT patients after the study concluded. Overall, findings in this area strongly suggest the need for continued research in this area.

While research has not yet elucidated psychological factors or disease-related factors that conclusively predict patients' response to intensive diabetes regimens such as MDI and CSII, many researchers and clinicians have emphasized caution when initiating these types of treatments. The cost of treatment, in the context of potential benefits, is an important consideration. In pediatric patients and young adults with T1DM, the use of CSII and MDI has shown improvements in metabolic control ranging from small to moderate (e.g., 0.5% difference in A1c values). Some argue that these differences are not large enough to "support the widespread use of intensified therapy" (Wysocki, et al., 2003b, p. 314). Furthermore, it is unlikely that funding sources such as private insurance and Medicaid will support the use of this type of treatment for all pediatric patients with T1DM. However, given the striking results of the DCCT (1993) which found that even decreases of 0.5% in A1c results may lead to a 25% reduction in the rates of diabetes-related complications, other medical professionals have posited that small improvements in metabolic control are clinically significant (Torrance, Franklin, & Greene, 2003).

Diabetes management: Adherence and metabolic control

In the past, adherence is a term that has been used interchangeably with compliance (Haynes, 1979; Meichenbaum & Turk, 1987). Compliance typically referred to the degree to

which patients follow their doctors' or health care providers' recommendations. Haynes has defined adherence as the "extent to which a patient's behavior coincides with medical or health advice" (Haynes, 1979). In recent literature, adherence is the more frequently used term, as there has been increasing recognition that for patients with chronic conditions there is a "voluntary collaborative involvement of the patient in a mutually acceptable course of behavior to produce a desired preventative or therapeutic result" (Meichenbaum & Turk, 1987, p.20).

At times there has been confusion between the terms adherence and measures of health status. This problem is especially salient in research focusing on T1DM. For pediatric patients with T1DM, some clinicians have used a biological index of health status (i.e., A1c test) as a measure of patients' adherence. However, Johnson (1994) suggests the relationship between adherence and health status is imperfect or unknown. In fact, Johnson and colleagues (1992) found in 377 children with T1DM, only 58% of the sample fell into the expected cells of (a) good adherence and good health status versus (b) poor adherence and poor health status. One hypothesis for the lack of a strong relationship between adherence and health status is that treatment effectiveness mediates this relationship. In other words, in patients with T1DM there is a strong relationship between treatment adherence and metabolic control only *if* the treatment regimen is effective. If a treatment regimen is weak or ineffective, then the relationship between adherence behaviors and health outcome will be weak or nonexistent. Other biological factors such as stress or pubertal status have also been postulated as potential mediators of the imperfect relationship between adherence and metabolic control (Johnson, 1994).

It has also been hypothesized that a 1:1 relationship between metabolic control and adherence has not been found because the measures used to assess adherence in pediatric patients with T1DM are inadequate. For example, it has been demonstrated that adherence to one aspect of the medical regimen does not predict adherence to other components of the regimen. Yet, in

the literature global measures of adherence are often used, which fail to take this finding into account (Johnson, 1992). In addition, reports of adherence are often obtained from different sources such as health care providers, parents, and patient self-reports. Various methodologies have been used to obtain adherence data such as behavioral observations, counting of permanent products, self-report interviews or questionnaires, and the 24-hour recall interview. However, each of these methods of measurement is fraught with inherent problems (e.g., bias, difficulty of measurement). Furthermore, T1DM treatment regimens have evolved quickly over the past decade and are much more complex than in the past. Consequently, new adherence measures have not been developed to address the rapid shifts in available and widely prescribed treatment regimens. For example, there have been few large-scale studies focusing on adherence in patients using an insulin pump. Current adherence measures cannot adequately measure this construct, given the fundamental differences between this form of treatment and more conventional insulin therapy.

Correlates of diabetes management

Demographic variables. Patient and family correlates of adherence can include child age, parent education level, work status, number of children in the home and socioeconomic status. Researchers have found younger children with T1DM are more likely to be adherent with the medication regimens than adolescents (Anderson, Auslander, Jung, Miller, & Santiago, 1990; LaGreca, Follansbee, & Skyler, 1990). Lower socioeconomic status (SES) and lower parental education levels have also been correlated with regimen nonadherence in children with T1DM (Auslander, et al., 1997; Overstreet, Goins, Chen, & Holmes, 1995). Correlations have also been found between adherence and family composition, with single parent households being related to poorer adherence (Auslander, et al., 1997).

Illness-specific variables. In addition to demographic variables, several illness and treatment related variables are also related to adherence in the pediatric T1DM population. Greater symptom severity and longer illness duration have been related to poorer adherence to regimens for pediatric patients with T1DM (Rapoff, 1999). In addition, pediatric patients with T1DM show an association between increased health problems and hospitalization for DKA, which results from poor adherence (Geffken et al., 1997). Previous research has also found that patients with more complex regimens tend to be less adherent to their prescribed regimen (McCaul, Glasgow, & Schafer, 1987). The higher financial burden of the more intensive diabetes treatments can also be particularly problematic for families with low economic status. Research findings such as these are important to consider when predicting adherence to treatment.

Psychosocial variables. A variety of psychosocial variables have been examined as correlates of adherence. In general, higher levels of stress and poorer psychological functioning have been consistently documented in children with T1DM and their parents, especially mothers (Hauenstein, Marvin, Snyder, & Clarke, 1989; Kovacs et al., 1985; Wysocki, Huxtable, Linscheid, & Wayne, 1989). For example, a recent study detailing a psychology consult service for children with T1DM in a tertiary care clinic documented a high incidence of distress and internalizing disorders in these patients (Gelfand et al., 2003). Moreover, prospective research has shown that in the 10 years following diagnosis with diabetes, 27% of youths with T1DM have an episode of major depression while 13% experience an anxiety disorder (Kovacs, Goldston, Obrosky, & Bonar, 1997). Furthermore, Brand, Johnson, and Johnson (1986) found that child stress, conceptualized as adverse life changes, was significantly related to the child's diabetes health status. In this study, higher levels of daily life stress was related to poorer health status. Although the extent to which these psychosocial variables impact diabetes self-

management has not been fully elucidated, it is likely that these issues lead to poorer adherence and metabolic control in pediatric patients (Wysocki, et al., 2003b).

Parental stress. Previous research has found that parents of children with chronic illnesses such as diabetes tend to report higher levels of general stress when compared to parents of healthy children (Hauenstein, et al., 1989). More specifically, parents of children with diabetes experience greater marital distress (Quittner, et al., 1998) and greater stress related to mealtime behaviors (Wysocki, et al., 1989). For parents of children with T1DM, stress also appears to be closely linked with child behavior problems. For example, parents of children with T1DM who also have externalizing behavior problems report higher levels of disease-related stress (Lewin et al., 2005). Although the presence of increased stress in parents of children with T1DM has been well documented, the implication of this finding in terms of adherence and metabolic control has not been adequately researched. Given the strong associations between family functioning, diabetes adherence, and health status measures, the effect of pediatric parenting stress on these constructs needs to be empirically evaluated (Lewin et al., 2005; Lewin et al., 2006).

Within pediatric populations, parenting stress has historically been measured using general measures of stress (e.g., Parenting Stress Index; PSI; Abidin, 1995). However, in more recent years researchers have begun to consider the importance of measuring disease-related stress experienced by parents of children with chronic diseases, termed "pediatric parenting stress" (Streisand, Braniecki, Tercyak, & Kazak, 2001). Thus, there has been a push to measure more specific disease-related parenting stress in pediatric chronic disease populations. The Pediatric Inventory for Parents (PIP; Streisand, et al., 2001) is one such measure designed to assess the stress of parents of children with chronic diseases. Within pediatric T1DM populations, pediatric parenting stress has been related to important issues such as parents' ability to learn

disease-management skills (Gillis, 1993) and the child's ability to engage in successful diabetes management (Auslander, Thompson, Dreitzer, & Santiago, 1997; Hanson et al., 1996). Although parenting stress was not significantly related to metabolic control in a recent study, the authors noted that there might be "aspects of the diabetes regimen itself that affect parenting stress" (Streisand, Swift, Wickmark, Chen, & Holmes, 2005, p. 518). Interestingly, Streisand and colleagues (2005) also found that parents of children using CSII experienced less frequent pediatric parenting stress. Future studies need to elucidate the relationships between pediatric parenting stress, metabolic control, and adherence behaviors in patients with T1DM, most notably those using more intensive treatment regimens.

Family variables. A body of research has investigated the relationship between family variables and outcomes in pediatric patients with T1DM. Studies have found that patients experiencing higher levels of family conflict also display poorer adherence or poorer metabolic control (Hauser et al., 1990; Miller-Johnson, et al., 1994). Anderson and colleagues (1990) also demonstrated that disagreements between parents and children regarding responsibility for T1DM related tasks predicted poorer metabolic control. Weaker relationships between family characteristics such as warmth, discipline, and cohesion and adherence or metabolic control have also been found (Hauser et al., 1990; Miller-Johnson, et al., 1994).

Parental monitoring of T1DM tasks is another family variable related to disease management, which has been found to be critically important in improving medication compliance for adolescents with chronic illness (Rapoff, 1999). In pediatric T1DM patients, Anderson and colleagues (1990) have found poorer adherence in families in which neither the parent nor child takes responsibility for monitoring diabetes-related tasks. Overall, these findings suggest that family factors play an important role in T1DM management. To date, no research has been conducted examining the role of family variables specifically in intensive

therapy. However, Boland and colleagues (1998) recognize the importance of family involvement in stating that "continued involvement of an older family member is a necessity" when initiating CSII (Boland, et al., 1998, p. 80). Given the strong relationship between family factors and diabetes adherence and metabolic control, these variables will be important to consider when investigating which pediatric patients may benefit most from intensive insulin therapy (Williams, Storch, Silverstein, Lewin, & Geffken, 2005).

Executive functioning. Executive functioning is a term that refers to a broad set of abilities controlled by the area within the frontal lobe region of the brain. Executive functioning dimensions include the ability to plan, self-monitor, and use working memory. Executive functioning can be measured by a variety of neuropsychological tasks (e.g., go-no-go paradigm, trails A and B, Wisconsin Card Sorting Task, Wechsler Intelligence Scale for Children – Third Edition Mazes subtest, and the Controlled Oral Word Association Test). However, these tasks are time-consuming and require neuropsychological training to administer. In recent years, parent report measures have been developed to measure the executive function abilities of children. The Behavior Rating Inventory of Executive Functioning (BRIEF, Gioia, Isquith, Guy, & Kenworthy, 2000) is a widely used and validated parent report measure, which is designed to examine "children's everyday executive skills in natural settings" (Donders, 2002).

Given that diabetes self-management requires significant planning, organization, and self-monitoring, executive functions are crucial abilities to possess in order to successfully perform diabetes self-care tasks. The role of executive functioning may prove especially noteworthy in patients using intensive T1DM treatment regimens, given that these treatments demand even greater problem solving abilities, planning, and organizational skill than traditional T1DM self-management routines (Anderson, 2003, Lorenz, et al., 1996; DCCT, 1993). In adolescents with T1DM, those randomly assigned to a 6-week problem solving intervention evidenced improved

problem solving scores and improved metabolic control at post-treatment assessment (Cook, Herold, Edidin, & Briars, 2002). Hill-Briggs (2003) conducted a review of the current literature pertaining to problem solving and T1DM which found that the majority of studies established a relationship between better problem solving skills and better self-management behaviors. However, in this review the relationship between problem solving and metabolic control was not as clear.

In recent pilot study, Alioto & Janusz (2004) found that for pediatric patients using intensive treatment regimens, executive functioning played a larger role in T1DM self-management than did other cognitive abilities, such as general intelligence and math achievement. These researchers also found that executive functioning was associated more strongly with adherence behaviors than with a proxy measure of metabolic control (% of in-range blood glucose values). Within a broader sample of T1DM patients using both conventional and intensive regimens, similar data has also been found. For example, parent-reported child executive functioning on the BRIEF was significantly related to diabetes management, with poorer executive functioning associated with poorer adherence (Bagner, Williams, Geffken, Storch, & Silverstein, 2007). However, results from this study did not find a relationship between executive functioning and A1c, a contradictory finding to that presented by Alioto and Janusz (2004). While these two preliminary investigations suggest mixed findings with regard to the relation between executive functioning and metabolic control, this may be due to the use of different measures of metabolic control (i.e., A1c versus % in-range blood glucose values). It may also suggest that the relation between these constructs is more complex. Given the preliminary nature of the research examining executive functioning and T1DM treatment outcomes, more studies are needed in this area. In particular, this relationship has not been adequately investigated specifically for patients using intensive insulin regimens, which

inherently require a great deal more planning, organization, and higher cognitive functioning subsumed under the construct of executive functioning.

Specific Aims and Hypotheses

The current study proposes to investigate the relationships of child, parent, and family level variables on adherence behaviors and metabolic control in pediatric T1DM patients using intensive regimens. The long-term objective of this line of research is to provide empirically supported criteria for evaluating child, parent, and family characteristics that predict diabetes management outcomes in pediatric patients using intensive regimens. This type of information may be used to guide clinical decision-making about which pediatric patients may be best suited for intensive diabetes treatment regimens. In the future, it may also help elucidate targets for intervention in pediatric patients with T1DM and their families who are struggling with poor diabetes management. Given these long-term objectives, the central goal of the current project is to evaluate a model predicting metabolic control within this patient population.

Specific Aim 1

The first aim of the proposed project is to investigate the association between child executive functioning and diabetes adherence behaviors in pediatric patients with T1DM using intensive insulin regimens.

Hypothesis 1a

Child executive functioning, as reported by their parent, will be significantly and positively related to adherence behaviors. Thus, we hypothesize that children with lower levels of executive functioning will display poorer adherence.

Hypothesis 1b

The relationship between child executive functioning and diabetes adherence will be moderated by child age. We hypothesize that executive functioning will be more strongly

associated with adherence in adolescents, given their increased responsibility for their diabetes care.

Specific Aim 2

The second aim of this project is to examine the relationship between disease-related parental stress and diabetes adherence behaviors in pediatric patients with T1DM.

Hypothesis 2a

Parenting stress will be significantly and inversely related to diabetes adherence. Thus, children with parents reporting higher parenting stress will display poorer adherence.

Hypothesis 2b

The relationship between parenting stress and diabetes adherence will be moderated by child age. We hypothesize that disease-related parenting stress will be more strongly associated with adherence in younger children, given that parents typically assume more responsibility for their child's diabetes care.

Specific Aim 3

The third aim of this study is to evaluate three mediation models in which adherence behaviors mediate the relationships between child (i.e., executive functioning), parent (i.e., parenting stress), and family variables (i.e., diabetes-specific family factors) and metabolic control.

Hypothesis 3a

Adherence will mediate the relation between child executive functioning and metabolic control.

Hypothesis 3b

Adherence will mediate the relation between parenting stress and metabolic control.

Hypothesis 3c

Adherence will mediate the association between diabetes-specific family factors (i.e., parental guidance and control, parental warmth and caring, parental criticism and negativity, no responsibility for diabetes care) and metabolic control. Lewin and colleagues (2006) demonstrated this mediation model in a population of children with T1DM using both conventional and intensive diabetes regimens (excluding CSII), thus this will be a replication of that prior finding in a sample of children using intensive regimens only.

Specific Aim 4

To examine a conceptual model including child, parent, and family variables to predict metabolic control in pediatric patients with T1DM using intensive treatment regimens. For hypothesis 4, in pediatric patients using intensive treatment regimens, metabolic control will be significantly predicted by diabetes-specific family factors, executive functioning, and pediatric parenting stress.

CHAPTER 2
METHODS

Participants

Participants were 72 youths with T1DM and their primary caregiver recruited from the tertiary Pediatric Endocrinology Clinic at the University of Florida in Gainesville, Florida. Inclusion criteria for study participation were (a) aged 8-18, (b) diagnosed with T1DM for at least six months, (c) living with and accompanied by their primary caregiver, (d) prescribed an intensive diabetes treatment regimen (i.e., either MDI or CSII) for at least 3 months, (e) no other chronic medical conditions (e.g., cystic fibrosis), and (f) both child and primary caregiver able to read and complete study measures (e.g., English-speaking, no mental retardation).

The current sample consisted of 43 girls and 29 boys ages 8.0 to 18.75 years (M =13.6 years, SD = 3.1). The ethnic distribution of participants was 75% Caucasian, 12.5% Hispanic, 9.7% African American, and 2.8% indicating membership in other ethnic groups. Participants were from predominantly two-parent families (72.2%) and the mothers were the primary caregiver respondents (80.6%), followed by fathers (15.3%) and other caregivers (4.2%). Participants in the study had been diagnosed with diabetes for an average of 4.8 years (SD = 3.2, range = 0.5-17 years). The average metabolic control of participants as measured by the A1c test was 8.3% (SD = 1.6; range = 5.8-12.5%), which is higher that the recommended target range (see Figure 2-1). Approximately 30.6% of children in the study experienced at least one episode of DKA post-diagnosis and 30% of children experienced 2 or more episodes of DKA (range 0-10 episodes). Sample characteristics are presented in Table 2-1 and Table 2-2.

Procedure

Participants were recruited during their regular visits to the Pediatric Endocrinology Clinic as part of a larger project entitled “Multivariate Assessment of Adherence and Metabolic Control

in Youths with Type 1 Diabetes." Clinic nurses identified patients meeting inclusion criteria and trained research staff approached patients and explained the study. Recruitment rate was approximately 92%, which is similar to past research recruitment within this clinic (Lewin et al., 2006). The most commonly cited reason for declining participation was time commitment required to complete study measures. The University of Florida Institutional Review Board approved this study and families received a $10 gift certificate for their participation. Signed informed consent was obtained from the legal guardian and caregiver of all participants and children provided assent when possible. Children and their caregivers were interviewed separately about T1DM treatment adherence and completed the remaining questionnaires independently. Most families required approximately 45 minutes to complete the study questionnaires. Finger-stick blood samples were obtained by nursing staff as part of the patients' regular clinic visit for the measurement of metabolic control (A1c test).

Measures

Demographic Information Form

The patient's primary caregiver completed a demographic information form including information such as age, sex, socioeconomic status (education and occupation), duration of T1DM, and family composition (one-parent family versus two-parent family).

Behavior Rating Inventory of Executive Functioning

Primary caregivers completed the Behavior Rating Inventory of Executive Functioning (BRIEF; Gioia, et al., 2000), an 86-item parent-report measure designed to assess 8 domains of executive functioning. Although the BRIEF includes 86 items, only 72 items are used in the calculation of scale and composite scores. The additional questions are considered to be items of clinical interest. The executive functioning domains measured by the BRIEF include the ability to solve problems flexibly (Shift scale), anticipate future events and set goals (Plan/Organize

scale), the ability to control impulses (Inhibit scale), the modulation of emotional responses (Emotional Control scale), the ability to start a task (Initiate scale), and the aptitude to retain information in one's mind for the completion of a task (Working Memory scale), the ability to keep materials orderly (Organization of Materials scale), and the ability to assess performance during or after a task (Monitor scale). The BRIEF also includes three indices: the Behavior Regulation Index (BRI; including the Inhibit, Shift, and Emotional Control scales), the Metacognition Index (MI; including the Initiate, Working Memory, Plan/Organize, Organization of Materials, and Monitor scales), and the Global Executive Composite (GEC; including all scales). Respondents used a three-point scale (Never, Sometimes, Often) to indicate how frequently each behavior occurred. BRIEF raw scores range from 0 to 238, with higher scores indicating poorer executive functioning. In addition, the BRIEF includes the Inconsistency and Negativity scales, which are used as measures of response validity. In the current study, all participants' Inconsistency and Negativity scales were within the acceptable ranges. Reliabilities for the BRIEF subscales and indices are satisfactory in both clinical and normative samples (α = .80-.98). In the current sample reliabilities ranged were in the satisfactory range as well (α = .81-.98) (See Table 2-3). Test-retest reliability across clinical scales was r = .81. Previous research suggests the use of the MI, BRI, and GEC indices, as these were most strongly related to adherence in a pediatric TIDM sample (Bagner, et al., 2007).

Pediatric Inventory for Parents

The Pediatric Inventory for Parents (PIP; Streisand, et al., 2001) is a questionnaire designed to measure parenting stress related to caring for a child with a chronic illness. The PIP consists of 42 items that assess the frequency and intensity of parenting stress. Four domains that may be affected by parenting stress due to chronic illness are included: 1) communication (e.g., with their child, partner, or medical team), 2) parent's emotional functioning (e.g., impact

of the child's illness on their sleep and mood), 3) child's medical care (e.g., adhering to the medical regimen), and 4) parent's role functioning (e.g., ability to work or care for other children). Parents responded to items using a 5-point Likert scale ranging from "never" (1) to "very often" (5) and also reported how often the event occurred during the past week. The PIP yields two subscales assessing the frequency of stress (PIP-F) and the level of difficulty the parent experiences managing stress (PIP-D) with higher scores indicating greater pediatric parenting stress. Past empirical investigations have found that PIP total scores are highly correlated with the Parenting Stress Index-Short Form, a general, non-illness specific measure of parenting stress (Streisand, et al., 2001). High internal consistencies for the PIP subscales have been demonstrated in parents of children with T1DM (PIP-F α = .94; PIP-D α = .94-.95) (Lewin, et al., 2005; Streisand, et al., 2005) and Cronbach's alpha were excellent for the current sample as well (PIP-F α = .95; PIP-D α = .96).

Diabetes Family Behavior Scale

The Diabetes Family Behavior Scale (DFBS; Waller et al., 1986) is a measure of T1DM-specific family functioning. This 60-item questionnaire is completed by youths with T1DM and has three subscales (warmth/caring, guidance/control, and problem solving) designed to assess child perceptions of family support related to T1DM self-management tasks. In previous research, the guidance/control and warmth/caring subscales have been correlated with metabolic control (r = .50 and .36, respectively). Past research has shown weak relations between the problem solving subscale, adherence behaviors, and metabolic control (Lewin, et al., 2006). Thus, this subscale was not used in the current study. Overall, the DFBS has good internal consistency (α = 0.82). Additionally, test-retest reliability coefficients for the warmth/caring and guidance/control subscales are good (α = .79 and .83, respectively) (Waller, et al., 1986). For the

current sample, internal consistency for the guidance/control subscale (α = .70) and the warmth/caring subscale (α = .81) were acceptable.

Diabetes Family Behavior Checklist

The Diabetes Family Behavior Checklist (DFBC; Schafer et al., 1986) is a 16-item instrument that measures supportive and non-supportive parental behaviors related to the pediatric T1DM self-management regimen. Children and their caregiver each completed this questionnaire independently. Although the DFBC contains both a Positive/Supportive Parening scale and a Nagging/Critical Parenting scale, previous research has found that the 7-item Nagging/Critical Parenting scale was most associated with T1DM adherence and metabolic control (Shafer, et al., 1986, Lewin, et al., 2006). Thus in the current study, only the Nagging/Critical Parenting scale items were used. Internal consistencies for both the parent and child Nagging/Critical Parenting scales were acceptable (α = .76 and .72, respectively) in the current sample.

Diabetes Family Responsibility Questionnaire

The Diabetes Family Responsibility Questionnaire (DFRQ, Anderson et al., 1990) is a questionnaire designed to assess family sharing of responsibilities for T1DM treatment. Parents and children completed this measure separately by indicating which family member assumes responsibility for 17 diabetes-specific tasks (e.g., "remembering medical appointments"). A parent-child dyad score was calculated to determine patterns of agreement and disagreement between the parent and child. Prior factor analyses of this measure indicate three domains of general health management tasks, regimen tasks, and social presentation of T1DM. Internal consistencies for the three subscales were acceptable, ranging from .69 to .85. In the current sample, internal consistencies were good for the child DFRQ (α = .81) and excellent for the parent DFRQ (α = .91). Previous research indicated that a lack of parent or child responsibility

taking, referred to as the "No Responsibility" index is related to poorer metabolic control (Lewin, et al., 2006). For the current study, a "Child Responsibility" score was also calculated by summing the number of tasks for which the child is primarily responsible (based on both the child and parent report on the DFRQ).

Diabetes Self-Management Profile

The Diabetes Self-Management Profile (DSMP; Harris et al., 2000) is a structured interview that assesses T1DM-specific adherence behaviors over the past three months. The DSMP consists of 23 questions in the areas of insulin administration/dose adjustment, blood-glucose monitoring, exercise, diet, and management of hypoglycemia. The DSMP interview was administered separately to parents and children with T1DM by trained research assistants and required approximately 15 minutes to complete. Participants' responses to each item were coded on scales ranging from 0 to 1, to 0 to 4, with higher numbers indicating better adherence. A total adherence score, ranging from 0 to 79, was then calculated from the sum of each item score. In past studies, investigators found good internal consistency (Cronbach's $\alpha = 0.76$) and inter-observer agreement (94%) for the DSMP. The predictive validity ($r = -0.28$, $p = 0.01$) indicates that the measure only accounts for 7.8% of the variance in metabolic control (i.e., A1c) (Harris et al., 2000). For the current study, an additional 3 questions specific to all intensive regimens (i.e., MDI and CSII) and 3 questions specific only to CSII were added to assess adherence behaviors related to intensive diabetes treatment regimens (e.g., "In the past 3 months, how often have you eaten something without taking short-acting insulin/a bolus?") (See Figure 2-2). Given the significant differences between conventional and intensive diabetes regimens, these questions were added to more accurately capture patients' adherence behaviors.

Metabolic Control

Metabolic control is a biological assessment of health status. The gold standard for metabolic is the A1c blood test. The A1c test provides an estimate of metabolic control over the previous 2-3 months with higher A1c values indicating poorer metabolic control. For youths with T1DM, findings from the DCCT suggest that the target range for good metabolic control is an A1c of less than 7.0% (DCCT, 2005, See Figure 2-1). In the current study, blood samples were analyzed using a Bayer DCA 2000+. All patients in the Pediatric Endocrinology Clinic with T1DM have an A1c test conducted during each clinic visit as part of standard medical care.

Metabolic control A1c value (%)	Mean blood glucose concentration (mg/dl)	Interpretation
4 5	65 100	Non-diabetic range
6 7	135 170	Target for individuals with diabetes
8 9	205 240	Action suggested
10 11 12 13	275 310 345 370	Severely poor metabolic control

Figure 2-1. Targets for metabolic control and relationship to blood glucose levels. Based on data from Rohlfing, et al., 2002, p. 275.

Additional intensive regimen questions (for MDI and CSII)

1. Some kids who use an insulin pump or Lantus find it hard to remember to take insulin every time they eat. In the past 3 months, how often have you eaten something without taking short-acting insulin/a bolus? This may be because you forgot, were too busy, or didn't have any insulin handy.
2. Sometimes it may be difficult to test your blood sugar every time before you eat. How often in the past 3 months have you eaten something (a meal or snack) without testing your blood sugar first? This may be because you forgot to test, didn't feel like testing, or didn't have your test kit with you.
3. Kids who use Lantus or an insulin pump usually count the carbohydrates in the food they eat so they know how much insulin to take. Sometimes kids and their parents find that it's hard to count the carbohydrates in everything they eat. In the past 3 months, how often have you not used carbohydrate counting to figure out how much insulin to take? This may be because you forgot how much you ate, you didn't know the carbohydrates in the food, or you just didn't feel like counting the carbohydrates.

Additional CSII questions

1. Some kids with diabetes find it hard to remember when to change their pump site. In the past 3 months, how often and when have you changed your insulin pump site? Is there any other time you change your pump site?
2. When changing your insulin pump site, it can be hard for some kids and parents to remember how to do it. In the past 3 months, when you changed your insulin pump site, how often did you have trouble remembering exactly how to do it? For example, you might have forgotten to prime the pump or maybe you put the site in the same place it was last time.
3. Insulin pumps are complicated and it can be hard to learn how to use them. Sometimes kids or parents can be unsure about how to use an insulin pump or what information, like beeps or messages, from your pump means. In the past 3 months, how often were you confused about how to use your pump or about what the information from your pump means?

Figure 2-2. DSMP-Revised questions.

Table 2-1. Child sample characteristics (n = 72)

Variable		Range
Child age in years (mean + SD, range)	13.6 ± 3.1	8.0 - 18.75
Child gender (n, %)		
Female	43 (59.7%)	
Male	29 (40.3%)	
Child ethnicity (n, %)		
Caucasian	54 (75.0%)	
Hispanic	9 (12.5%)	
African American	7 (9.7%)	
Other	2 (2.8%)	
Years since diagnosis (mean + SD, range)	4.8 ± 3.2	0.5 - 17
Child A1c (mean + SD, range)	8.3 ± 1.6	5.8 - 12.5
Treatment regimen (n, %)		
MDI	51 (70.8%)	
CSII	21 (29.2%)	
DKA after diagnosis (n, %)[a]		
No	47 (65.3%)	
Yes	22 (30.6%)	
More than 1 episode of DKA (n, %)[b]		
No	50 (70.0%)	
Yes	22 (30.0%)	

[a] Three participants (4.2%) did not respond to this question. [b] One participant (1.4%) did not respond to this question.

Table 2-2. Family sample characteristics (n = 72)

Variable	*n* (%)
Participating caregiver (*n*, %)	
Mother	58 (80.6%)
Father	11 (15.3%)
Other	3 (4.2%)
Family composition (*n*, %)	
Two-parent household	52 (72.2%)
Single-parent household	20 (27.8%)
Estimate of annual household Income (*n*, %)[a]	
Less than $25,000	18 (28.6%)
$26,000 - $50,000	17 (27.0%)
$51,000 - $75,000	20 (31.7%)
$76,000 - $100,000	5 (8.0%)
Over $100,000	3 (4.8%)
Mother education (*n*, %)	
Some high school or less	3 (4.2%)
Completed high school	22 (30.6%)
Some college/trade school	24 (33.3%)
College degree or beyond	23 (31.9%)
Father education (*n*, %)[b]	
Some high school or less	7 (9.8%)
Completed high school	23 (31.9%)
Some college/trade school	27 (37.5%)
College degree or beyond	10 (13.9%)

[a] 12.5% of participants did not report annual household income. [b] 6.9% of participants did not report father education.

Table 2-3. BRIEF scale and composite index reliabilities

BRIEF scale/composite index	Cronbach's alpha (α)
Inhibit	.93
Shift	.90
Emotional Control	.92
Initiate	.81
Working Memory	.93
Plan/Organize	.94
Organization of Materials	.89
Monitor	.89
Behavior Regulation Index	.96
Metacognition Index	.97
Global Executive Composite	.98

CHAPTER 3
RESULTS

All statistical analyses were conducted using Statistical Product and Service Solutions (SPSS) Version 14.0 (SPSS, 2006). Graphs displaying interaction analyses were created using Interaction! Version 1.0.1280 (Sopher, 2006).

Descriptive Analyses

Measures

BRIEF score distributions

Given that the BRIEF has not, to our knowledge, been administered to a large sample of pediatric patients with TIDM using intensive regimens, score distributions were analyzed for the current sample. Participants raw scores on the BRIEF-MI, BRI, and GEC composites were converted T-scores based upon age and gender norms. BRIEF T-scores of 65 or higher are considered clinically significant (Gioia, et al., 2000). In the current sample, 14 participants (19.4%) were in the clinically significant range on the BRIEF MI composite, suggesting clinically significant difficulties with planning, organizing, and future-oriented problem solving. On the BRIEF-BRI composite, 13 participants (18.1%) fell in the clinically significant range suggesting difficulties the ability to shift cognitive set and modulate emotions and behaviors appropriately. Thirteen participants (18.1%) met criteria for clinically significant difficulties with overall executive functioning, as suggested by the BRIEF-GEC.

Correlation analyses between the BRIEF-BRI, MI, and GEC evidenced strong correlations between these three indices. Relations with dependent variables (e.g., A1c and parent- and child-reported adherence) were also similar in magnitude. Given these findings, and the fact that the BRIEF-GEC represents a composite of the BRI and MI, the GEC was used in all subsequent analyses.

DSMP-Revised

For the purposes of this study, three "Intensive Regimen" questions were added to the DSMP. With these added questions the overall internal consistency for the Parent DSMP-Revised (α = .78) and the Child DSMP-R (α = .77) was good and similar to that of the original DSMP. Additionally, item-to-total correlations were calculated for the DSMP-Revised (See Tables 3-1 and 3-2) and the additional Intensive Regimen scale evidenced acceptable correlations. The 3 questions specific to CSII were also analyzed and evidenced good internal consistency and item-to-total correlations as well. However, given that only a small proportion of participants (n = 21) in the current study managed their diabetes with CSII, these questions were not included in further analyses.

The predictive validity of the DSMP-R was also examined. The original DSMP accounted for 7.8% of the variance in A1c (Harris, et al., 2000). Multiple regression analyses were conducted with separately for the Parent and Child versions of the DSMP-R. The Parent DSMP-R predicted an additional 18% of the variance in A1c over and above demographic variables (F (2, 69) = 12.1, p = .000). The Child DSMP-R predicted an additional 5% of the variance in A1c after the contribution of demographic variables was controlled (F (2, 69) = 5.28, p = .007). However, it is important to note that in the current sample, the original version of the Child DSMP predicted only 5% of the variance in A1c (F (2, 69) = 5.09, p = .009). Interestingly, the DSMP-R Intensive Regimen scale was more strongly correlated with the BRIEF-GEC (r = -.301, p = .01) than any of the original DSMP scales after demographic variables were controlled. Given the promising psychometric analyses of the Intensive Regimen scale, the DSMP-R was used in all subsequent adherence analyses for child and parent report of adherence.

Study Variables

Relations between demographic characteristics and study variables

Adherence and metabolic control. Independent sample t-tests, ANOVAs, and correlational analyses were conducted to elucidate relationships between dependent variables (i.e., child and parent-reported adherence, A1c) and demographic and disease characteristics. For child-report of adherence on the DSMP-R, family composition was the only demographic variable with significant group differences. An independent samples t-test indicated that children from single parent households reported significantly poorer adherence (M = 63.8, SD = 9.8) than those from two-parent households (M = 69.8, SD = 10.5; t (70) = -2.38, p = .03). Correlational analyses indicated that duration of time with diabetes was significantly related to parent-reported adherence on the DSMP-R (r (72) = -.42, p = .000), with parent's reporting poorer adherence related to longer duration of diabetes. In terms of metabolic control, correlational analyses indicated that duration of time with diabetes (r (72) = .28, p = .02) and family income (r (72) = -.251, p = .05) were significantly related to child A1c. These analyses suggested that children with longer disease duration and lower family income have worse metabolic control. Although other demographic (e.g., child age, gender, ethnicity) and disease-related variables (e.g., diabetes-related hospitalizations) were investigated no further relationships with dependent variables were found. All demographic variables evidencing relationships with study variables were controlled for in subsequent analyses.

Intensive regimen characteristics. Given the inclusion of patients using both MDI and CSII, analyses were conducted to determine whether there were significant differences between demographic and study variables based on the prescribed regimen. Patients utilizing CSII were significantly younger (M = 12.1 years, SD = 2.7) than those using MDI (M = 14.2 years, SD = 3.0); t (70) = 2.9, p = .01). Furthermore, significantly more girls were using CSII than boys

(t (70) = -2.4, p = .02) in the current sample. Finally, patients using CSII had better metabolic control (M = 7.8%, SD =1.3) than patients using MDI (M = 8.6%, SD = 1.7); t (70) = 2.3, p = .03). There were no differences in prescribed treatment regimen based up on ethnicity, family composition, or duration with diabetes.

Executive functioning. Parent-report of child executive functioning on the BRIEF-GEC was not associated with any child demographic variables, family variable, or regimen type.

Pediatric parenting stress. Correlational analyses indicated a significant relation between child age and frequency of pediatric parenting stress (PIP-F, r = -.343, p = .003) as well as difficulty of parenting stress (PIP-D, r = -.247, p = .04). Participants were split into two age groups a) 8-12 years and b) 13-18 years and a t-test indicated that parents of younger children (PIP-F M = 106.8, SD = 26.1) reported significantly more frequent stress than those of older children (PIP-F M = 84.7, SD = 19.7); t (70) = 2.3, p = .03). Similarly, parents of younger children reported significantly more difficulty with parenting stress (PIP-D M = 94.6, SD = 28.7) than parents of older children (PIP-D M = 78.4, SD = 28.3; t (70) = 2.4, p = .02). Pediatric parenting stress was not related to any other demographic variables.

Diabetes-specific family factors. An ANOVA analyses of child ethnicity elucidated significant between group differences on the DFRQ no responsibility index and race (F (3, 68) = 14.4, p = .007). Tukey post-hoc tests indicated that Caucasian patients had significantly lower scores on the DFRQ-no responsibility scale (M = 1.9, SD = 1.7) than did African American patients (M = 4.1, SD = 2.2). Child report of nagging/critical parenting on the DFBC was significantly associated with duration of diabetes (r = .276, p = .02) and family income (r = -.243, p = .05). Child age was negatively associated with child report of guidance/control on the DFBS (r = -.263, p = .03). Additionally, t-tests revealed significant differences in diabetes family factors based on family composition. Children from two parent families reported more

guidance/control on the DFBS (M = 44.4, SD = 9.01) than did children from single parent families (M = 39.9, SD = 6.70; t (70) = -2.34, p = .02). Parents from single parent families reported more negative/critical behavior on the DFBC (M = 18.3, SD = 6.39) than did parents from two parent families (M = 15.0, SD = 4.83 , t (70) = 2.06, p = .05).

Intercorrelations among study variables. Several study variables based on the same measure were intercorrelated as would be expected (e.g,. the BRIEF indices and composite scores). In addition to relations with the outcome variables (i.e., metabolic control and adherence), other relations were elucidated (see Table 3-3). The PIP-F scale was inversely correlated with the DFBS-Warmth/Caring scale and positively correlated with the BRIEF-GEC, BRI, and MI. The DFBS-Warmth/Caring scale was also inversely correlated with the BRIEF-GEC and BRI. Finally, the PIP-D scale was correlated with the two BRIEF indices and the composite score.

Hypothesis testing

Relation between executive functioning and adherence. To examine hypotheses 1a that poor executive functioning is related to poorer adherence, a hierarchical multiple linear regression analysis was conducted. Child and parent reports of adherence were analyzed in two separate analyses. For each regression, demographic variables identified as covariates were entered into the first block of the equation. The BRIEF-GEC was then entered into the second block of the regression to examine whether it accounted for a portion of the variance in adherence above demographic variables. For child-reported adherence on the DSMP-R, the BRIEF-GEC predicted an additional 7% of the variance in adherence (F (2, 69) = 5.36, p = .007) over demographic variables. The BRIEF-GEC standardized beta weight (β = -.274, p = .007) in the final block of the regression suggested a negative relationship between executive functioning and child report of adherence, supporting the study hypothesis. For parent-reported adherence

on the DSMP-R, the BRIEF-GEC predicted an additional 4% of the variance (F (2, 69) = 9.15, p = .000). However, in the final block of the regression for parent-reported adherence, the BRIEF-GEC standardized beta weight was only approaching significance (β = -.191, p = .07).

Age as a moderator of executive functioning and adherence. To test hypothesis 1b, the Baron and Kenny (1986) criteria for moderation were utilized. These criteria state that moderation is present if there is a significant interaction between the moderator (i.e., age) and executive functioning after the effects of both variables are controlled. Moderation was tested for the BRIEF-GEC using hierarchical regression analyses. Demographic variables identified as covariates in earlier analyses were entered into the regression first, followed by child age and BRIEF-GEC scores. Finally, the age by executive functioning interaction term was entered into the final block. No support for this hypothesis was found as the interaction term was nonsignficant. The same procedure was used to determine whether the DFRQ "Child Responsibility" index moderated the relation between executive functioning and adherence. However, this interaction was also nonsignficant.

Relation between parenting stress and adherence. To examine hypothesis 2a that higher levels of parenting stress will be related to poorer adherence, a hierarchical multiple linear regression analysis was conducted. Child and parent reports of adherence were analyzed in separate analyses as were the PIP frequency and difficulty scales. For each regression, demographic variables identified as covariates were entered into the first block of the equation. Neither the PIP-F nor the PIP-D significantly predicted child-reported adherence on the DSMP-R. For parent-report on the DSMP-R, the PIP-F significantly predicted an addition 10% of the variance in adherence above demographic variables (F (2, 69) = 12.5, p = .000). The standardized beta weight for the PIP-F in the final block of the regression (β = -2.96, p = .004) indicates a negative relationship between parent reports of adherence and frequency of parenting

stress. Similar results were found with the PIP-D, which predicted 11% of the variance in parent-report of adherence (F (2, 69) = 13.6, p = .000). The PIP-D standardized beta weight (β = -.333, p = .002) also suggests a negative relationship between and parent-reported adherence and perceived difficulty with parenting stress.

Age as a moderator of parenting stress and adherence. As described above, the Baron and Kenny (1986) criteria for moderation were used to test hypothesis 2b as well. Moderation was tested separately for the two PIP Indices (i.e., PIP-F and PIP-D) using hierarchical regression analyses. Results did not support the hypothesis that age moderates the relation between parenting stress and adherence as the interaction term was nonsignificant.

Adherence mediates relations between executive functioning and metabolic control. Baron and Kenny's (1986) criteria for mediation were used to test models of the influence of executive functioning, parenting stress, and diabetes-specific family factors on metabolic control via adherence. These guidelines state that criteria for mediation is met if: (I) the predictor (i.e., executive functioning) is significantly associated with the outcome (i.e., metabolic control), (II) the predictor is significantly associated with the mediator (i.e., adherence), (III) the mediator is associated with the outcome variable, and (IV) the addition of the mediator to the model reduces the relationship between the predictor and outcome variable.

For hypothesis 3a, in order to test criteria (I) a regression analyses was conducted predicting metabolic control from executive functioning. However, the relationship was nonsignficant, which initially suggested that continuing to test the mediation model was not warranted. However, given the significant relationship found in prior analyses between executive functioning and adherence, an alternative moderation model was tested whereby adherence would moderate the relation between executive functioning and metabolic control. This moderation analyses would elucidate relationships between executive functioning and

metabolic control, depending on the child's level of adherence. For example, it may be that for children with poor adherence there is a significant relationship between executive functioning and metabolic control. This model was tested separately for child and parent reports of adherence. On the parent DSMP-R, no significant moderation effect of adherence on the relation between executive functioning and metabolic control was found. However, for child-reported adherence, a significant moderation effect (i.e., interaction, see Figure 3) was found (F (5, 66) = 4.2, p = .002, β = 1.7, p = .02). For children reporting good adherence, there was a positive relationship between executive functioning and metabolic control, in that poor executive functioning was related to poor metabolic control (r = .400, p = .02). However, for children reporting poor adherence an inverse relationship was found (r = -.575, p = .002), suggesting that children with poor executive functioning have good metabolic control.

Given that adherence was found to be a significant moderator of the relation between executive functioning and metabolic control, separate analyses were run for children reporting relatively better adherence (n = 39) and those reporting relatively worse adherence (n = 33), based on a median split. For the relatively better adherence group, the Baron & Kenny (1986) criteria were used and criterion (I) was supported in that child executive functioning (predictor) significantly predicted 14% of the variance in metabolic control (outcome variable) when controlling for demographic variables (F (2, 31) = 3.92, p = .018, β = .375, p = .02). Criterion (II) was also supported in that executive functioning significantly predicted 7% of the variance in parent-reported adherence (F (1, 37) = 9.45, p = .001, β = -2.02, p = .05). Parent-reported adherence also significantly predicted 9% of the variance in metabolic control, meeting criterion (III) (F (1, 37) = 3.28, p = .05; β = -.39, p = .04). Finally, the full regression model was analyzed and the addition of the mediator (adherence) decreased the relation between the predictor (executive functioning) and the outcome variable (metabolic control) to nonsignficance,

supporting criterion (IV) and indicating a mediation effect for the relatively better adherence group (see Table 3-4).

Analyses were also conducted for the relatively worse adherence group to determine whether adherence mediates the relation between executive functioning and metabolic control in this subsample. Mediation criterion (I) was met in that executive functioning significantly predicted 28% of the variance in metabolic control (F (2, 26) = 6.83, p = .002; β = -.525, p = .002). However, criterion (II) was not met as there was no significant relationship found between executive functioning and adherence. Thus, the mediation hypothesis was not supported in the subsample of children reporting relatively worse adherence.

Posthoc analyses to examine differences in the relation between executive functioning and metabolic control in children based on reports of adherence. Given the unexpected finding that poor executive functioning was related to good metabolic control in children reporting relatively worse adherence, a series of posthoc analyses were conducted to determine the nature of this relationship. It was hypothesized that family factors (i.e., nagging/critical parenting, no responsibility for diabetes regimen, parental warmth/caring, and parental guidance/control) would differ between the relatively better adherence children and the relatively worse adherence children, thus explaining the findings of contrary relations between executive functioning and metabolic control in the two groups. First the child report of nagging/critical parenting was examined. In the relatively better adherence group (n = 39), DFBC-nagging/critical parenting surrounding the diabetes regimen was significantly correlated with metabolic control (r = .433, p = .006); however, in the relatively worse adherence group (n = 33), this relation was not significant. Furthermore, there was a significant difference between the DFRQ-No responsibility score in the relatively better adherence (M = 1.7, SD = 1.5) versus the relatively worse adherence group (M = 2.8, SD = 2.2; t (70) = 2.7, p = .008). Furthermore, an inverse correlation was found

in the relatively better adherence group (r = -.400, p = .04) on the DFRQ "Child Responsibility" index, suggesting that children in this group with poor executive functioning were responsible for fewer diabetes-related tasks. No relationship between these variables was found in the relatively worse adherence group. Finally, in the relatively worse adherence group, a significant relation was found between executive functioning and nagging/critical parenting on the DFBC (r = .407, p = .02), which suggests that children in the relatively worse adherence group with poor executive functioning report that their parents nag and criticize them more often.

Adherence as a mediator of the relation between parenting stress and metabolic control. For hypothesis 3b, as before mentioned, the frequency (PIP-F) and difficulty (PIP-D) scales were examined in separate analyses and parent-report of adherence was used due to the a priori hypothesis, as well as prior studies that have suggested that parent-report of adherence is more strongly associated with metabolic control (Lewin, et al., 2006). For the PIP-F, the frequency of pediatric parenting stress was significantly predictive of 6% of the variance in metabolic control (F (3, 59) = 5.51, p = .002; β = .265, p = .03) meeting criterion (I). The PIP-F also significantly predicted 10% of the variance in parent-reported adherence (F (2, 69) = 12.5, p = .000; β = -.306, p = .004) meeting criterion (II). Prior analyses have supported the significant relation between parent-reported adherence and metabolic control (criterion III). Finally, in the full mediation model, the contribution of the frequency of pediatric parenting stress on metabolic control was reduced to a nonsignificant value when parent-report of adherence was added into the model, indicating a mediation model (see Table 3-5).

The same analytical procedures were utilized to test for a mediation effect of adherence on the relation between the difficulty of pediatric parenting stress (PIP-D) and metabolic control. The difficulty of pediatric parenting stress significantly predicted 7% of the variance in A1c (F (3, 59) = 5.64, p = .002; β = .275, p = .02), meeting criterion (I) for mediation. Consistent with

criterion (II) the PIP-D was also significantly predictive of 11% of the variance in parent-reported adherence (F (2, 69) = 13.6, p = .000; β = .333, p = .002). The relation between parent-reported adherence has been supported in prior analyses. Finally, in the full mediation model the effect of the PIP-D was reduced to nonsignficance, supporting the hypothesis that the relation between the difficulty of pediatric parenting stress and metabolic control is mediated by parent-report of adherence (see Table 3-6).

Replication of adherence as a mediator of the relations between and diabetes-specific family factors and metabolic control in patients using intensive regimens. Prior analyses have supported a model in which adherence partially mediates the relation between a combination of diabetes-specific family factors and metabolic control (Duke, et al., 2007; Lewin, et al. 2006). These analyses were replicated in the current sample of pediatric patients utilizing intensive treatment regimens in order to test hypothesis 3c. The diabetes-specific family factors included in the model were a) child report of parental guidance/control (DFBS-Guidance/ Control), b) child report of parental warmth/caring (DFBS-Warmth/Caring), c) parent and child report of no-responsibility for diabetes tasks (DFRQ-No Responsibility), and d) child report of nagging/critical parent behaviors related to the diabetes regimen (DFBC-Nagging/critical Parenting). Baron and Kenny criterion (I) was met in that the combination of the four family factor indices significantly predicted 10% of the variance in metabolic control (F (6, 56) = 3.14, p = .01). However, it is important to note that only the DFBC-Nagging/Critical Parenting scale evidenced a significant relation with metabolic control in the model (β = .34, p = .01). Criterion (II) was also met as the combination of diabetes-specific family factors significantly predicted 7% of the variance in metabolic control (F (5, 66) = 4.2, p = .002). As with the prior analysis, the DFBC-Nagging/Critical Parenting scale was the only diabetes-specific family factor with a significant relation with the predicted variable of parent-reported adherence and this relation was

approaching significance (β = -.204, p = .08). Prior analyses have confirmed a significant relation between adherence and metabolic control, meeting criterion (III). The full mediation model was run and predicted 42% of the variance in metabolic control. Although the relation between diabetes-specific family factors and A1c was reduced, it was not rendered nonsignficant, thus suggesting partial mediation as per criterion (IV) (see Table 3-7).

Prediction of metabolic control by diabetes-specific family factors, executive functioning, parenting stress, and adherence. To test hypothesis 4, a combined model predicting metabolic control from diabetes-specific family factors, executive functioning, parenting stress, and adherence, a hierarchical regression analysis was conducted. Demographic variables (duration of diabetes, family income) related to the metabolic control were entered into the first block of the regression. Next, the diabetes-specific family variables (i.e., DFBS-Guidance/Control, DFBS-Warmth/Caring, DFRQ-No Responsibility, and DFBC-Nagging/Critical Parenting) were entered into the equation. Executive functioning (BRIEF-GEC), parenting stress (PIP-F), and parent-report of adherence (Parent DMSP-R) were entered separately into subsequent blocks of the regression equation. Given that prior analyses found very similar results for the PIP-F and PIP-D scales, only the PIP-F scale was used as it evidenced a slightly stronger relationship with metabolic control. Results of the model in the full sample are shown in Table 3-8 and suggested that the combination of these variables predicted 43% of the variance in metabolic control in a sample of patients utilizing intensive insulin regimens (F (9, 53) = 4.45, p = .000). Analysis of the beta weights from the final block of the regression suggested that the DFBC-Negative/Critical Parenting factor and parent-reported adherence were the only variables contributing significantly to the model's prediction of metabolic control.

Given prior findings of significant differences in the relations between family factors, executive functioning, and metabolic control based on child-report of adherence, the full

regression model was also examined separately in youth reporting relatively better adherence (n = 39) and relatively worse adherence (n = 33). For the relatively better adherence group, the model including all variables predicted 56% of the variance in metabolic control (F (9, 24) = 3.3, p = .009) (see Table 3-9). Beta weights from the final block of the regression suggested that certain diabetes specific family factors (DFBS-Guidance/Control, DFBS-Warmth/Caring, DFBC-Nagging/Critical Parenting) and parent-report of adherence contributed to the model, although these relations were approaching significance. For the relatively worse adherence group the model including all variables predicted 80% of the variance in metabolic control (F (9, 19) = 8.3, p = .0009) (see Table 3-10). In this subsample, the DFBS-Guidance/Control index, the BRIEF-GEC, and parent-report of adherence contributed significantly to the model. The PIP-D contribution was also approaching significance.

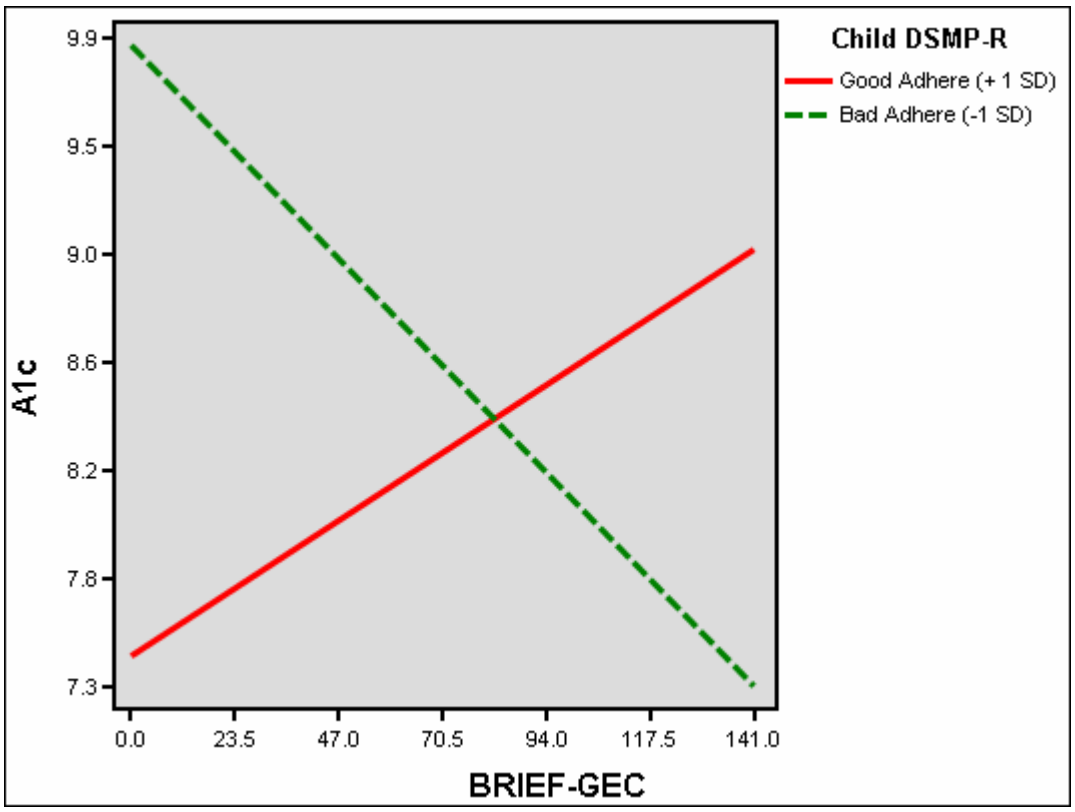

Figure 3-1. Child adherence moderates relation between executive functioning and metabolic control. Higher scores on the BRIEF-GEC are indicative of poorer executive functioning. Higher A1c values are indicative of poorer metabolic control.

Table 3-1. Child DSMP-R item-to-total correlations

DSMP Scale	Item Number	Item-to-Total Correlation
Exercise	1	.371
	2	.219
	3	.204
Hypoglycemia	4	.592
	5	.207
	6	.285
Diet	7	.361
	8	.364
	9	.408
	10	.227
	11	.308
	12	.299
	13	.339
	14	-.025
	15	.353
Blood Glucose Testing	16	.205
	17	.207
	18	.186
	19	.343
Insulin	20	.462
	21	-.050
	22	.475
	23	.485
Intensive Regimen[a]	24	.536
	25	.546
	26	.253

[a] Intensive regimen items developed and added for this study.

Table 3-2. Parent DSMP-R item-to-total correlations

DSMP Scale	Item Number	Item-to-Total Correlation
Exercise	1	.185
	2	.274
	3	.274
Hypoglycemia	4	.188
	5	.197
	6	.339
Diet	7	.527
	8	.368
	9	.321
	10	.208
	11	.364
	12	.257
	13	.138
	14	.164
	15	.040
Blood Glucose Testing	16	.249
	17	.222
	18	.176
	19	.218
Insulin	20	.617
	21	.234
	22	.411
	23	.539
Intensive Regimen[a]	24	.559
	25	.535
	26	.417

[a] Intensive regimen items developed and added for this study.

Table 3-3. Intercorrelations between study variables

Measure	*1*	*2*	*3*	*4*	*5*	*6*	*7*	*8*	*9*	*10*	*11*	*12*
1. A1c	--	*-.50***	*-.26**	*.05*	*.03*	*.04*	*.26**	*.27**	*.37***	*.02*	*-.06*	*-.02*
2. P-DSMP		--	*.40***	*-.15*	*-.19*	*-.18*	*-.29**	*-.31***	*-.33***	*.25**	*.00*	*-.03*
3. C-DSMP			--	*-.30**	*-.32***	*-.32***	*.02*	*-.04*	*-.28**	*.10*	*.02*	*-.35***
4. BRIEF BRI				--	*.82***	*.93***	*.29**	*.40***	*.19*	*-.26**	*-.00*	*.17*
5. BRIEF MI					--	*.97***	*.27**	*.46***	*.23*	*-.23*	*.04*	*.06*
6. BRIEF GEC						--	*.29**	*.46***	*.22*	*-.25**	*.02*	*.11*
7. PIP-F							--	*.87***	*.19*	*-.25**	*.07*	*-.16*
8. PIP-D								--	*.23*	*-.20*	*.02*	*-.11*
9. DFBC N/C									--	*-.21*	*-.09*	*.11*
10. DFBS W/C										--	*-.19*	*-.14*
11. DFBS G/C											--	*.10*
12. DFRQ												--

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

Table 3-4. Mediation analysis for relatively better adherence group predicting A1c[a]

Step	Variable(s)	R^2	ΔR^2	F	β
1		.14	.14	2.6	
	Duration of diabetes				.08
	Family income				-.30*
2		.31	.17	4.6**	
	Parent reported adherence				-.38*
3		.38	.07	4.4**	
	Child executive functioning				.27

[a] all standardized regression coefficients are from the final block of the regression. * $p < .05$. ** $p < .01$

Table 3-5. Mediation regression analysis with full sample predicting A1c[a]

Step	Variable(s)	R^2	ΔR^2	F	β
1		.15	.15	5.3**	
	Duration of diabetes				.14
	Family income				-.23*
2		.36	.21	11.1***	
	Parent reported adherence				-.45***
3		.37	.01	8.6***	
	Frequency of pediatric parenting stress				.11

[a] all standardized regression coefficients are from the final block of the regression. * $p < .05$. ** $p < .01$. *** $p < .001$.

Table 3-6. Mediation regression analysis with full sample predicting A1c[a]

Step	Variable(s)	R^2	ΔR^2	F	β
1		.15	.15	5.3**	
	Duration of diabetes				.13
	Family income				-.22*
2		.36	.21	11.1***	
	Parent reported adherence				-.45***
3		.37	.01	8.5***	
	Difficulty of pediatric parenting stress				.10

[a] standardized regression coefficients are from the final block of the regression. * $p < .05$. ** $p < .01$. *** $p < .001$.

Table 3-7. Mediation regression analysis with full sample predicting A1c[a]

Step	Variable(s)	R^2	ΔR^2	F	β
1		.15	.15	5.3**	
	Duration of diabetes				.08
	Family income				-.18
2		.36	.21	11.1***	
	Parent reported adherence				-.45***
3		.42	.06	5.7***	
	DFBS-Guidance/Control				.05
	DFBS-Warmth/Caring				.13
	DFRQ-No Responsibility				-.10
	DFBC-Nagging/Critical Parenting				.25*

[a] standardized regression coefficients are from the final block of the regression. * $p < .05$. ** $p < .01$. *** $p < .001$.

Table 3-8. Multiple regression analysis with full sample predicting A1c[a]

Step	Variable(s)	R^2	ΔR^2	F	β
1		.15	.15	5.3**	
	Duration of diabetes				.09
	Family income				-.16
2		.25	.10	3.1**	
	DFBS-Guidance/Control				.04
	DFBS-Warmth/Caring				.14
	DFRQ-No Responsibility				-.07
	DFBC-Nagging/Critical Parenting				.25*
3		.25	.00	2.7*	
	BRIEF-GEC				-.07
4		.31	.05	3.0**	
	PIP-D				.12
5		.43	.12	4.4***	
	Parent DSMP-R (adherence)				-.42***

[a] standardized regression coefficients are from the final block of the regression. * $p < .05$. ** $p < .01$. *** $p < .001$.

Table 3-9. Regression analysis with relatively better adherence group predicting A1c[a]

Step	Variable(s)	R^2	ΔR^2	F	β
1		.14	.14	2.6[b]	
	Duration of diabetes				.10
	Family income				-.22
2		.42	.28	3.3*	
	DFBS-Guidance/Control				.31[b]
	DFBS-Warmth/Caring				.32[b]
	DFRQ-No Responsibility				-.20
	DFBC-Nagging/Critical Parenting				.31[b]
3		.49	.07	3.5**	
	BRIEF-GEC				.26
4		.49	.00	3.0*	
	PIP-D				-.06
5		.56	.07	3.3**	
	Parent DSMP-R (adherence)				-.36[b]

[a] standardized regression coefficients are from the final block of the regression. [b] approaching significance. * $p < .05$. ** $p < .01$. *** $p < .001$.

Table 3-10. Regression analysis with relatively worse adherence group predicting A1c[a]

Step	Variable(s)	R^2	ΔR^2	F	β
1		.18	.18	2.8[b]	
	Duration of diabetes				.30*
	Family income				-.16
2		.26	.08	1.3	
	DFBS-Guidance/Control				- .25*
	DFBS-Warmth/Caring				.04
	DFRQ-No Responsibility				.01
	DFBC-Nagging/Critical Parenting				.01
3		.57	.31	4.0**	
	BRIEF-GEC				-.61***
4		.73	.16	7.0***	
	PIP-D				.32[b]
5		.80	.07	8.3***	
	Parent DSMP-R (adherence)				-.33*

[a] standardized regression coefficients are from the final block of the regression. [b] approaching significance. * $p < .05$. ** $p < .01$. *** $p < .001$.

CHAPTER 4
DISCUSSION

The goal of this study was to elucidate relationships between child and family factors and the management of T1DM with intensive insulin regimens. Although intensive regimens are becoming more popular given increasing focus on better metabolic control, this is the first study, to our knowledge, to examine correlates of metabolic control and adherence specifically in these patients. Particularly given the higher demands and increased complexity involved in intensive treatment regimens it is important to examine factors that may predict better disease management in these patients.

In our examination of the relation between child executive functioning, diabetes adherence, and metabolic control, some interesting relationships were elucidated. Child executive functioning showed significant inverse relationships with parent-report of adherence and child-reported adherence, as hypothesized, although these relations were modest. Thus, youth with poor executive functioning tend to also have poor adherence to their diabetes regimen. This finding makes sense given that intensive diabetes treatment regimens, in particular, require a great deal of planning, organization, and problem solving. However, our initial analysis showed no relation between executive functioning and metabolic control, rendering a mediation analysis unwarranted according to Baron & Kenny (1986). Given the significant association between executive functioning and adherence, we tested a moderation model, hypothesizing that perhaps the relationship between executive functioning and metabolic control would be significant for a subgroup of youth based on adherence. Although parent report of adherence did not moderate the relation between executive functioning and metabolic control, the moderation model (i.e., interaction) was significant for child-reported adherence. This moderation model showed that for youth reporting relatively better adherence (n = 39), poor executive functioning was

significantly related to poor metabolic control. However, for youth identified by a median split as reporting relatively worse adherence (n = 33), a paradoxical relationship was found in that youth with worse executive functioning showed better metabolic control and vice versa.

Given the strength of the unexpected nature of this finding we were confident a yet to be identified variable would be elucidated by post hoc analyses. We hypothesized that differences in diabetes-specific family factors were likely driving the different relationships found between executive functioning and metabolic control at different levels of adherence. The overall sample was portioned into two samples using a median split; thus, leaving a "relatively better adherence" group and a "relatively worse adherence" group. Then, differences in family factors between these two groups were investigated. When comparing children in the relatively better adherence group to those in the relatively worse adherence group, there was a significant difference in scores on the DFRQ-No Responsibility index. Youth in the relatively worse adherence group tended showed less agreement about who takes responsibility for diabetes related tasks (i.e., parents stated that the child was responsible, while the child stated the parent was responsible). We also found that in the relatively worse adherence group, poor executive functioning was associated with child perception of more nagging/critical parenting on the DFBC. Neither of these relationships was found in the group of youth reporting relatively better adherence. In addition, for youth in the relatively worse adherence group, when executive functioning was identified as being worse, parents identified themselves as more nagging and critical on the DFBC.

Although the relation between executive functioning and metabolic control for youth in the relatively worse adherence group seems counterintuitive, these post hoc analyses shed some light on possible explanations. Past research has shown that the DFBC-Nagging/Critical Parenting scale is associated with poor metabolic control (Lewin, et al., 2006), a finding that is

theoretically consistent with the coercive cycle proposed by Patterson (1986). However, it may be that frequent parental reminders (even if presented in a negative manner) help youths with worse executive functioning maintain better metabolic control. For the subset of youths in the relatively worse adherence group, the intensive regimen requirements of remembering blood glucose checks, insulin administration, and overall planning and problem solving about their diabetes care regimen would indeed be very difficult given poor executive functioning. We also found that youth in the relatively worse adherence group have parents who report themselves to be nagging and critical about diabetes-related tasks. These parents recognize their children's difficulties and are providing frequent reminders about diabetes tasks, which both the youth and the parent interpret as nagging.

Conversely, youth in the relatively worse adherence group with good executive functioning show poor metabolic control. Again, while counterintuitive at first glance, it may be that these youth appear to be capable of managing their diabetes tasks independently, and thus receive little help from their parents. Supporting this hypothesis is the DFRQ finding that a dyadic pattern of no one (i.e., neither parents nor children) taking responsibility for diabetes tasks is related to poor metabolic control (Anderson, et al., 1990; Lewin, et al., 2006). Thus, these youth with good executive functioning are likely are left to manage their diabetes tasks independently, when in fact, neither they nor their parents are taking appropriate responsibility for their regimen, leading to both poor adherence and poor metabolic control.

Despite the unexpected findings in youth in the relatively worse adherence group, for those in the relatively better adherence group, the relationship between executive functioning and metabolic control was in the expected direction. That is, youth with poor executive functioning also have poorer metabolic control. Within this subset of participants reporting relatively better adherence, our original proposed mediation model was supported. Thus, parent-reported

adherence mediated the relation between executive functioning and metabolic control. This suggests that for these youth utilizing intensive insulin regimens, worse executive functioning is related to poor adherence behaviors and consequently poor metabolic control. In these youth in the relatively better adherence group with worse executive functioning, it seems that parents are not effectively intervening in the diabetes care regimen on their behalf.

Our hypotheses that age would moderate the relationship between executive functioning and adherence was not supported in the current study. The current findings are consistent with more recent data that has been reported (Bagner, et al., 2007). However, Bagner and colleagues hypothesized that perhaps child level of responsibility for diabetes-related tasks would moderate this relationship, rather than age, given that there may be significant variability in the age at which a child primarily manages their diabetes regimen. Although we tested this hypothesis by computing a "child responsibility score" on the DFRQ, this variable was not found to moderate the relation between executive functioning and adherence. While this is an unexpected finding, it may suggest that poor child executive functioning affects adherence regardless of child age or level of responsibility for the diabetes regimen. Given that executive functioning is thought to have a biological basis, it is also possible that executive functioning difficulties has a familial basis. Thus, a child with poor executive functioning may be more likely to have a parent with similar difficulties, thus the diabetes regimen would be negatively affected regardless of who manages diabetes tasks. Given our surprising finding related to executive functioning, metabolic control, and poor child-reported adherence, it is also reasonable to assume that the relation between diabetes management and executive functioning is much more complex than expected.

In the current study, our hypothesis that adherence mediated the role between pediatric parenting stress and metabolic control was supported. Thus, for both the difficulty and frequency scales of the PIP, parenting stress was related to metabolic control through adherence.

Although we hypothesized that this relation would be moderated by child age or their level of responsibility for the diabetes regimen, this was not supported. Consequently, our findings suggest that regardless of child age or the level of responsibility they take for their diabetes regimen, parent report of stress related to their child's health issues is associated with worse parent-reported adherence behaviors and worse metabolic control. In our analyses, both parent report of the *frequency* of stress and the *difficulty* of stress related to their child's health issues was related to adherence and metabolic control. Given the cross-sectional and correlational nature of the current study it is not possible to determine causal relationships. Therefore, it may be that for youth engaging in poor adherence (and thus having poor metabolic control) their parents experience more stress related to the child's health issues. It may also be that parents who inherently find their child's health issues more stressful are less able to effectively support and intervene with the youth's diabetes regimen, which leads to worse adherence and worse metabolic control.

The current study also sought to replicate prior findings highlighting the relation between diabetes-specific family factors, diabetes adherence, and metabolic control in a sample of youth utilizing intensive insulin regimens. Lewin and colleagues (2006) found that diabetes-specific family factors (i.e., no responsibility for diabetes tasks, nagging critical parenting) and adherence predicted 49% of the variance in metabolic control. In our sample, we found that 42% of the variance in metabolic control was predicted by a combination of diabetes-specific family factors and parent-reported adherence. Similar to prior studies, within our sample of youths using intensive insulin regimens, the strongest predictor of metabolic control was child-report of nagging/critical parenting on the DFBC. We also tested the Baron and Kenny (1986) criteria for mediation and replicated the finding that adherence partially mediates the relation between diabetes-specific family factors and metabolic control within our sample.

Given the significant relations between executive functioning, pediatric parenting stress, diabetes-specific family factors, adherence, and metabolic control, we sought to test a regression model including these constructs to predict metabolic control in our sample of youth utilizing intensive insulin regimens. In the full sample, the combination of study variables predicted 43% of the variance in metabolic control; however, only child-report of Nagging/Critical Parenting on the DFBC and parent-reported adherence contributed significantly to the model. The other variables included in the model (i.e., parenting stress, child executive functioning, no responsibility for diabetes tasks, parental warmth/caring, parental guidance control) did not add significant predictive value.

Given that there was a significant interaction effect between executive functioning and metabolic control for youths reporting relatively better versus relatively worse adherence, we maintained the median split of the sample (based on child-reported adherence) and tested the full regression model in each group separately. Interestingly, these models evidenced different patterns of significant results. For children in the relatively better adherence group (n = 39), a combination of pediatric parenting stress, diabetes-specific family factors, and parent-reported adherence predicted 56% of the variance in metabolic control. However, examination of the beta weights in the final block of the regression suggested that only diabetes-specific family factors and parent-report of adherence contributed to the model predicting metabolic control. More specifically, the family factors contributing to the model were child-report of parental warmth/caring and guidance/control (DFBS) as well as child-report of nagging/critical parenting (DFBC). It is important to note that the contribution of each of these family factors was approaching significance while parent report of adherence had a strong, significant relation to metabolic control. In contrast, for youth in the relatively worse adherence group (n = 33) a very different pattern emerged. For this group of youth, the model including executive functioning,

pediatric parenting stress, diabetes-specific family factors, and parent-reported adherence predicted 80% of the variance in metabolic control. However, child executive functioning, child-report of parental guidance/control (DFBS), parenting stress, and parent-report of adherence were the strongest predictors in the model. Child executive functioning, was by far the strongest predictor of metabolic control in the model ($\beta = -.61$, $p = .000$), and again suggested that worse executive functioning, in the group of children reporting relatively worse adherence, is related to better metabolic control. Given that child-reported parental guidance/control was also inversely related to metabolic control in this model, our prior theory about parents effectively intervening within this subgroup of youth is supported. Thus, the data suggests that within these youth reporting relatively worse adherence, parents effectively intervene in the diabetes regimen when children have poor executive functioning, which results in better metabolic control. In addition to the interesting and unexpected nature of this finding, it is also important to note that, to our knowledge, no prior study has reported predicting such a large portion of the variance in metabolic control.

It is also important to note that several relationships between demographic and disease characteristics and study variables were found. Youth from single parent families tended to have poorer child-reported adherence, less parental guidance/control (DFBS), and more parent-reported nagging/critical parenting (DFBC). Longer duration of diabetes was related to poorer parent-reported adherence, poorer metabolic control, and more child-reported nagging/critical parenting (DFBC). Findings related to poorer adherence and metabolic control as youths have diabetes for longer durations are consistent with prior results suggesting that adherence and metabolic control generally declines over time (Anderson, et al., 1990). Youths from families with less annual income tended to have worse metabolic control and more child-reported nagging/critical parenting (DFBC). This finding may suggest that these families have fewer

resources and thus struggle to manage the youth's TIDM. Younger children tended to report more parent guidance/control (DFBS) and their parents tended to report more pediatric parenting stress. These findings are consistent with prior work and suggest that parents take a more active role in the care of diabetes when children are young and that they are also more stressed by their child's health issues (Streisand, et al., 2005). Interestingly, we found higher scores on the no responsibility index of the DFRQ for African American families compared to Caucasian or Hispanic families. To our knowledge, this result has not been reported previously. This may suggest important differences in the way that African American families manage diabetes using intensive insulin regimens, may be indicative of our specific sample, or could also suggest cultural biases in the DFRQ. Finally, in our sample, use of CSII was more frequent in girls and younger children and these patients tended to have better metabolic control. It is likely that the finding related to metabolic control is confounded by patient/physician self-selection biases, in that it is often only the most motivated patients and families that opt to use CSII (Bode, et al., 2002). The finding that younger children and girls use CSII more frequently has not been reported previously, but may suggest that studies citing the safety of CSII usage even in very young patients have made this form of treatment more accepted in young children (e.g., Weinzimer, Swan, Sikes, & Ahern, 2006). Gender differences in CSII usage may be specific to our sample but could also suggest differences in treatment preference between boys and girls or their parents.

This study also provides important information about the use of the BRIEF, a parent-report measure of executive functioning, in a pediatric diabetes sample. In this sample, 18-19% of the children and adolescents met criteria for clinically significant executive dysfunction as determined by their parents' responses on the BRIEF. To our knowledge, this is the first study to document the occurrence of "everyday" executive functioning difficulties in this disease

population (Gioia, et al, 2000, p. 14). Gioia and colleagues have noted that the BRIEF is designed to measure executive difficulties that may interfere with daily activities, such as school and self-care tasks. Given that the BRIEF is typically used to aid in clinical treatment planning rather than as a diagnostic tool, normative data has not been published on the prevalence of executive functioning in children with or without chronic conditions, other than neurocognitive conditions such as traumatic brain injury and epilepsy. The high percentage of youth in this study with clinically significant executive dysfunction may be indicative of the true prevalence of these difficulties within a pediatric TIDM population or may be a result of sample characteristics inherent in the tertiary clinic from which participants were recruited.

Another important contribution of the current project is the development of the DSMP-R, which has shown promising internal consistency and predictive validity. In fact, the parent version of the DSMP-R predicted 18% of the variance in metabolic control, which is much higher than the original DSMP (Harris, et al., 2000). Given that the original DSMP was developed before the increasing popularity of intensive insulin regimens, many of the questions are outdated (e.g., "Are there ever times when you "skip" eating your meals or when you don't eat at all when you should without making adjustments in your insulin?") due to the flexibility of CSII and MDI treatment regimens. Thus, the DSMP-R appears to be a promising measure for use with intensive regimen patients. Clearly, further investigation of the newly developed items is warranted. Test-retest reliability as well as comparisons with other measures of diabetes adherence (e.g., the Self-Care Inventory, 24-hour recall) could be of value. Additionally, although CSII-specific questions were also developed for the current study, these questions were not used in subsequent analyses due to the small number of participants utilizing CSII. Further study of these questions is also warranted.

Limitations

One important limitation of the current study is the use of self-report questionnaires. Although such questionnaires are often used in pediatric psychology research, they are subjective in nature. In particular, it would be useful to have other forms of data on child executive functioning in addition to self-report. In the past, other researchers have used tasks such as the Wisconsin Card Sort and subtests of the Wechsler Intelligence Scale for Children (e.g., mazes) to provide performance data regarding child executive functioning. Given the large sample size needed and time constraints in the diabetes clinic environment, these types of measures were not feasible for use in this study. It is also important to note that the BRIEF was designed as a measure of "everyday behavior associated with specific domains of self-regulated problem solving" (Gioia, et al., 2000, p. 14). Thus, it may provide data about a child's executive abilities that is more generalizable to real world tasks such as managing the diabetes care regimen. The developers of the BRIEF have suggested that children's performance on traditional objective measures of executive functioning do not strongly predict their abilities to perform everyday tasks (e.g,. a math problem in school), thus the use of the BRIEF may more accurately capture a child's true ability to appropriately problem solve and perform complex tasks requiring planning (Gioia & Isquith, 2004). Furthermore, it would also be useful to gather information on parent executive functioning. As these neuropsychological functions are thought to have a biological basis, it would be reasonable to hypothesize that children with poor executive functioning would more often have parents with poor executive functioning. Particularly for younger children, whose parents presumably take more responsibility for the diabetes care regimen, it may be that parent executive functioning is an important correlate of diabetes adherence and metabolic control. Finally, it is possible that results of the current study are confounded by the effects of T1DM on a child's executive functioning abilities. Prior research has shown that hypoglycemia

can negatively impact a child's cognitive skills, at least temporarily during the hypoglycemic episode (e.g., Samo, 1990). However, more long term follow-up has suggested no long-term deleterious effects on the cognitive functioning (including executive functioning skills such as problem solving) of patients with T1DM (DCCT/EDIC Research Group, 2007).

The current study may have been strengthened by other methods of assessing diabetes adherence. The interview format of the DSMP may lead to participants providing socially-desirable responses. However, attempts to minimize this effect were utilized in the current study (e.g., separating parents and children during the interview, normalizing difficulties with diabetes adherence). Given the nature of diabetes treatment regimens, measures of adherence not based on self-report used in other pediatric disease populations (e.g., MEMS caps, pill counts, prescription records) do not provide useful treatment information about diabetes adherence. However, other researchers have used other measures of adherence in the pediatric diabetes population, such as the 24-hour recall questionnaire, which is administered on 3 occasions via phone to both parents and children with diabetes (Johnson, 1992). While the 24-hour recall shows high reliability and may minimize errors that may occur when patients recall adherence over lengthier periods of time, it has not evidenced a strong link with metabolic control in a large, longitudinal study (Johnson, et al., 1992). Furthermore, as newer technologies are developed, the measurement of diabetes management has become even more sophisticated. Researchers are now utilizing technologies such as Continuous Glucose Monitor Systems (CGMS) to measure minute-to-minute diabetes management (Williams, et al., 2007) and the addition of such measurement techniques would have strengthened the current study. However, the DSMP adherence measure used in the current study has been well-validated and has been used in a number of studies (Duke, et al., 2007; Lewin, et al., 2006). Furthermore, additional intensive regimen questions were added to update the DSMP to more accurately assess

adherence behaviors related to newer, intensive diabetes treatment regimens (i.e., MDI and CSII). Although the intensive regimen questions show promise given their good internal consistency, relation to the original DSMP, and strong relation with metabolic control, further research is needed.

The diabetes-specific family measures utilized in the current study have been well tested and validated. However, they are self-report measures and thus subject to reporting bias. Other researchers have used observational coding systems such as the Mealtime Interaction Coding Systems (MICS) based on the McMaster Model of Family Functioning to assess interaction patterns within families of children with diabetes (Piazza-Waggoner, et al., in press); however, this is a general measure of family functioning at mealtimes and does not provide diabetes-specific data. To our knowledge, an observational coding system related to diabetes-specific family functioning does not currently exist.

Although the current sample size was adequate for the testing of the proposed hypotheses, some of the post-hoc analyses between the relatively better and relatively worse adherence groups may have been strengthened by the addition of more participants. It is possible that further differences between these groups were not uncovered due to the relatively small number of participants in each group (i.e., 39 and 33 participants, respectively). Although the current study classified both CSII and MDI as intensive treatment regimens, with a larger sample size, it might also be useful to investigate any differences in relations among study variables, adherence, and metabolic control between these two treatment regimens.

Finally, the participants included in the current study were primarily Caucasian and over half reported an annual household income of less than $50,000/year. These sample characteristics are not surprising given that the Pediatric Endocrinology Clinic from which participants were recruited serves a primarily Caucasian and low-income patient population.

Furthermore, there is also some evidence that the participants in the current study evidenced a higher rate of diabetes-related hospitalizations and DKAs. Twenty-percent of participants reported more than one diabetes-related hospitalization and 31% of children in the current study had at least one episode of DKA since their initial diagnosis. These sample characteristics suggest that the current study may not generalize to other less tertiary populations of pediatric patients.

Future Directions

One of the goals of this study was to identify patient and family characteristics that lead to the successful use of intensive insulin regimens. Although longitudinal medical studies have shown that when properly used, intensive regimens lead to better metabolic control and subsequently fewer diabetes-related complications (e.g., DCCT, 1993), these more complex regimens are not feasible for all patients. Anecdotal clinical observations suggest that some patients achieve better metabolic control using more traditional diabetes treatment regimens. Furthermore, the cost and additional time commitment required for properly implementing intensive diabetes regimens can be prohibitive for some families and medical professionals. Interestingly, long-term follow-up of initial cohort of patients participating in the DCCT showed that initial differences in metabolic control based on intensive therapy versus conventional therapy (1.8% difference) had decreased to nonsignficant levels 8 years later. This suggests that without the frequent support provided by research studies (but rarely provided in typical clinical practice) patients may find it difficult to maintain the gains in metabolic control that can be afforded by intensive therapies. However, it is also important to note that despite the regression to the mean that occurred in the DCCT study participants, those patients who were randomized to intensive therapy continued to show significantly lower levels of diabetes related

complications (DCCT Writing Team, 2003). Given this finding, it continues to be important to investigate correlates of successful intensive therapy.

Future studies in this line of research should continue to confirm and further elucidate factors that predict outcome on intensive regimens. Although the current study suggests that executive functioning is one such factor, at least in children reporting relatively better adherence, this relation needs to be further explored. Given findings from this project, pediatric parenting stress as well as diabetes-specific family factors are also important constructs to consider. The long-term goal of this line of research is continue to identify factors related to successful use of intensive insulin regimens in order for medical professionals or pediatric psychologists to help families evaluate their readiness for utilizing MDI and CSII. This model of evaluating patients' readiness for medical treatments is utilized in the organ transplant field (e.g., Collins & Labott, 2007; Shaw & Taussig, 1999). For patients with diabetes, the goal of these readiness evaluations would not be to prevent families from choosing their preferred diabetes treatment regimen, but rather to provide them with evidence-based information about what characteristics are most likely to lead to success. For children and families who have characteristics that may lead to difficulties with intensive treatment regimens, it will be important to study diabetes education or preventative behavioral interventions to enhance their readiness.

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BIOGRAPHICAL SKETCH

In May 2001, Laura Bimbo Williams received her Bachelor of Arts in psychology with highest honors and highest distinction from the University of North Carolina at Chapel Hill. She furthered her education in the graduate program in clinical and health psychology at the University of Florida beginning in August 2001. In May of 2003, she received her Master of Science in clinical psychology from the University of Florida. Her completed thesis was titled *Family Factors in Pediatric Patients with Type 2 Diabetes: The Development of a Questionnaire*. In July 2006, Ms. Williams began her clinical internship focusing on pediatric psychology at Cincinnati Children's Hospital Medical Center in Cincinnati Ohio. Ms. Williams completed her dissertation with her faculty chair, Dr. Gary Geffken, and received her Doctor of Philosophy in Clinical Psychology in August 2007. Her graduate work has focused on the field of pediatric psychology and more specifically on the correlates of metabolic control and adherence in pediatric patients with type 1 and type 2 diabetes. After receiving her degree, Ms. Williams will continue her training as a Postdoctoral Fellow in Child Behavior and Nutrition at Cincinnati Children's Hospital Medical Center, with research supervisor Dr. Scott Powers.