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## Increasing Blood Glucose Monitoring in Adolescents with Type 1 Diabetes: Effects of a Prompt

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INCREASING BLOOD GLUCOSE MONITORING IN ADOLESCENTS  
WITH TYPE 1 DIABETES: EFFECTS OF A PROMPT

by

Stephen J. Albrecht

A Dissertation  
Submitted to the  
Faculty of The Graduate College  
in partial fulfillment of the  
requirements for the  
Degree of Doctor of Philosophy  
Department of Psychology  
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Western Michigan University  
Kalamazoo, Michigan  
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# INCREASING BLOOD GLUCOSE MONITORING IN ADOLESCENTS WITH TYPE 1 DIABETES: EFFECTS OF A PROMPT

Stephen J. Albrecht, Ph.D.

Western Michigan University, 2005

A series of single-subject designs (AB, ABAB) were used to assess the effects of an antecedent prompting procedure (i.e., prompts) on blood glucose monitoring in young individuals diagnosed with type 1 diabetes. Prompts were delivered through portable, automated paging technology. Frequency of blood glucose checks was obtained across meter, baseline, and intervention phases. Metabolic control was assessed by obtaining blood glucose levels for each check across baseline and intervention phases, and hemoglobin (HbA<sub>1c</sub>) values at study entry and follow-up. Results indicated that the prompt increased blood glucose monitoring for three participants, and metabolic control improved for 2 participants when the prompts were used. Results also indicated that telephone contacts used in this study led to modest improvements in blood glucose monitoring, which may have attenuated the intervention effects for 2 participants. Efforts to gradually reduce the frequency of prompts while maintaining adequate rates of blood glucose monitoring were partially successful for 1 participant. Findings from this study suggest that prompts delivered through automated paging technology has the potential to improve blood glucose monitoring and metabolic control in the short-term among young individuals diagnosed with type 1 diabetes.

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## Introduction

The pediatric literature shows that many children and adolescents diagnosed with a chronic medical condition may experience problems adhering to their prescribed medical regimen, which in turn may adversely affect both their physical and psychological well-being. Medical conditions that require intensive and complex treatment regimens include, but are not limited to, asthma, cystic fibrosis (CF), sickle cell disease (SSD), juvenile rheumatoid arthritis (JRA), and type 1 diabetes. Each of these conditions requires adherence to a detailed, prescribed regimen in order to maximize effective management of the medical condition. Unfortunately, many pediatric patients diagnosed with these conditions fail to adhere to their prescribed medical regimens (Rapoff & Christophersen, 1982; Johnson et al., 1982; Kovacs, Goldston, Obrosky, & Iyengar, 1992).

A substantial number of research studies have documented high rates of treatment non-adherence found among these groups of patients (Baum & Creer, 1986; Johnson et al., 1982; Kovacs, Goldston, Obrosky, & Iyengar, 1992; Litt & Cuskey, 1980; Rapoff & Christophersen, 1982; Varni & Jay, 1984). The overall non-adherence rate for pediatric patients with chronic medical conditions is approximately 50% (Rapoff & Christophersen, 1982; Litt & Cuskey, 1980). In terms of type 1 diabetes specifically, non-adherence rates to one treatment component of the medical regimen (i.e., monitoring of blood glucose levels) fall between 30% and 80% (Johnson et al, 1982; Kovacs, Goldston, Obrosky, & Iyengar, 1992). Pediatric patients who fail to adhere to their prescribed medical regimen may place themselves at a greater risk for developing long-term,

negative health consequences. Moreover, higher rates of treatment non-adherence may indirectly increase overall health-care utilization costs and rates (Rapoff, 2001).

Over the past two decades, numerous studies have investigated the prevalence, correlates, and negative consequences of treatment non-adherence. However, relatively fewer studies have focused on the actual development of effective intervention strategies for improving treatment adherence in patients with chronic medical conditions (La Greca & Schuring, 1995; Lemanek, Kamps, & Chung, 2001; Rapoff, 2001). Several empirical reviews of the extant literature have concluded that the development and investigation of methods of enhancing treatment adherence for many chronic medical conditions are sorely needed (Drotar & Lemanek, 2001; Holden, Deichmann, & Levy, 1999; Janicke & Finney, 1999; McGrath, Mellon, & Murphy, 2000; McQuaid & Nassau, 1999; Mellon & McGrath, 2000; Powers, 1999; Walco, Sterling, Conte, & Engel, 1999). In today's environment of managed health care, it is also imperative that in developing these interventions, attention is paid to ensuring that the interventions are cost-effective, time-efficient, and relatively easy to implement in the context of the general medical setting (Rapoff, 2001).

With the emergence of more advanced medical treatments and technology, health care professionals have developed more complex and sophisticated medical regimens (La Greca & Schurman, 1995). For example, innovative technology has allowed patients with type 1 diabetes to use an electronic device (i.e., blood glucose monitor) to monitor their blood glucose levels from home. Technological advances such as home-based blood glucose monitors have vastly improved the quality of treatment for patients with chronic medical conditions; however, they have also indirectly increased the complexity of

medical regimens. As more complicated medical regimens are being developed, health care professionals will place increasing demands and expectations on pediatric patients and their families for more consistent adherence to the prescribed regimen (La Greca & Schuman, 1995).

Pediatric psychologists are in a unique position to deal with these new demands and challenges for increased treatment adherence to complex medical regimens. Psychologists have the unique knowledge, skills, and training in conducting applied research and intervention design to enhance treatment adherence (Drotar, 1995; Kelleher, 1999; Perrin, 1999; Wertlieb, 1999). With these new challenges, it has become vital for psychologists to familiarize themselves with the various medical regimens, participate on multidisciplinary health care teams, and to develop collaborative relationships with other health-care professionals (Drotar, 1995). Since many patients are at-risk for developing serious health complications, ongoing collaboration with the health care team throughout the research project is essential to overcome various practical issues often encountered in real-world medical settings. Because of the rapid development of medical technology, it will be also crucial for pediatric psychologists to begin exploring how they can integrate modern medical technology with their intervention methods and research outcomes.

In this study, we were specifically interested in improving treatment adherence among young patients diagnosed with type 1 diabetes. Using portable, automated paging technology, we developed an antecedent prompting procedure designed to increase the frequency of blood glucose monitoring in patients with type 1 diabetes. More specifically, external prompts for blood glucose monitoring were delivered through automated paging technology. Although portable paging technology is relatively

expensive, many medical settings already have preexisting paging system capability. Consequently, automated paging technology may prove to be a cost-effective and time-efficient intervention for improving treatment adherence to complex medical regimens.

### Types of Diabetes

The two main forms of diabetes that occur in the United States are Type 1 and Type 2 diabetes (Kenny, Aubert, & Geiss, 1995). Type 1 diabetes, which will be the primary focus of this review, is also referred to as Insulin-Dependent Diabetes Mellitus (IDDM). Type 1 diabetes is typically diagnosed in early childhood or less frequently, in the adolescent years. Due to pancreatic failure, patients with type 1 diabetes are unable to produce insulin, an important endogenous hormone needed to break down glucose in the bloodstream (Johnson, 1995). Without insulin, glucose is unable to move from the bloodstream into the cells (i.e., muscle, brain) where it is needed for energy. Consequently, patients with type 1 diabetes are required to administer daily injections of exogenous insulin to maintain blood glucose levels within the normal range (Silverstein, 1994). Type 2 diabetes, also known as Non-Insulin Dependent Diabetes Mellitus (NIDDM), is diagnosed more frequently in older adult populations, although the extant literature is documenting an alarming and increasing trend among younger individuals (Rubin & Peyrot, 2001). With type 2 diabetes, the pancreas produces insulin, but not in adequate amounts to keep blood glucose levels within the normal range. Since patients with type 2 diabetes produce small amounts of endogenous insulin, patients can control their blood glucose levels by closely monitoring their diet, obtaining plenty of physical exercise, reducing body weight, and taking oral medications (Johnson, 1995; Rubin & Peyrot, 2001).

## Epidemiology

Type 1 diabetes affects approximately 1 in 600 school-age children (LaPorte & Matsushima, & Chang, 1995; LaPorte & Tajima, 1985; Silverstein, 1994). The risk of developing type 1 diabetes is much greater than a number of other well-known childhood chronic diseases, including childhood cancer, juvenile rheumatoid arthritis, cystic fibrosis, and muscular dystrophy (LaPorte & Cruickshanks, 1985). Research has also demonstrated that Caucasian American children are 1.5 times more likely to develop type 1 diabetes than African American children (LaPorte & Cruickshanks, 1985; Zimmet, 1983). However, for those children with type 1 diabetes who are of African-American descent, recent research shows that they have poorer metabolic control and higher hospitalization rates (Auslander, Anderson, Bubb, Jung, & Santiago, 1990; Delamater, Albrecht, Postellon, & Gutai, 1991; Delameter et al., 1999).

## Etiology

The etiology of type 1 diabetes has not been clearly established, although many genetic researchers have hypothesized that the immune response genes HLA-DR3 and – DR4 are implicated in the development of this medical condition (Wolf, Spencer, & Cudworth, 1983). However, only 1 in 50 offspring of parents with type 1 diabetes will develop the condition before the age of 20 (Laporte & Cruickshanks, 1985). Moreover, when examining concordance rates, only 60% of identical twins will both develop type 1 diabetes (Barnett, Eff, Leslie, & Pyke, 1981). More recently, researchers speculate that an autoimmune process, which destroys insulin-producing islet cells within the pancreas, is a possible triggering mechanism for developing type 1 diabetes. However, the factors that trigger this mechanism have not been clearly identified (Thai & Eisenbarth, 1993).

### Medical Treatment of Type 1 Diabetes

The medical regimen for type 1 diabetes is complex and involves multiple treatment components (Peyrot, McMurry, & Kruger, 1999; Rubin & Peyrot, 2001). The regimen requires patients to make a number of significant life-style changes, including following strict dietary guidelines, obtaining plenty of physical exercise, and scheduling insulin injections and blood glucose checks in a timely manner (Johnson, 1995). In addition, patients are encouraged to control or minimize other well-known factors that have been found to affect metabolic control, including physical illness, negative emotional states, and stress (Johnson, 1995).

The most important treatment goal for type 1 diabetes patients is to maintain blood glucose levels within the normal range (Peyrot, McMurray, and Kruge, 1999). This will help facilitate normal growth and development and prevent the development of long-term, negative health complications (Silverstein, 1994; Johnson, 1995). Blood glucose levels should be maintained in the range of 80-120 mg/100 ml, especially before each meal and at bedtime. In order to maintain blood glucose levels within this relatively narrow range, patients frequently monitor their blood glucose levels and administer daily injections of insulin as needed. Unfortunately, the current method of administering exogenous insulin only crudely approximates the more accurate functioning of a normal, healthy pancreas (Johnson, 1995).

To counteract these inaccurate approximations, patients with type 1 diabetes are strongly encouraged to closely monitor their blood glucose levels on a daily and consistent basis. Close monitoring is necessary to properly adjust other important treatment components of the regimen, including insulin dose, type of diet, and quantity of exercise (Rubin & Peyrot, 2001). Currently, standard recommended guidelines suggest

that patients should monitor their blood glucose levels four times per day, particularly before each meal and at bedtime (DCCT, 1994). Checking of blood glucose levels is accomplished by pricking the finger or another part of the body (i.e., forearm) to obtain a small sample of blood. The blood sample is then placed on a reagent strip and read by an electronic device (i.e., blood glucose monitor) that calculates the blood glucose level. The majority of the monitors in use today also have a built-in memory feature that stores the date, time, and blood glucose level for each check (Johnson, 1995).

If patients do not adhere to their blood glucose checks, they will be at a higher risk for developing hyperglycemic (i.e., high blood sugar levels) and hypoglycemic (i.e., low blood sugar levels) episodes. Hyperglycemia is a condition in which blood glucose levels rise above the normal range, while hypoglycemia occurs when levels drop significantly below the recommended range. Hypoglycemia can be a dangerous and potentially life-threatening condition. Since many patients fear hypoglycemic episodes, they may intentionally maintain their blood glucose levels in the above normal range. Unfortunately, high blood glucose levels over extended periods of time can often result in a number of diabetes-related complications, including eye and kidney disease (i.e., retinopathy), cardiovascular disease, neurological problems, gangrene, and joint mobility problems (Dormal & LaPorte, 1985; Rubin & Peyrot, 1999; Silverstein, 1994).

#### The Diabetes Control and Complications Trial (DCCT)

For many years, endocrinologists, who specialize in the treatment of type 1 diabetes, have hypothesized that by maintaining blood glucose levels within or close as possible to the normal range, many of the diabetes-related complications could be either delayed, significantly minimized, or even eliminated (Johnson, 1995). A prospective study called the Diabetes Control and Complications Trial (DCCT) was purposely



conducted to evaluate this hypothesis (DCCT, 1994). Specifically, this study investigated the effects of “tight control” (i.e., maintaining blood glucose levels in or close to the normal range) versus “conventional care” in a group of adolescents’ aged 13 to 17 years (DCCT, 1994). Adolescent patients were randomly assigned to either the “conventional care” condition (i.e., one or two daily injections of exogenous insulin and only one daily check of blood glucose level) or the “intensive therapy” condition. The intensive therapy condition required participants to administer three or more daily injections of insulin. To ensure that participants in the intensive therapy condition were obtaining “tighter” metabolic control, participants were also required to monitor their blood glucose levels at least four times per day. The positive effects of frequent monitoring of blood glucose levels were clearly demonstrated in the DCCT study. Adolescent patients assigned to the “intensive therapy” condition significantly reduced the onset or risk of developing neurological and other types of macrovascular complications. For example, the intensive therapy condition reduced the risk of developing retinopathy by 53% (DCCT, 1994).

#### Defining Treatment Adherence

Researchers have used a variety of different definitions for conceptualizing “treatment adherence” (La Greca & Schuman, 1995). The majority of investigators have elected to define treatment adherence as “the extent to which a person’s behavior . . . coincides with medical or health advice” (Haynes, 1979, pp. 2-3). One particular problem with this approach to defining adherence is related to the fact that many individuals, even with the same medical diagnosis (e.g., type 1 diabetes), may be prescribed different medical regimens (La Greca, 1990; La Greca & Schuman, 1995). In addition, due to the fact that many medical regimens are complex, this definition may include a number of different types of adherence behaviors, including taking medications (i.e., pills, daily

insulin injections), monitoring blood glucose levels, exercising, following prescribed diets, completing self-monitoring logs, and any other important lifestyle changes required by the medical regimen. In the present study, we will be focusing on only one individual treatment component (i.e., blood glucose monitoring) of the diabetes regimen. In terms of blood glucose monitoring, the DCCT study clearly indicated that patients with type 1 diabetes should be checking their blood glucose levels four times per day. Consequently, we will define treatment adherence to blood glucose monitoring as the extent to which the patient's blood glucose checking behavior coincides with the standard recommended frequency of 4 checks per day.

Three main strategies have been used to operationalize adherence behavior. The first strategy involves classifying adherence into different categories. Using a categorical approach, a patient may be labeled as "adherent" or "nonadherent" by establishing some type of criterion or cut-off score (Phipps & DeCuit-Whalley, 1990). For example, patients who remember to take their medications only 50% of the time may be grouped into the nonadherent category. Second, investigators have taken a more comprehensive approach that considers all behaviors required in a medical regimen (e.g., taking required dosage of medications, monitoring blood glucose levels, completing self-monitoring tasks). By using this approach, an overall index score can be calculated to represent the patient's degree of overall compliance with the treatment regimen (Becker, Drachman, & Krischt, 1972). The third approach, which operationalizes adherence on a continuous scale, involves calculating adherence rates for specific behaviors required in the medical regimen (Carney, Schechter, & Davis, 1983; Johnson et al., 1986; Lowe & Lutzker, 1979; Rapoff, Lindsley, & Christophersen, 1984; Rapoff, Purviance, & Lindsley, 1988).

For example, an investigator may calculate an overall adherence rate by dividing the number of adherence behaviors (i.e., swallowing medications) completed by the patient by the number of pills prescribed each week. Using this methodology, separate adherence rates can be calculated for each of the different components of the medical regimen (Johnson, 1995). Compared to the other approaches, this latter approach has the distinct advantage over other methods because of its increased objectivity by individually monitoring one or more components of the medical regimen. In the proposed study, adherence to blood glucose monitoring will be operationalized on a continuous scale of measurement.

#### Assessment of Treatment Adherence

As many authors point out, one of the more difficult challenges facing pediatric psychologists who are conducting applied research involves the issue of how to actually measure treatment adherence (La Greca, 1990a; La Greca & Schuman, 1995). As in all clinical research, it is extremely important to obtain reliable and valid assessments of your target behavior. La Greca and Schuman (1995) outlined some of the more commonly used assessment methods in treatment adherence research, which include drug assays, patient and parental verbal report, adherence ratings by health care professionals, pill counts, and electronic monitoring devices (i.e., blood glucose monitors). Many of these methods have their own distinct advantages and limitations. For example, although verbal self-reports by the patient are relatively easy to obtain, they are often biased in socially desirable ways and tend to overestimate the true level of treatment adherence (Rapoff & Christophersen, 1982).

Rapoff (1999) proposes that there is no “gold standard” for measuring treatment adherence. However, Rapoff (1999) and Lemanek, Kamps, and Chung (2001) posit that

assessment of treatment adherence should consist of automated monitoring through electronic devices (i.e., blood glucose monitors), structured telephone interviews on a frequent basis, periodic checks by parents to ensure regimen tasks are being completed, and frequent checks through blood assays to verify that the medications are being ingested. By and large, blood assays are recognized as being one of the more reliable and objective methods for quantifying treatment adherence. With type 1 diabetes, a sample of blood is often taken during the patient's clinic visit to obtain a laboratory index of metabolic control (i.e., glycosylated hemoglobin A<sub>1c</sub>). Research has shown that this is a more reliable indicator of treatment adherence than verbal reports by the adolescent patient or their parents. Even when downloaded data is obtained from the blood glucose monitors, the reliability of the data can be questioned as many youngsters with type 1 diabetes may know how to manipulate the monitors (i.e., test someone else's blood, use water on the reagent strip to obtain a better reading).

### Interventions for Enhancing Treatment Adherence

Intervention strategies aimed at improving treatment adherence can be generally categorized into one of the following categories: (1) educational; (2) organizational; and (3) behavioral (La Greca & Schurman, 1995; Lemanek, 1990; Lemanek, Kamps, & Chung, 2001; Rapoff & Barndard, 1990). We will briefly review several studies conducted in each these categories.

### Educational Interventions

A large number of published studies have incorporated educational components into their intervention designs. The foremost goal of educational approaches is to ensure that patients' and families' know how to carry out the medical regimen effectively (La Greca & Schuman, 1995). At the time of initial diagnosis education is particularly

important, even more so with complex medical regimens. Patients and families require knowledge and skills to recognize disease-related symptoms and complications, to perform complicated tasks (e.g., administering insulin injections), and to efficiently organize their schedules around the timing of medications (La Greca & Schuman, 1995; Lemanek, Kamps, & Chung, 2001). With complex medical regimens, it is even more crucial for patients to receive some type of educational training. Education components can be provided through verbal instruction, videos, and other written materials (Lemanek, Kamps, & Chung, 2001). For example, Gilbert et al. (1982) used an educational film procedure to teach children aged 6 to 9 years how to perform daily injections of insulin. The results of this study suggested that older girls obtained higher scores on a measure of self-injection skills; however, younger girls and boys did not benefit as much from this procedure (Gilbert et al., 1982).

The overall assumption of educational approaches is that by educating patients and families about the disease, positive changes in adherence behaviors will follow. However, many authors argue that interventions that rely solely on educational approaches are not sufficient in increasing adherence behaviors, especially for complex medical regimens (La Greca & Schuman, 1995; La Greca & Skyler, 1991). Many researchers have concluded that education-alone interventions need to be complemented with additional treatment components, including increased social support, parental monitoring, family therapy, problem solving, and operant-based reinforcement procedures (La Greca & Skyler, 1991; La Greca & Schuman, 1995; Lemanek, Kamps, & Chung, 2001).

### Organizational Interventions

Organizational interventions strategies focus on changing specific components of the medical regimen or the way in which the office-based visits are conducted. For example, researchers have simplified various components of the diabetes regimen by providing self-monitoring forms, calendars, pill counters, or schedules for administering medications, and other written instructions to follow (Johnson, 1995). In one study conducted by Anderson, Brackett, Ho, and Lafel (1999), adolescents in a “teamwork intervention” significantly improved their metabolic control when compared to those assigned to a “control condition”. The teamwork intervention condition consisted of written materials emphasizing the importance of family teamwork and strategies for avoiding parent-adolescent conflicts. This intervention was unique in that it was cost-effective and relatively easy to implement in the context of the general medical setting.

### Behavioral Interventions

Interventions using behavior modification principles consistently have obtained the most positive outcomes in improving treatment adherence, especially when only one component of the medical regimen is targeted (Gross et al., 1985). When more than one treatment component is targeted, more inconsistent results have been obtained (Anderson et al., 1989). The majority of these types of interventions have enhanced treatment adherence by using reinforcement-based contingencies (Johnson, 1995; La Greca & Schuman, 1995; Lemanek, Kamps, & Chung, 2001). In many of these studies, researchers used positive reinforcement to increase the frequency of the targeted adherence behavior. Below, we will review a sample of studies that have achieved success with reinforcement-based interventions.

### Reinforcement-Based Interventions

Intervention strategies that rely on reinforcement-based principles have had the most success when only one treatment component (i.e., medication compliance) is targeted (Rapoff, 1989; Rapoff, Purviance, & Lindsley, 1988). Carney, Schechter, and Davis (1983) conducted a study in which they applied an intervention consisting of two main components – parental contingent praise and a token economy program (i.e., points). The intervention was designed to increase self-monitoring of blood glucose levels. Significant improvements in blood glucose monitoring for two of the three subjects were obtained during intervention and at a 4-month follow-up session. With a larger sample size, Wysocki et al. (1989) conducted a similar study by offering monetary rewards to adolescents when they completed their blood glucose checks. Higher rates of blood glucose monitoring were obtained when the participants received the added incentives than when compared to those who did not receive such incentives.

Similarly, Rapoff, Purviance, and Lindsley (1988) and Rapoff, Lindsley, and Christophersen (1984) conducted several studies investigating the effectiveness of positive reinforcement (i.e., praise by parents) and a token economy program (i.e., tokens) in increasing medications and splint wearing compliance among children diagnosed with juvenile rheumatoid arthritis (JRA). The investigators of these studies indicated that behavioral strategies were quite effective in improving medication compliance. A large number of published studies have documented improved adherence to a variety of regimen tasks, including following dietary guidelines, exercising, weight reduction, and appointment keeping (Finney, Lemanek, Brophy, & Cataldo, 1990; Greenan-Fowler, Powell, & Varni, 1987; Da Costa, Rapoff, Lemanek, & Goldstein, 1997; Killam, Apodaza, Manella, & Varni, 1983; Magrab & Papadopoulou, 1977).

### Behavioral Family Systems Therapy (BFST)

In another line of research, Wysocki et al. (2001a; 2001b; 2000; 1995) have investigated the effectiveness of Behavioral Family Systems Therapy (BFST). During the adolescent years, health care professionals and parents often hold expectations that adolescents will begin to take greater individual responsibility for managing their medical condition (Anderson et al., 1990; Wysocki et al., 1992). The adolescent years are characterized by an increased push for independence; consequently, this time period may result in increased levels of parent-adolescent conflict (Arnett, 1999). In both cross-sectional and prospective research, higher rates of parent-adolescent conflict have been found to be significantly associated with poorer treatment adherence and metabolic control, and an increased risk for developing many diabetes complications (Bobrow, AvRuskin, & Siller, 1985; Gustafsson, Cederblad, Ludvigsson, & Lundin, 1987; Hauser, Jacobson, Lavori, Wolfsdorf, Herskowitz, Milley, & Wertlieb, 1990; Koski, Ahlas, & Kumento, 1976; Lorenz & Wysocki, 1991; Miller-Johnson, Emery, Marvin, Clarke, Lovinger, & Martin, 1994; Wysocki, 1993).

Using BFST, Wysocki and colleagues attempted to reduce the level of parent-adolescent conflicts within the family system. These investigators hypothesized that an intervention strategy designed to reduce the level of parent-adolescent conflict within the family system may improve treatment adherence to the diabetes regimen. BFST consists of four treatment components: (a) problem-solving training; (b) communication skills training; (c) cognitive restructuring; and (d) functional and structural family therapy (Wysocki et al., 2001). Results of this research suggest that BFST is quite effective in improving the quality of parent-adolescent relationships among adolescents with type 1



diabetes. Furthermore, increased treatment adherence rates were evident for many participants at follow-up sessions (Wysocki et al., 2001; Wysocki et al., 2000).

#### Antecedent Prompting Interventions

Although the studies reviewed above have clearly documented the efficacy of behavioral strategies, one disadvantage is the relatively high level of physician, patient, and parental involvement that is required to implement the interventions. Such labor-intensive procedures may not be the most efficient and cost-effective strategies to use in the context of real-world medical settings. Another effective behavioral strategy that has not been widely applied in pediatric settings is the use of antecedent prompting procedures. Antecedent prompting generally involves providing patients with a visual cue (e.g., written or verbal reminder) or other type of prompt to remind the patient to complete a specific management task. A prompt is a supplemental stimulus that increases the probability of performing the appropriate response (Touchette & Howard, 1984).

Few studies to date have examined the effectiveness of antecedent prompting procedures in improving treatment adherence to prescribed medical regimens. In one of the few studies on treatment adherence that has used antecedent prompting procedures, Lowe and Lutzker (1979) used a written memo (i.e., written prompt) to increase adherence to urine testing, foot care, and dietary-related tasks in a 9 year-old girl diagnosed with type 1 diabetes. The written memo (i.e., prompt) was posted in easy-to-find locations, including the kitchen and bathroom. The memo contained a list of “self-care tasks” that needed to be completed on a daily basis. If the subject engaged in noncompliant behavior, the subject’s mother would provide a verbal prompt to complete the required task (Lowe & Lutzker, 1979). Significant improvements were found in the girl’s adherence to dietary-related tasks. No significant effects were evident in her

adherence to urine testing or foot-care (Lowe & Lutzker, 1979). However, after implementing a token economy program, the girl's adherence rates in these other areas improved significantly (Lowe & Lutzker, 1979).

Wong, Seroka, and Ogisi (2000) used a written checklist prompt in a memory-impaired patient with type 1 diabetes to increase adherence to the blood glucose monitoring component of the medical regimen. The written checklist consisted of visual stimuli designed to improve performance to blood glucose monitoring. Results of this study showed that an inexpensive and portable written checklist prompt could be used to increase adherence to an individual treatment component in a patient with diabetes and severe memory impairment.

In a more recent study, Berlant (2004) investigated the effects of two different types of behavioral prompts on the level of treatment adherence to the exercise component of the diabetes regimen. The two behavioral prompts were delivered on a bi-weekly basis through telephone contacts. Participants were randomly assigned to one of two conditions. One group received "motivational enhancement prompts", while the other group received "standard behavioral prompts." Results from this study indicated improvements in the exercise level for both the standard behavioral and the motivational enhancement prompt; however, greater levels of behavioral change were found with the motivational enhancement prompt. The results of this study suggest that an antecedent prompt delivered through bi-weekly telephone calls can be effective in enhancing treatment adherence to the exercise component of the diabetes regimen.

Antecedent prompting procedures have also been used more widely in other areas of research. For example, antecedent prompting procedures have been found to be

effective in improving various self-management tasks among children with severe intellectual disabilities (Lancioni, O'Reilly, & Campodonico, 2002; McClannahan & Krantz, 1997; Taylor & Levin, 1998). Lancioni, O'Reilly, and Campodonico (2002) investigated the efficacy of a verbal prompt with an individual diagnosed with multiple disabilities. In this study, the investigator used verbal prompts to significantly increase the individual's performance in various self-help tasks (i.e., dressing, turning on the water tap, washing hands, brushing teeth, etc.). The verbal prompts were also automatically delivered through portable paging technology. The results of this study suggest that the paging intervention was effective in improving the individual's performance in completing various self-help tasks.

Other researchers have also used antecedent prompting strategies to increase social interactions in children diagnosed with autism and other developmental disorders. Investigators presented either textual or tactile prompts to increase the frequency of verbal initiations (Krantz & McClannahan, 1998; McClannahan & Krantz, 1997; Taylor & Levin, 1998, Shabani, Katz, Wilder, and Beauchamp, 2002). The prompts used in these studies consisted of printed words and/or pictures on index cards. The tactile prompts, which were delivered through portable paging technology, were in the form of a beeper sound and/or vibration. A remote control device activated the tactile prompts. Shabani et al (2002) and Taylor and Levin (1998) concluded that tactile prompts are an effective strategy for increasing verbal initiations in children with developmental disabilities.

Antecedent prompting procedures have also been applied in other settings to increase various safety-related behaviors in adults. For example, Austin, Alvero, and Olson (1998) conducted a study investigating the effectiveness of a verbal prompt in

increasing safety belt use among patrons at a local restaurant. As patrons of the restaurant exited the restaurant, hostesses provided a verbal prompt by stating, “Don’t forget to buckle up” (Austin, Alvero, & Olson, 1998). The prompting intervention increased safety belt use from 57% at baseline to 77% during the intervention condition (i.e., prompting conditions). The results of this study clearly demonstrate the effectiveness of a verbal prompt in increasing safety-related behavior. Other researchers in this area have also obtained similar results with verbal prompts (Engerman, Austin, & Bailey, 1997; Geller, Johnson, & Pellton, 1982). The authors of these studies note that verbal prompts are particularly appealing, as they have been shown to be a cost-effective method for improving safety-related behaviors.

Antecedent prompting procedures may have several advantages over other reinforcement-based interventions. First, they rely less on extensive physician, patient, and parental involvement. Second, antecedent prompting strategies may be more cost-effective and less time consuming, especially if the prompts are delivered through automated paging technology.

Antecedent prompting procedures also encourage patients to take more responsibility in the management of their disease. With adolescent populations, taking increasing responsibility in managing their diabetes regimen may be particularly crucial. As children get older, parents and health care professionals may develop higher expectations for the young adolescent to assume greater independence in carrying out diabetes-related tasks. When such tasks are not adhered to satisfactorily, greater levels of parent-adolescent conflict may ensue (Wysocki et al., 2001). Research has consistently revealed that higher levels of parent-adolescent conflict are significantly associated with

poorer treatment adherence among adolescent patients with type 1 diabetes (Bobrow, AvRuskin, & Siller, 1985; Davis et al., 2001; Gustafsson, Cederblad, Ludvigsson, & Lundin, 1987; Hauser et al., 1990; Kosi, Ahlas, & Kumento, 1976; Lorenz & Wysocki, 1991; Miller-Johnson, Emery, Marvin, Clarke, Lovinger, & Martin, 1994; Wysocki, 2000a; 2000b; 2001).

It is reasonable to hypothesize that an intervention that relies less on parental involvement may potentially reduce the level of parent-adolescent conflict, which may potentially enhance treatment adherence among adolescent patients with type 1 diabetes. As Wysocki and colleagues have demonstrated, reducing the level of parent-adolescent conflict has the potential to enhance treatment adherence at follow-up sessions (Wysocki et al, 2001). Therefore, as La Greca and Schuman (1995) suggest, antecedent prompting procedures (i.e., visual cues, written reminders) may be particularly appropriate in cases where family members are attempting to increase the adolescent's involvement in the medical regimen. Furthermore, prompting procedures may allow for more effective transfer of stimulus control to stimuli in the adolescent's natural environment. That is, prompting procedures may effectively increase adolescent's adherence during times when they cannot be closely monitored (i.e., when they are away from home). Use of automated paging technology may also be a particularly useful way of delivering prompts in these situations.

#### Limitations of Previous Research

Although some of the studies reviewed above used single-subject research designs, the majority of the published studies on treatment adherence have used large-scale correlation designs (Howard, Moras, Brill, Martinovich, & Lutz, 1996; Lemanek, Kamps, & Chung, 2001). Many of these studies have utilized inconsistent assessment

measures, treatment protocols, and research designs, which limit the utility of the research findings (Lemanek, Kamps, & Chung, 2001). Lemanek, Kamps, & Chung (2001) also point out that previous research on treatment adherence has focused more on identifying behavioral correlates of treatment nonadherence with little emphasis on the actual process of designing effective intervention strategies to modify the behavior of interest. In addition, in many of the studies reviewed above, investigators combined multiple treatment components (i.e., education, praise, token economy programs) to improve treatment adherence. As a result, it is difficult to determine what specific components of the intervention package are effective (La Greca & Schuman, 1995). The present study used a series of single-subject research designs to redress some of these deficiencies by allowing us to more specifically address the effectiveness of an antecedent prompting intervention specifically. It will also facilitate a more in-depth examination of the treatment progress for each individual participant. Since this intervention approach used in this study is novel, a single-subject research design approach also allowed us to pay closer attention to what modifications would be needed to successfully implement the intervention in a real-world medical setting.

#### Statement of Purpose

This study evaluated the impact of a behavioral procedure on treatment adherence in young individuals diagnosed with type 1 diabetes who demonstrated poor treatment adherence to the blood glucose monitoring component of the medical regimen. By using automated paging technology, antecedent prompts were delivered to encourage and promote increased blood glucose checking. An antecedent prompting procedure was selected as the intervention strategy for several reasons. We believe that many parents forget to provide verbal prompts or the teenagers themselves forget to complete their

blood glucose checks, perhaps due to a busy school, work, family, or social schedule (Rapoff, 1999). The antecedent prompting procedure was selected as it may be an effective way to remind adolescents to check their blood glucose levels when away from home. A portable and automated intervention strategy also seemed to be a feasible treatment option for promoting increased independence to the medical regimen. In light of the managed health-care environment, the behavioral approach used in this study was also seen as advantageous because the intervention would be time-efficient and relatively easy to implement in the context of the general medical setting.

There were several aims of this study. A primary aim of this study was to test the feasibility of implementing an antecedent prompting procedure (i.e., prompts) delivered through automated paging technology in the context of a real-world medical setting. A second aim was to identify whether or not patients would be interested in an innovative intervention designed to improve blood glucose monitoring. As with all studies, another objective was to identify what modifications would be needed in the research design and intervention to successfully implement the intervention with this population. And finally, this study was interested in obtaining preliminary data on the effects of the intervention for improving blood glucose monitoring and health outcomes. As this was a study investigating the use of an innovative intervention approach in a real-world medical setting, more detailed information on the practical application of the intervention will be provided as needed.

## Method

### Participants

Six participants were recruited from an endocrinology clinic located in a tertiary medical center, situated in a relatively large Midwestern city. By using standard clinic-

based procedures, board-certified endocrinologists completed medical chart reviews and informal evaluations to determine eligibility. Patients and families were provided with a recruitment script and informational flyer inviting them to contact the student investigator by phone (see Appendix A; Page 74). Upon being contacted by the family, the student investigator provided additional information about the study and scheduled an office-based visit (see Appendix B; Page 78). To be eligible for the study, the patients had to meet all of the following criteria: (a) diagnosis of type 1 diabetes for at least one year; (b) at least be 12-years-old; (c) at least one annual office visit to the endocrine clinic during the past year; (d) no diagnosis of any other serious medical conditions; and (e) no newly diagnosed or severe psychiatric conditions (i.e., cognitive impairment). Patients also had to demonstrate an average adherence rate of 50% or less over a 3-month period.

Adherence rates were calculated by dividing the total number of blood glucose checks completed by the number of checks prescribed for a 3-month period and multiplying by 100%. We recruited only those patients with extremely low adherence rates to the blood glucose monitoring component of the diabetes regimen because we wanted to evaluate whether or not the intervention would produce positive treatment outcomes for a difficult-to-treat population (i.e., extremely poor treatment adherence). If positive treatment outcomes were found within this population, it was believed that the intervention may be effective for patients with higher treatment adherence rates as well.

The minimum age requirement was selected for several reasons. First, adolescents 12-years-old or older are often encouraged to take increased individual responsibility in the management of the diabetes regimen. As adolescents achieve more independence from their families, health care professionals will have greater expectations for them to



successfully adhere to all treatment components of the medical regimen (Anderson, Auslander, Jung, Miller, & Santiago, 1990). Second, we recruited adolescents because the extant literature has consistently shown that higher levels of parent-adolescent conflict are often associated with lower treatment adherence rates and poorer metabolic control (Anderson, Brackett, Ho, & Laffel, 1999). A third reason for selecting adolescents was to ensure that they had the requisite skills to properly operate the electronic pagers in a responsible manner.

### Equipment

Each participant received a Motorola™ alphanumeric pager with numeric and text messaging capability. Each pager had a specific pager number, internet email address, and a quarterly service contract with statewide and national coverage plans. Statewide and national coverage plans were selected in the event that participants traveled far away from home on vacations or school trips. The service plan also consisted of an unlimited number of numeric and/or text pages per month. A software program (PageMaster™) was installed on a Dell™ desktop computer, which functioned by automatically paging the participants at pre-determined times through a standard computer modem. The PageMaster™ software program was set-up to automatically dial-up the participant's pager number and deliver a prompt (i.e., "Megan. It is 8:00 AM. It is time to check your blood sugar level").

### Measures

Blood Glucose Monitoring. The primary dependent measure was the total number of blood glucose checks performed each week. Treatment adherence to blood glucose monitoring was assessed with a blood glucose monitor (i.e., meter), an electronic device that records and stores the exact date, time, and blood glucose level of each check. In

order to minimize the research demands and increase the overall convenience for families, clinic visits and home-based visits were not completed to download the monitor data. Rather, participants verbally reported the number of blood glucose checks performed during scheduled telephone contacts with the student investigator. While talking with the investigator on the phone, participants reviewed and verbally reported the stored data by viewing a digital display on their monitors. The exact time, date, and blood glucose level of each check was collected to evaluate the timing of the blood glucose checks and to assess for changes in metabolic control over time. To encourage accurate and honest reporting, participants were required to have the monitor in-hand during the telephone contacts and to precisely report the exact date, time, and blood glucose level of each check. Participants were also told that medical chart reviews would be completed to cross-check for accuracy of verbal reporting. Although parent self-report of the monitor data may have reduced the risk of socially biased responding, this option was not selected since this study was specifically interested in promoting increased adherence among adolescents.

Demographic Questionnaire. Demographic questionnaires were completed at study enrollment to collect personal information on the families, largely for descriptive purposes. Participants and their respective parent(s) reported standard demographic information, including age, gender, ethnicity, employment status, and educational level. Specific information was also obtained on the parent-adolescent relationship, the adherence level to other treatment components of the diabetes regimen, the presence of conflicts surrounding the medical regimen, the situations in which blood glucose

monitoring was less likely to be completed, and whether or not parental verbal reminders were used to prompt the completion of the diabetes-related tasks.

Teen Adjustment to Diabetes Scale (TADS; Wysocki, 1993). While the primary goal of this study was to evaluate the impact of the intervention on blood glucose monitoring, additional measures were used to gather qualitative data on other ancillary behaviors that may have been impacted by the intervention. The TADS is a 21-item Likert-type scale that yields scores on both the parent's and adolescent's adjustment over the past 3-months in the following areas: Behavioral, Affective, and Attitudinal (Wysocki, 1993). The TADS was selected to gather pilot data to evaluate the potential effects of the intervention on other diabetes-related behaviors and attitudes. Higher total scores on the TADS indicate better overall adjustment to the diabetes regimen over the past 3 months. This measure has been evaluated on more than 600 participants and has been shown to have good internal consistency (alpha = .88 for adolescents; alpha = .91 for mothers; alpha = .84 for fathers; Wysocki et al., 2001).

Self-Care Inventory (SCI; Greco et al., 1990). The SCI is a 14-item instrument designed to assess adolescents' level of treatment adherence to the diabetes regimen for the past 3 months. The SCI has been demonstrated to significantly correlate with hemoglobin A<sub>1c</sub> values, an objective laboratory measure of metabolic control. Higher scores on the SCI indicate better overall treatment adherence to the medical regimen. The SCI has both a parent and adolescent form. The SCI has demonstrated internal consistency (Greco et al., 1990). The SCI was used to assess for intervention effects not only on blood glucose monitoring, but to other components of the medical regimen, including diet, exercise and insulin injections.

Diabetes Responsibility and Conflict Scale (DRC; Rubin, Young-Hyman, & Peyrot, 1989). Because higher rates of parent-adolescent conflict have been found to be significantly associated with poorer treatment adherence and metabolic control, and an increased risk for developing negative health complications, the DRC was used to determine if the intervention had an ancillary impact on the level of parent-adolescent conflict. The DRC consists of items designed to assess the degree of conflict over 15 diabetes-related tasks. Higher scores on the DRC indicate greater levels of parent-adolescent conflict surrounding the diabetes regimen. The DRC has demonstrated high internal consistency ( $\alpha = .92$  for adolescents;  $\alpha = .86$  for mothers;  $\alpha = .89$  for fathers; Wysocki et al., 2001).

Medical Chart Reviews. Medical chart reviews as well as contact with pertinent health care professionals were used to obtain data on age of diagnosis, hemoglobin A<sub>1c</sub> values, and number of emergency room visits and hospitalizations in the previous year. Metabolic control was measured by hemoglobin A<sub>1c</sub> values, an indirect and retrospective objective laboratory measure of average blood glucose levels over the previous 2- to 3-months. Higher A<sub>1c</sub> values indicate higher blood glucose levels, thus indicating poorer metabolic control. Medical chart reviews were also used to collect available follow-up data on the frequency of blood glucose checking, appointment keeping in the endocrine clinic, and the number of hospitalizations or emergency room visits since study participation.

#### Procedure

Meter (Pre-Baseline). At a pre-baseline session, informed consent to participate in the study was obtained during a brief office-based visit, which ranged in time from 45 to

60 minutes (see appendix D; Page 97). Adolescents and their respective parent(s) were asked to complete the demographic and self-report study questionnaires. Specific instructional support was then provided about the telephone contact procedures, intervention (i.e., prompts delivered through automated paging technology), and the operation and rules of the alphanumeric electronic pagers (see appendix E; Page 110). An operation manual containing detailed instructions on the available pager features were provided to the participants. Brief practice sessions were also conducted to familiarize the participants with the operation of the pager and to ensure that they clearly understood how to properly operate the pager in a responsible and safe manner. Behavioral rehearsal was used to verify that the participants could correctly report the exact date, time, and blood glucose level of each check by viewing the built-in digital display on their blood glucose monitors. Participants were informed that the investigator would complete telephone contacts every 3-days at agreed-upon dates and times. Participants also identified times at which they usually eat breakfast, lunch, and dinner, and when they typically go to bed each night. Participants were asked to record four convenient times to receive the prompts designed to remind them to complete the recommended number (i.e., 4 checks) of blood glucose checks per day. Before leaving, each participant was provided with a Motorola<sup>TM</sup> alphanumeric pager.

Telephone contacts were conducted every three days to collect baseline data on the frequency of blood glucose monitoring (see appendix F; Page 115). The exact date, time, and blood glucose level of each check was recorded on a data collection form (see appendix G; Page 117). Qualitative data on the number of days that the participants' reportedly adhered to other diabetes-related tasks (i.e., diet, exercise, insulin injections)

were recorded on a second data collection form (see Appendix G; Page 117). In order to facilitate consistent telephone contacts, an effort was made to contact the participants at convenient times. When unforeseen circumstances impacted the availability of the participants, several attempts were made to contact the participants at agreed-upon times. If participants refused to complete the telephone contacts or could not be reached for an extended period of time, participants were officially dropped from the study, with the exception of family emergencies or extended vacations.

Baseline. During the baseline phase, participants did not receive any prompts (i.e., pages) nor did they have access to the free paging service. No attempt was made during baseline to improve blood glucose monitoring. Participants were contacted by telephone every 3-days to determine the total number of blood glucose checks performed each day. A probe assessment approach (i.e., every 3 days) was selected because it has been shown to approximate data collected on a more continuous basis (Bijou, Peterson, Harris, Allen, & Johnson, 1969). In addition, it was believed that probe assessments would significantly reduce the potential risk of participant reactivity impacting blood glucose monitoring during the baseline phase (Kazdin, 1982). Baseline data were graphed and continually monitored, and visual inspection was used to assess for stability, trend, and variability in the data. If baseline data declined by more than 20% (i.e., downward trend), the intervention was immediately implemented. A decreasing trend was determined on an individual basis, taking into consideration the participant's initial adherence rate in the 2-weeks prior to study entry.

Intervention. After baseline, participants were contacted by telephone and informed by the student investigator that their alphanumeric pager had been activated and

that they would start receiving prompts (i.e., pages) the following day. While on the phone with the investigator, a confirmation prompt was sent to the participant to confirm that the electronic pager was functioning properly. The main goal of the intervention (i.e., antecedent prompting procedure) was to provide antecedent prompts in the form of text messages (i.e., “Megan. It is 8:00 AM. It is time to check your blood glucose level”) to remind participants to perform the recommended 4 blood glucose checks per day. The 4 prompts were sent at the predetermined times identified during the office-based visit. The times of the prompts were selected to closely approximate the times in which the participants typically ate their meals (i.e., breakfast, lunch, dinner) and went to bed each night. Standard medical guidelines indicate that these are the most ideal times to perform blood glucose monitoring. It was also anticipated that these paging times would not significantly interfere with the participant’s academic functioning in school. Participants were asked to carry the pager with them at all times, even when away from home or at school. In order to increase treatment integrity, each participant was provided with a specific pager number and encouraged to freely use the pager service with their family and friends. During school hours, participants were instructed to set the silent mode feature and to not abuse or misuse the paging service. Although many school districts allow the use of electronic devices in school settings for medical reasons, an official letter was provided to each participant in the event that school officials questioned the use of the pager (see appendix H; Page 118).

During the intervention phase, participants were sent four prompts at pre-determined times. For example, one participant in this study chose to be paged at the following times: (a) 7:30 AM; (b) 12:00 PM; (c) 5:00 PM; and (d) 9:00 PM. Telephone

contacts were completed once per week to collect intervention data on the total number of blood glucose checks performed each week. As in the baseline phase, the exact time, date, and blood glucose level of each check were collected from the participants. For this study, a positive treatment outcome was defined as a 30% or more increase in the frequency of blood glucose monitoring from the baseline to the intervention phase. The intervention remained in effect for each participant for several weeks, unless a significant negative trend was found in the data, at which time the participant was officially dropped from the study and referred back to the endocrinologist(s) for additional treatment options. If visual inspection indicated a significant treatment outcome, the intervention was gradually withdrawn through the use of a 3-week prompt fading procedure. During prompt fading, prompts were sent on a random basis based upon the predetermined times. A block-randomization procedure was used to randomize the test prompt times because it was expected that random prompts would be less resistance to extinction. The fading procedure consisted of 3 prompts per day for the first week, 2 prompts per day during the second week, and 1 prompt per day during the final week. After completing the intervention phase, participants returned to the baseline phase. Medical chart reviews were used to collect available 3- and 6-month follow-up data on blood glucose monitoring.

### Experimental Design

A series of single-subject designs (ABAB; AB) were used to evaluate the effects of the prompts (i.e., antecedent prompting procedure) on blood glucose monitoring and blood glucose levels. Initially, a multiple baseline across-participants design was planned for use in this study, but was discontinued due to ceiling effects obtained during baseline. The total number of blood glucose checks performed in the 2-weeks before study entry



was also collected and graphed to establish a pre-baseline meter condition. Although 3- and 6-month follow-up reviews were planned to collect post-intervention data, medical chart reviews did not reveal any long-term follow-up data on blood glucose monitoring. However, follow-up hemoglobin A<sub>1c</sub> values for several participants were obtained by medical chart review to assess for changes in metabolic control.

## Results

### Participant 1

Megan was a 14-year-old girl diagnosed with type 1 diabetes for approximately 5 years. Megan did not have any hospitalizations over the past year. She had relatively stable, high hemoglobin A<sub>1c</sub> values in the 2 years before study enrollment, ranging from 8.5 % to 11.2 %. Her pre-study A<sub>1c</sub> value of 11.2 % indicated an average blood glucose level of approximately 320 mg/dl in the 2- to 3-months before study enrollment. Megan obtained a baseline DRC total score of 60 (score range of 14 to 70), indicating a high level of parent-adolescent conflict surrounding the diabetes regimen. Her mother obtained a baseline DRC total score of 24, indicating a substantially lower reported level of parent-adolescent conflict. Megan's total scores on the SCI (score range of 14 to 70) and TADS (score range of 21 to 105) were 46 and 76, respectively. Total scores on the SCI and TADS for her mother were 44 and 70. Collectively, SCI and TADS results indicated less-than-ideal overall adjustment to and adherence to the medical regimen. Megan acknowledged that she sometimes purposely did not perform her blood glucose checks when angry at her parent(s) and during times of high levels of parent-adolescent conflict. Megan most often forgot to perform her blood glucose checks when at school, before meals, and occasionally at bedtime. Megan and her mother also reported that

verbal prompts were frequently used to prompt the completion of various diabetes-related tasks, including blood glucose checks and insulin injections.

Figure 1 shows Megan's weekly percentage adherence to blood glucose checks across meter, baseline, intervention, prompt fading, and return to baseline phases (see Appendix I; Page 123). During the meter phase, blood glucose checking was 28% and 21% of the recommended frequency (i.e., 4 checks per day or 28 checks per week) in the two weeks preceding study enrollment. During baseline, blood glucose monitoring increased to a high of 93% before the actual implementation of the paging intervention, which indicates a percentage improvement of 357%. Throughout the baseline condition, Megan repeatedly asked when her pager would be activated and explained that she was looking forward to using the free paging service with her family and friends. Since performance remained stable, even after a prolonged baseline, the paging intervention was implemented. During intervention, blood glucose checking increased by 4% (percentage improvement of 4%) and remained stable at nearly 100% for the first two weeks. Performance decreased from 93% to 79% (percentage decrease of 18%) during prompt fading, but increased slightly and remained relatively stable at approximately 82% (percentage increase of 4%) after return to baseline. Medical chart review revealed no follow-up data on blood glucose monitoring, due to Megan not bringing-in her blood glucose meter for a scheduled clinic visit.

Because of the ceiling effect found during baseline, the times of Megan's blood glucose checks were also examined in order to determine if the prompts had any impact on the timing of her checks. In order to determine if Megan became more regular in the timing of her checks, the number of blood glucose checks that fell within a defined target

range (i.e., check successfully completed within 15 minutes of the designated time) were calculated across the baseline and intervention phases. Results showed a modest increase in the timing of her blood glucose checks from baseline to the intervention phase. During baseline, 33% of her checks fell within the target range; during the intervention phase, 43% of her checks fell within the target range, indicating a 10% improvement in the timing of her checks.

Figure 3 shows the results of Megan's mean 7-day blood glucose levels across meter, baseline, intervention, and return to baseline. The horizontal line represents Megan's average blood glucose level ( $A_{1c}$  value of 11.2% = 320 mg/dl) for the 2- to 3-months prior to study entry. Examination of Megan's mean 7-day blood glucose readings shows substantial improvement in metabolic control. Mean 7-day blood glucose dropped from a high of 268 mg/ml to 168 mg/ml at the end of baseline, and to a low of 150 mg/ml at the start of the intervention. Mean 7-day blood glucose increased and then remained relatively stable at roughly 210 mg/ml. Following return to baseline, mean 7-day blood glucose was more variable, ranging from a low of 195 mg/ml to a high of 277 mg/ml. All of Megan's mean 7-day blood glucose values across experimental conditions were considerably below the approximate 320 mg/dl level that she maintained in the 2- to 3-months before study entry. Changes in  $A_{1c}$  values from study entry to follow-up were also examined. For Megan,  $A_{1c}$  values decreased from 11.2 % at study entry to 9.6 % at intervention completion. At a 4-month follow-up clinic visit, Megan's  $A_{1c}$  value remained stable at 9.7 %.

Follow-up questionnaire data were also obtained from Megan and her mother. For Megan, there was a 4-point increase on both the SCI and TADS, indicating a negligible

change in her overall adjustment and level of treatment adherence to the diabetes regimen. A 7-point drop was obtained on the parent version of the SCI, indicating a slight decline in Megan's overall level of treatment adherence as rated by her mother. In contrast, a 35-point drop was found in Megan's DRC score from pre- to post-intervention indicating that Megan was reporting a significant reduction in the level of parent-adolescent conflict surrounding the diabetes regimen.

### Participant 2

Sara was a 16-year-old girl diagnosed with type 1 diabetes for approximately 13 years. Medical chart review indicated that she did not have any emergency room visits or hospitalizations over the past year. She had stable, relatively high hemoglobin A<sub>1c</sub> values in the 2 years prior to study entry, ranging from 10% to 11.1%. Her pre-study A<sub>1c</sub> value of 9.0% indicated an average blood glucose level of approximately 240 mg/dl in the 2- to 3-months before study enrollment. Sara had a baseline DRC total score of 20 (score range of 14 to 70), indicating a mild level of parent-adolescent conflict surrounding the diabetes regimen. In contrast, her mother had a baseline DRC total score of 56, suggesting that Sara's mother noted more significant problems with parent-adolescent conflict. Sara's total score on the SCI (score range of 14 to 70) and TADS (score range of 21 to 105) were 30 and 53, respectively. Total scores on the SCI and TADS for her mother were 44 and 69. Ratings on the SCI and TADS revealed less-than-ideal overall adjustment to and adherence to the medical regimen. Sara admitted that she sometimes deliberately did not check her blood glucose levels when mad or angry with her mother. Identified times or circumstances in which Sara most often forgot to perform her blood glucose checks included the following: at school; before breakfast; before dinner; when she felt fine;

when she forgot her diabetes supplies; when feeling sick; while hanging out with friends; and when she did not want to know her blood glucose level. Sara and her mother also indicated that verbal prompts were often provided to prompt blood glucose checking. The following written statement was also obtained from Sara: “I get irritated when they remind me to do my checks all of the time.” Sara’s mother also noted that she had recently stopped providing verbal reminders due to Sara becoming too upset and anxious.

Figure 1 shows Sara’s weekly percentage adherence to blood glucose checks across meter, baseline, and intervention phases. Data obtained from Sara’s blood glucose meter indicated that she was performing 11% to 14% of the recommended frequency in the 2-weeks prior to study enrollment. During baseline, performance increased to 25% of the recommended frequency, indicating a percentage improvement of 79% to 127% over pre-baseline levels. Implementation of the paging intervention increased blood glucose monitoring to 54% and 61% of the recommended frequency for the first two weeks of the intervention, indicating a percentage improvement of 116% to 144% over her baseline performance. A rapid decline to a low of 7% of the recommended frequency (percentage decline of 771%) was observed during the third and fourth week of the intervention, but performance increased to nearly 39% (percentage increase of 457%) for the two weeks prior to study withdrawal. The number of blood glucose checks that fell within the defined target range (i.e., check successfully completed within 15 minutes of the designated time) was also calculated across the baseline and intervention phases. During baseline, 14% of her checks fell within the target range; during the intervention phase, 24% of her checks fell within the target range, indicating a 10% improvement in the timing of her checks.

Sara's mean 7-day blood glucose readings across baseline and intervention conditions are shown in Figure 3. The horizontal line represents Sara's average blood glucose level ( $A_{1c}$  value of 9.0% = 240 mg/dl) in the 2- to 3-months preceding study entry. Mean 7-day blood glucose was at 175 mg/ml at baseline, increased to a high of 295 mg/ml during the second week of the intervention phase, and decreased to a low of 186 mg/dl at the fourth week of the intervention. At study withdrawal, mean 7-day blood glucose was at 222 mg/dl. Although Sara did not demonstrate improved metabolic control, four of her mean 7-day blood glucose values were below the approximate 240 mg/ml level (based on her pre-study  $A_{1c}$  value of 9.0%) that she maintained in the 2- to 3-months before study enrollment.

Return to baseline data were not available for comparison due to Sara dropping out of the study during the intervention phase. Medical chart review also indicated that she had not followed through with a clinic visit in the following 12-months after study drop out. Consequently, no follow-up  $A_{1c}$  values were available on Sara for comparison. Identified reasons for withdrawing from the study included time constraints and the inconvenience of the frequent telephone contacts and prompts.

### Participant 3

Debra was a 15-year-old girl diagnosed with type 1 diabetes for approximately 3 years. Since the time of diagnosis, Debra had a total of 7 hospitalizations. She had stable, relatively high hemoglobin  $A_{1c}$  values in the 2 years prior to study entry, ranging from 12.4 % to greater than 14.0 %. Her pre-study  $A_{1c}$  value of 13.5 % indicated an average blood glucose level of greater than 380 mg/dl in the 2- to 3-months before study enrollment. Debra had a baseline DRC total score of 21 (score range of 14 to 70),

indicating a mild level of parent-adolescent conflict surrounding the diabetes regimen. In contrast, her mother obtained a baseline DRC total score of 57, indicating a higher level of parent-adolescent conflict reported by the mother. Debra's total scores on the SCI (score range of 14 to 70) and TADS (score range of 21 to 105) were 31 and 55, respectively. Total scores on the SCI and TADS for her mother were 42 and 61, respectively. Self-report ratings by Debra and her mother revealed less-than-ideal overall adjustment and adherence to the medical regimen. Debra admitted that she had frequent conflicts with her parent(s) about checking her blood glucose levels and she sometimes intentionally did not complete her checks when she was angry with her parent(s). Identified times or circumstances in which Debra most often forgot to perform her blood glucose checks included the following: before bedtime and meals; while hanging out with friends; during the summer months; and when on a vacation or weekend trip. Debra and her mother indicated that parental reminders were often provided to prompt Debra to complete her blood glucose checks. Debra also acknowledged that she became angry with her parent(s) when she was reminded to complete various diabetes-related tasks, including her blood glucose checks.

Figure 1 shows Debra's weekly percentage adherence to blood glucose checks across meter and baseline phases. Results showed a positive trend in performance in the 2-weeks before study entry. During baseline, performance remained stable at nearly 100% for 1 week. Debra was dropped from the study after repeated efforts to contact her by telephone were unsuccessful. Although limited data was collected, results showed a rapid increase in performance immediately preceding study enrollment. At study entry, Debra obtained an A<sub>1c</sub> hemoglobin value of 13.5 %. Medical chart reviews completed at

3- and 6-months following participation in this study showed A<sub>1c</sub> values of 12.6 % and 14.0 %, respectively. Results indicate a 0.9 % decrease in her A<sub>1c</sub> value at 3-months, and a 0.5 % increase at 6-months when compared to her pre-study A<sub>1c</sub> value of 13.5%.

Medical chart review did not reveal any follow-up data on frequency of blood glucose monitoring. Medical chart review did not indicate any hospitalizations during study enrollment or follow-up.

#### Participant 4

Robert was an 18-year-old male diagnosed with type 1 diabetes for approximately 3 years. Since the time of diagnosis, Robert had a total of 4 emergency room visits and hospitalizations. He had fairly stable, high hemoglobin A<sub>1c</sub> values in the 2 years prior to study entry, ranging from 11.8 % to 13.9 %. His pre-study A<sub>1c</sub> value of 12.8 % indicated an average blood glucose level of greater than 345 mg/dl in the 2- to 3-months before study enrollment. Robert had a baseline DRC total score of 20 (score range of 14 to 70), indicating a low level of parent-adolescent conflict surrounding the diabetes regimen. His mother obtained a baseline DRC total score of 30, suggesting a slightly higher reported level of parent-adolescent conflict. Robert's total score on the SCI (score range of 14 to 70) and TADS (score range of 21 to 105) was 31 and 68, respectively. Total scores on the SCI and TADS for his mother were 33 and 33, respectively. Ratings on the SCI and TADS suggested less-than-ideal overall adjustment to and adherence to the medical regimen. Robert reported the presence of frequent conflicts and arguments with his parent(s) about completing his blood glucose checks. He also noted that he purposely did not check his blood glucose levels at times when angry with his parent(s) or after they had provided verbal reminders. Robert's mother indicated arguments about a variety of



diabetes-related issues, including blood glucose monitoring, recording levels in the log book, eating the proper foods, and remembering to take diabetes supplies to school. Robert most often forgot to perform his blood glucose checks before meals and at bedtime, while hanging out with friends, when he did not want to know his level, and when feeling sick. Robert estimated that he forgot to complete his blood glucose checks 16 to 20 times per week.

Robert's weekly percentage adherence to blood glucose checks across meter, baseline, and intervention phases are depicted in Figure 2. During the meter phase, Robert's performance was at 0 % and 4% of the recommended frequency for the 2-weeks prior to study enrollment. During baseline, performance remained stable at 4% of the recommended frequency for one week. Following the implementation of the intervention, performance increased to 25% of the recommended frequency for one week, indicating a percentage improvement of 525% from baseline to intervention. During the second and third week of the intervention, Robert's blood glucose meter failed, resulting in lost data. Anecdotal reports also indicated that he did not receive all of his prompts in the second- and third-week of the intervention phase due to him being "out-of-range" while spending vacation time in a remote location. Robert was dropped from the study after repeated attempts to contact him by telephone were unsuccessful. Anecdotal comments obtained from a health care team member revealed that Robert stopped participating in the study due to time constraints, boredom, and the inconvenience of the telephone contacts and prompts. The timing of his checks across baseline and intervention phases was also examined. During baseline and intervention phases, none of his checks falls within the target range.

Mean 7-day blood glucose was not calculated for the baseline phase since Robert only completed 1 blood glucose check (value of 432 mg/ml) during baseline. For the one-week of the intervention phase, mean 7-day blood glucose was 425 mg/ml. Robert obtained an A<sub>1c</sub> value of 12.8% at study enrollment. A medical chart review completed 4-months after study withdrawal revealed an A<sub>1c</sub> value of 12.7%, indicating no significant improvement in overall metabolic control. No follow-up data on blood glucose monitoring was obtained by medical chart review.

#### Participant 5

Susan was a 20-year-old female diagnosed with type 1 diabetes for approximately 13 years. Susan had recently stopped attending high school after completing the 11<sup>th</sup> grade. Susan had a total of 8 hospitalizations since diagnosis, but there were no hospitalizations in the year before study entry. She had relatively stable, high A<sub>1c</sub> values in the 2 years prior to study entry, ranging from 9.1 % to 11.1 %. Her pre-study A<sub>1c</sub> value of 11.1 % indicated an average blood glucose level of approximately 310 mg/dl in the 2- to 3-months before study entry. Susan had a baseline DRC total score of 18 (score range of 14 to 70), indicating a low level of parent-adolescent conflict surrounding the diabetes regimen. Her mother obtained a baseline DRC total score of 22, further suggesting a low level of parent-adolescent conflict. However, qualitative analysis of individual items revealed the presence of frequent parent-adolescent conflicts about blood glucose monitoring. Susan's total score on the SCI (score range of 14 to 70) and TADS (score range of 21 to 105) was 35 and 66, respectively. Total scores on the SCI and TADS for her mother were 37 and 65, respectively. Ratings on the SCI and TADS indicated less-than-ideal overall adjustment to and adherence to the medical regimen. Susan most often

forgot to complete her blood glucose checks before breakfast, when she felt fine, and when she did not want to know her blood glucose level. Both Susan and her mother indicated that verbal prompts were provided to encourage more consistent blood glucose monitoring, which often resulted in Susan getting mad or angry with her parents.

Susan's weekly percentage adherence to blood glucose checks across meter, baseline, and intervention phases are shown graphically in Figure 2. Performance was at 21% and 14% of the recommended frequency during the meter phase. During baseline, performance increased to 29%, indicating a percentage improvement of 38% to 107% over pre-baseline levels. Performance increased to 61% and 57%, respectively, for the first 2 weeks of the intervention, indicating a percentage improvement of 97% to 110% from baseline to intervention. Performance decreased to 46% of the recommended frequency during the third week, indicating a percentage decline of 33%. Susan dropped out of the study after only completing 3-weeks of the intervention phase. Susan anecdotally noted that she withdrew from the study due to time constraints and the inconvenience of the frequent telephone contacts and prompts. Examination of the timing of her checks across baseline and intervention phases were also completed. During baseline, 13% of her checks fell within the target range; during the intervention phase, 20% of her checks fell within the target range, indicating a 7% improvement in the timing of her checks.

Figure 3 shows the results of her mean 7-day blood glucose level across baseline and intervention phases. The horizontal line represents Susan's average blood glucose level ( $A_{1c}$  value of 11% = 310 mg/ml) in the 2- to 3-months preceding study entry. For Susan,  $A_{1c}$  values decreased from a high of 276 mg/ml during baseline, to a low of 225

mg/ml during the 2nd week of the intervention, and increased to a high of 328 mg/ml before dropping out. Follow-up A<sub>1c</sub> values were not available for comparison due to Susan not showing up for a clinic visit in the 12-months following study recruitment.

#### Participant 6

Gretchen was a 15-year-old female diagnosed with type 1 diabetes for approximately 13 years. She had 1 hospitalization over the last year. She had stable, relatively high A<sub>1c</sub> values in the 2 years prior to study entry, ranging from 9.2 % to 10.7 %. Her pre-study A<sub>1c</sub> value of 10.7 % indicated an average blood glucose level of approximately 310 mg/dl in the 2- to 3-months before study enrollment. Gretchen had a baseline DRC total score of 26 (score range of 14 to 70), indicating a mild level of parent-adolescent conflict surrounding the diabetes regimen. Her mother obtained a baseline DRC total score of 17, suggesting a lower reported level of parent-adolescent conflict. Gretchen's total score on the SCI (score range of 14 to 70) and TADS (score range of 21 to 105) were 39 and 69, respectively. Gretchen reported that she only performed her blood glucose checks 25 % or less than the recommended frequency. Total scores on the SCI and TADS for her mother were 45 and 66, respectively. As was found with the other study participants, ratings on the SCI and TADS by Gretchen and her mother indicated less-than-ideal overall adjustment to and adherence to the medical regimen. Gretchen most often forgot to complete her blood glucose checks at school, when she forgot her equipment, before dinner and bedtime, at an evening dance or party, when hanging out with friends, and when she felt embarrassed. Gretchen noted that her parent(s) frequently provided verbal reminders for her to complete her blood glucose

checks more consistently. She also acknowledged that she purposely did not complete her blood glucose checks at times when mad or angry with her parent(s).

Gretchen's weekly percentage adherence to blood glucose checks across meter and baseline phases are shown in Figure 2. Results indicated that Gretchen was performing 25% and 75% of the recommended frequency during the meter phase. An increasing trend in her performance was observed in the 1-week before study enrollment. Performance increased to 96% during the second and third week of baseline, indicating a percentage improvement of 28% to 284% over pre-baseline levels. Although the intervention was implemented, no intervention data was obtained due to repeated failures to contact Gretchen by telephone. During a follow-up telephone contact several weeks after drop out, Gretchen indicated that the frequent telephone contacts were "too much of a hassle" because she was "never home." Medical chart review completed approximately 6- and 12-months after Gretchen withdrew from the study revealed that she had not attended a scheduled clinic appointment. As such, follow-up data are not available for comparison with baseline data.

#### Treatment Acceptability

Treatment acceptability ratings were obtained from one participant (Megan) and her mother. A Likert-type scale (1 = *strongly disagree* to 6 = *strongly agree*) was used to assess intervention acceptability and social validity of the paging intervention. Ratings (parent ratings are shown in italics) by Megan and her mother for several items were as follows: this intervention increased the level of blood glucose checking (strongly agree; *agree*); this intervention was practical in the amount of time required (agree; *agree*); this intervention improved the parent-adolescent relationship (strongly agree; *slightly agree*);

this intervention was practical in the amount of time required to talk with the researcher on the phone (slightly agree; *agree*). The overall effectiveness of the intervention was also rated by using a Likert-type scale (1 = *not effective* to 10 = *very effective*). Both Megan and her mother provided ratings of 8. The following two written statements were also provided by Megan and her mother: “I got a pager to help me out and it got my A<sub>1c</sub> down” and “The pages made my child more accountable.” Although treatment acceptability was assessed for only one family, these preliminary findings indicate that the intervention approach may be promising and acceptable, making it feasible to implement in the context of a medical setting. However, as previously indicated, adjustments to the telephone contact procedures and the number of prompts will likely be needed to increase the overall social acceptability of the intervention.

### Discussion

The primary goal of this study was to obtain preliminary data on the efficacy of an innovative behavioral procedure designed to improve treatment adherence to the blood glucose monitoring component of the diabetes regimen. Another aim of this study was to test the feasibility of implementing a new intervention approach for a difficult population (i.e., extremely poor treatment adherence) in the context of a real-world health care setting. As with all studies, careful attention was paid to what modifications would be needed to improve the clinical utility of the intervention. Since the extant literature shows that few studies have focused on the actual development of new intervention strategies, another aim of this study was to call attention to the practical problems encountered and lessons learned. In the discussion that follows, preliminary inferences about the impact of the intervention, limitations of the present results, the methodological and practical issues

encountered, and cogent recommendations for the future application of the intervention will be discussed.

The behavioral procedure used in this study provides preliminary support for using automated paging technology to deliver prompts to increase blood glucose monitoring. Two participants demonstrated short-term positive treatment outcomes (i.e., increase of 30% or greater in the frequency of blood glucose monitoring) as a function of the paging intervention. Sara and Susan demonstrated performance increases of 36% and 33%, respectively. Robert's more modest increase of 21% did not meet the established criterion to be considered a positive treatment outcome. The effect of the intervention on Megan's performance is unclear; however, the 7% increase in performance at the onset of the intervention and the decreasing trend found during prompt fading provides some evidence, albeit limited, that the intervention may have had some impact on her behavior. There was also a 10% improvement in the timing of her blood glucose checks during intervention. Modest improvements in the timing of blood glucose checks were also found for Sara and Susan. Sara demonstrated a 10% improvement in the timing of her checks, while Susan showed a 7% improvement. Five participants also demonstrated noticeable increases in blood glucose monitoring (i.e., ceiling effect) during baseline or immediately before study entry. The implications of this finding will be discussed in a later section of this discussion. Intervention effects for two participants, Debra and Gretchen, could not be evaluated due to early drop out.

Although not directly targeted, another aim of this study was to assess for positive health outcomes. Preliminary data indicated that two participants demonstrated clinically significant improvements in metabolic control. Megan demonstrated a substantial

decrease of 118 mg/ml in her mean 7-day blood glucose levels from baseline to intervention. Susan demonstrated a more modest change of 51 mg/ml. The 1.6% reduction in Megan's hemoglobin A<sub>1c</sub> value also supported a long-term positive health outcome. Although Debra was dropped from the study before completing the intervention, she also demonstrated a 0.9 % reduction in her A<sub>1c</sub> value at a 3-month follow-up. Reductions of A<sub>1c</sub> values in the range of 1% to 2% are considered to be clinically significant as even these small changes in metabolic control have been associated with a 26% to 76% decrease in long-term negative health complications (DCCT, 1993). Despite Sara and Robert exhibiting performance increases during intervention, there is no evidence that these changes lead to improvements in metabolic control, thus mitigating definite conclusions that the intervention reliably produced positive health outcomes for these two participants. This finding is consistent with previous research that raises uncertainty about the existence of a veridical relationship between treatment adherence and positive health outcomes (Rapoff & Barnard, 1991). Examination of Robert's A<sub>1c</sub> value at follow-up did not show any positive improvement in metabolic control. For Sara, Susan, and Gretchen, follow-up A<sub>1c</sub> values were not available for comparison.

Preliminary findings from this study indicate that the antecedent prompting procedure may be a feasible treatment option for increasing blood glucose monitoring and improving metabolic control in the short-term. However, conclusions about the impact of the intervention are tentative and inconclusive in light of several methodological problems, including ceiling effects, early drop out from the study, failure to complete the entire intervention, failure to return to baseline levels, and lack of follow-



up data. Although initial data provide some preliminary support for the short-term effectiveness of the intervention, the limitations of the present findings as well as the methodological and practical issues encountered need to be more fully addressed.

Visual inspection appears to support a short-term veridical change in Sara's, Robert's, and Susan's performance at the onset of the intervention; however, there may be other plausible behavioral explanations for these performance changes. One potential explanation to consider is that the baseline and intervention phases did not remain distinct from each other. In this study, parents were not specifically asked to make any changes in their parenting behaviors due to concerns that this would decrease the quality of parental supervision over the medical regimen. However, unknown changes in the parents' behaviors may account for the performance increases found with Sara, Robert, and Susan. For example, when the intervention was introduced, the parents may have inadvertently increased their level of parental monitoring, perhaps due to an increased interest in the potential effects of the intervention. The extant literature has indeed documented a positive association between parental monitoring and treatment adherence. The parents may have also increased their use of contingent praise or rewards (i.e., reinstatement of privileges), even if the intervention produced some initial positive changes in performance. Although parent behavior was not formally assessed, anecdotal comments obtained from the parents implied that they did not make any significant changes in their parenting behaviors. Parents were also instructed at study enrollment to not make any specific changes to their usual parenting practices. Given the immediacy and magnitude of the performance change with Sara and Susan at the onset of the intervention, a fairly strong case can be made that the intervention rather than other

extraneous events (i.e., history, reactivity) led to the performance changes. In addition, given the prolonged history of poor compliance and the lack of improvement from other clinic-based intervention strategies for these two participants, it is plausible that the short-term performance increases were accounted for by the intervention. However, demonstrating performance changes without returning to baseline levels limits definite conclusions about the impact of the intervention.

Another plausible explanation for the performance increases may have been due to two operating reinforcement contingencies such as negative and positive reinforcement. For example, as will be discussed later in this discussion, the arrival of the prompt before the blood glucose check was actually performed may have functioned as an aversive condition for some of the participants. As such, the participants may have performed the blood glucose check to avoid the presentation of the aversive condition (i.e., no blood glucose check performed when the prompt arrives). If the blood glucose check was performed before the prompt arrived, then the prompt may have functioned as a positive reinforcer.

One problem encountered in the implementation of this study was the ceiling effects obtained during the baseline phase. At the outset, this study planned on using a concurrent multiple-baseline design across individuals to avoid the practical issues related to withdrawing the intervention and returning to baseline. However, due to ceiling effects during baseline, this design was not feasible as the conditions of the design would not be met. With the exception of Robert, all participants displayed noticeable increases in blood glucose monitoring either during baseline or immediately before study enrollment. Even with the use of a probe-assessment technique and a prolonged baseline,

performance remained relatively stable and no regression towards the mean was observed. This may have been due to problems with reactive assessment or multiple-treatment interference (i.e., the telephone contacts functioned as a treatment component). Interestingly, the ceiling effects imply that modest performance increases can be obtained by conducting telephone contacts similar to the ones used in this study. This finding is consistent with previous research that has demonstrated that telephone prompts can facilitate increased adherence behaviors (La Greca & Schuman, 1995).

Performance increases during baseline may have also attenuated the intervention effects found with Megan, Sara, and Susan. There are several plausible explanations for the observed performance increases during baseline. Expectancy effects during the baseline phase may have led to systematic changes in blood glucose checking. The participants may have been influenced during baseline by the increased awareness that their performance was being more closely monitored. As previously mentioned, the telephone contacts used during baseline may have inadvertently functioned as a treatment component. Another potential explanation is that the participants established a rule statement (i.e., establishing operation) during baseline to earn a delayed, reinforcing consequence (i.e., access to a free pager service). Anecdotal comments indicated that Megan was strongly motivated to obtain access to the free paging service. It is also noteworthy to point out that the majority of the participants asked for clarification on when the pager would be activated. Although not directly assessed in this study, the establishment of a rule statement cannot be discounted as a positive motivating condition for the increased blood glucose checking found during the baseline phase. Similarly, it is not unreasonable to hypothesize that a rule statement (e.g., "If I continue checking by

blood glucose levels, I can continue to use this free paging service”) will be able to continue or other unknown motivating condition, rather than the prompts alone, were responsible for the performance increases found in Sara, Susan, and Robert during the intervention phase.

### Methodological Issues

There are several limitations to this study that need to be addressed. As with all studies, the small sample size and a lack of a control group limit the generalization of results. Other limitations of this study included high participant attrition, failure to complete the entire intervention and return to baseline due to early study drop out, and inconsistent follow through with scheduled clinic visits. Three of the six participants enrolled in this study failed to show-up for a scheduled clinic appointment in the 12-months following withdrawal or being dropped from the study. Of the three participants who showed-up for a clinic visit, no follow-up data on blood glucose monitoring was obtained by medical chart review, making it difficult to assess for maintenance effects or to cross-check for accuracy of verbal reporting. Anecdotal comments from health-care team members revealed a variety of reasons for the lack of follow-up data, including forgetting to bring-in the blood glucose monitor, failure to download the monitor data due to time constraints, and software malfunctions during downloads. Our clinic observations indicate that it is not unusual for patients to forget to bring-in their blood glucose monitors. In addition, the downloading of monitor data during clinic visits is often complicated by software malfunctions as many monitor models require their own designated software program. Unfortunately, critical errors often occur during the

downloading process due to the software program not matching-up with the model type, which further complicates the collection of reliable follow-up data.

The unreliability of the data collection procedure used in this study also needs to be addressed. Frequency of blood glucose monitoring was obtained by verbal self-report during scheduled telephone contacts. To encourage accurate and honest self-reporting, participants were asked to have their blood glucose monitors in-hand during telephone contacts in order to precisely report the exact date, time, and blood glucose level of each check. Participants were also told that the investigator would perform medical chart reviews to cross-check for accuracy of self-reporting. Unfortunately, due to the lack of follow-up data on blood glucose monitoring, inter-observer reliability checks could also not be calculated to determine the accuracy of self-reporting. Although we do not have any direct evidence, we cannot discount the possibility that the participants provided socially desirable responses during the telephone contacts.

Along similar lines, we did not directly verify if the participants were in fact carrying the electronic pagers with them at all times or if the pagers remained on. This is particularly concerning since several of the participants noted that the daily prompts became too burdensome and time-consuming. Although it was thought that access to a free paging service would create built-in incentives for consistent carrying of the pagers, there was no procedures in-place to rule-out this potential threat to internal validity. In the initial planning stages, the option of using two-way electronic pagers was considered, but was later dropped from the final research design due to the increase costs and more sophisticated technology.

Another limitation of this study is the high attrition rate. Only one participant completed the entire intervention phase, which raises serious questions about the appropriateness of the telephone contacts and/or prompts used in this study. Several of the participants anecdotally noted several factors (i.e., time constraints, annoyance with the telephone contacts and/or prompts) that interfered with their commitment to the study protocol. Attrition problems may have also been related to the prompts functioning as a learned aversive stimulus for the participants. Follow-up data obtained by medical chart review also did not reveal any significant improvements in metabolic control for the dropped participants, suggesting that those with more poorly controlled diabetes may be less likely to adhere to the study protocol. Yet, it should be noted that several of the participants who elected to enroll in this study had repeatedly declined invitations in the past to participate in more conventional clinic interventions and research projects. The novelty of the behavioral approach (i.e., prompts) used in this study may have helped to recruit a subgroup of patients who had previously declined to participate in any form of intervention. However, important modifications to the intervention procedures will be needed in the future to reduce problems with attrition rates as well as improve the social acceptability of the intervention.

#### Advantages of Antecedent Prompting Procedure

Despite the aforementioned limitations, there are several advantages of the behavioral procedure that should be discussed. Since the prompts could be delivered through automated paging technology, the antecedent prompting procedure relied less on extensive patient, parent, and health-care team involvement. Less than 15 minutes was typically needed during the office-based visit to hand-out and to explain how to use the electronic pager. Prompts delivered through automated paging technology may also be

relatively cost-effective. The costs of the pager and the monthly service were relatively inexpensive, only costing \$19.95 per month. Costs could be further reduced by removing the statewide and national coverage plans that were used in this study. Prompts could also prove to be a viable and cost-effective treatment option for reducing the risk of hospitalization in the short-term. For example, during times of physical illness, emotional distress, and adolescent puberty, the action or efficiency of insulin is often compromised, thus requiring some minimal level of blood glucose monitoring to prevent hypo- or hyperglycemic episodes. Another added benefit is that the patient is encouraged to take increased individual responsibility of the medical regimen. Prompts delivered through automated paging technology are particularly well-suited in situations where there is increased pressure by the health care team or families for more independence. In addition, since automated paging technology is portable, prompts have an added benefit of promoting adherence when the young patient is away from home and receiving less parental monitoring. Several participants in this study reported that they forgot to perform blood glucose monitoring checks at school, suggesting that prompts may be particularly useful in the school setting. A final advantage is related to the novelty of using automated paging technology to deliver prompts designed to improve treatment adherence. Several of the participants who had declined previous offers to participate in alternate clinic-based treatment options elected to participate in this study. Overall, this behavioral procedure has several advantages, including a strong interest by parents and youngsters in an innovative treatment approach, its simplicity and portability, and the potential reduction of short-term health risks.

### Implications for Future Research

Since an aim of this study was to consider what modifications would be needed to successfully implement the intervention in the context of a real-world medical setting, it was also important to identify ways in which to modify the research design and intervention procedures for use with this population. Several recommendations for the future application of the intervention will be discussed here.

Specific modifications to the research design are needed to prevent the ceiling effects found during baseline in this study. Ceiling effects during baseline prevented the use of the multiple-baseline design across participants, a design that avoids the practical issues of temporarily withdrawing the intervention. One option is to use the downloaded data from the blood glucose monitors to establish the baseline phase and to immediately implement the intervention (i.e., prompts). However, this may not entirely eliminate ceiling effects, since ceiling effects and increasing trends in performance can also be found in the weeks before study enrollment. A second option is to eliminate all telephone contacts and to collect all study data by downloading the monitors at a follow-up office-based visit. If downloaded monitor data indicate that performance is already close to a zero rate before study entry, it may also be unpractical to establish a baseline level of performance. When the rate of blood glucose monitoring is already near zero, immediate intervention may be called for, particularly in light of the significant health risks associated with extreme noncompliance to this component of the diabetes regimen.

Another option to consider in future studies is to use an alternative research design such as the changing-criterion design. Although this design requires a baseline phase, no withdrawal or withholding of the prompts would be needed to demonstrate the effect of the intervention. If the option to immediately start the intervention is selected



without first establishing a baseline phase, then it may be a reasonable option to proceed as a BABA design. However, the ethical issues of using phase reversals in research in the area of treatment adherence needs to be carefully considered. If the prompts lead to significant improvements in blood glucose monitoring, important ethical issues are raised about withdrawing the intervention and returning to baseline levels. Although phase reversals are often needed to clarify the impact of the intervention, attempting to return behavior back to a baseline level may not be in the best interest of patients diagnosed with a chronic medical condition, since this may result in serious, deleterious health consequences. The use of phase reversals in this population raises important questions about the clinical practicality of applying ABAB or similar designs. Unfortunately, as was found in this study, unanticipated research design problems resulted in inconclusive findings about the impact of the prompts on blood glucose monitoring and interfered with ruling-out other threats to internal validity.

Modifications to the data collection and/or intervention procedures are also needed to improve participation rates, reduce the research demands, and to improve the social acceptability of the prompts. Anecdotal reports indicated that the weekly telephone contacts and prompts may have been too time-consuming, burdensome, and overwhelming for several participants. The study protocol may have had the unfortunate effect of adding another treatment component to an already complex medical regimen. Reducing the frequency of telephone contacts or using alternative data collection procedures may help to reduce research demands and improve overall retention rates. For example, the use of blood glucose monitors with built-in wireless technology, albeit more costly, would simplify the data collection process and reduce time constraints as the data

would be automatically sent from the monitor to the investigator for analysis. Wireless technology would also allow the use of optional intervention procedures. For example, analysis of the data in real-time may reveal dramatic improvements in blood glucose monitoring and metabolic control over a period of time, which could be reinforced by sending a “bonus” prompt (e.g., “Keep up the excellent work. You’re blood glucose checks and levels look great”).

Adding other reinforcement-based procedures (i.e., monetary rewards, small gifts) may also enhance participation in the telephone contacts and minimize participant attrition. The optimal number of prompts required to obtain a desired positive treatment outcome should also be determined in future research. Fewer prompts (i.e., 1 versus 4 per day) may produce similar treatment outcomes while reducing other potential threats to internal validity, including maturation factors (i.e., tiredness, boredom). Preliminary findings suggested that the prompts improved the timing of the blood glucose checks by 7% to 10% for several of the participants. Since the timing of blood glucose checks are just as important as the frequency of checking, a randomized procedure of the times could be used to not only reduce the total number of prompts, but also to ensure that patients are randomly paged at the appropriate times. Perhaps only 3 random pages or less per week would be effective in improving blood glucose monitoring while reducing the risk of the prompts becoming an aversive stimulus.

In future studies, the patients and families who decline to participate or withdraw early should also be closely assessed to shed light on the potential limitations of using this behavioral procedure in this population. As Riekert and Drotar (1999) point out, when conducting research on treatment adherence, the research demands need to be

appropriately adjusted and/or modified in order to make participation more convenient, less time consuming, and to improve participant retention rates across all experimental conditions. A modification that was helpful for one study participant (i.e., Sara) involved adjusting the frequency and timing of the telephone contacts. During the intervention phase, Sara indicated that she was contemplating her withdrawal from the study due to time constraints. However, after minor adjustments were made to the time of the telephone contacts, particularly during busier weeks, she elected to remain in the study for a longer period of time.

Another important future consideration is to ensure that participants are provided with adequate and dependable diabetes supplies (e.g., blood glucose monitors, testing strips) before study entry. Each participant in future studies should also be provided with the same brand of blood glucose monitor in order to prevent software malfunctions and to encourage reliable data collection. For one participant (Gretchen), significant financial barriers were also encountered after her health insurance was unexpectedly dropped, which resulted in her paying out-of-pocket expenses for medical supplies. During the intervention phase, Gretchen quickly depleted her supply of testing strips, which effectively prevented her from performing her blood glucose checks. This not only resulted in the loss of valuable intervention data, but it also created a potentially dangerous health situation for Gretchen. Likewise, participants should be provided with new blood glucose monitors with adequate built-in memory capabilities in order to store large amounts of data and to reduce the risk of monitor failures. The importance of providing participants with reliable monitors was evident after one participant's (Robert) monitor stopped working properly. These real-life examples not only reveal the

importance of ensuring that participants have adequate medical supplies at study entry, but they also illuminate some of the practical issues commonly encountered in conducting applied research with this population.

The use of two-way paging technology in future studies will also help to address concerns that participants turn off the pagers or do not consistently carry them. By using two-way paging technology, patients could be required to send back confirmation prompts, perhaps on a random basis, in order to determine if the prompts were actually received. The use of two-way paging technology may also be more feasible in the future as the costs of this type of technology are significantly decreasing. In addition, many cellular phones available on the market today have built-in two-way text paging capabilities. Providing patients with cellular phones with built-in text paging technology may also be a more acceptable treatment option as cellular phones tend to be more popular among youth in contrast to standard paging technology. Developing contingency management procedures to control the participant's access to the free service should also be considered in future research. For example, a behavioral contingency could be arranged in which the patient would be required to achieve a predetermine criterion level (i.e., 28 checks per week) in order to earn access to the cellular phone or paging service. If the performance criterion was not reached, arrangements could be made to temporarily disconnect the service or the parents could be asked to remove the patient's access through a penalty procedure (i.e., temporary loss of access to the service).

Future studies should also attempt to replicate these initial findings with a larger sample size and obtain long-term follow-up assessments to assess for maintenance effects. Replication of this study across research sites, patients, and different medical

regimens (i.e., asthma) would also likely increase the external validity of findings. Although this study recruited patients with extremely poor treatment adherence, future studies should also consider applying the intervention to populations with less severe treatment noncompliance. It was assumed that patients with very poor treatment adherence would be most likely to acquire positive health outcomes from the prompts; however, it is not unreasonable to hypothesize that patients with less severe treatment noncompliance would also benefit from prompting procedures. Although the participants enrolled in this study had poor metabolic control (i.e.,  $A_{1c}$  values ranged from 9% to 12%) at study entry, a predetermined  $A_{1c}$  value was not a required enrollment criterion for eligibility. Future studies should consider recruiting only those patients with abnormally high  $A_{1c}$  values. Perhaps only patients with higher  $A_{1c}$  values (i.e.,  $A_{1c}$  values over 14%) would benefit the most from the intervention approach.

Efforts also need to be made to collect more objective data to assess the impact of the intervention on other diabetes-related behaviors that may affect metabolic control. Pilot data was collected in this study for descriptive purposes and to qualitatively evaluate whether or not the intervention had any ancillary impact on other diabetes-related tasks. Participants in this study were asked to informally report the number of days per week that they adhered to other diabetes-related tasks (i.e., diet, insulin injection, exercise). Informal inspection of these ratings did not reveal any noteworthy performance changes to the other diabetes-related tasks. No participant indicated any significant problems with performing daily insulin injections. This is consistent with clinic observations that relatively few patients with type 1 diabetes neglect to perform the insulin replacement component of the diabetes regimen. However, the number of days in

which participants adhered to the dietary and exercise components of the medical regimen were more variable and often less-than-ideal.

Additional data will also be needed to evaluate the impact of the prompts on the overall level of treatment adherence, parent-adolescent conflict, and adjustment/coping to the medical regimen. Unfortunately, due to participant attrition, loss of contact with participants, and refusal to complete the questionnaires at study dropout, follow-up questionnaire data was obtained for only one participant (Megan) and her mother. For Megan, there was only negligible improvement in her overall adjustment and level of treatment adherence to the diabetes regimen. Although follow-up questionnaire data was only collected on one participant, these results are consistent with previous research that has shown that improvement to one treatment component (i.e., blood glucose monitoring) does not necessary imply that concomitant changes will be found with the other regimen tasks (Johnson, 1995).

In contrast, the 35-point drop found in Megan's DRC score from pre- to post-intervention indicated that Megan was reporting a significant reduction in the level of parent-adolescent conflict surrounding the diabetes regimen. This finding may indicate that the prompts had more widespread behavioral effects on the overall family system for Megan and her family. Despite the lack of follow-up data on the level of parent-adolescent conflict for the other participants, most of the families reported a high level of parent-adolescent conflict surrounding the diabetes regimen at study entry. The majority of the participants also noted that they had become angry with their parent(s) when reminded to perform blood glucose monitoring checks. In fact, several participants reported that they had intentionally not performed blood glucose checks when mad or

angry with their parent(s). In future studies, it may be beneficial to consider adding an additional treatment component by asking parents to refrain from providing verbal prompts to their adolescent in order to allow the prompts to temporarily replace the negatively viewed parental reminders. If prompts can be used to temporarily reduce negative behavioral exchanges, the frequency of parent-adolescent conflicts may decline, which may further enhance treatment adherence. Another option is to add the prompts to an already existing treatment package such as Behavioral Family Systems Therapy (BFST). Perhaps adding prompts to the BFST family therapy approach would produce more immediate improvements in treatment adherence by more quickly reducing the level of parent-adolescent conflict (Wysocki et al., 2001).

Since the extant literature suggests that reminders alone (i.e., visual or verbal prompts) may be inadequate in improving adherence levels for some patients, additional reinforcement-based contingencies in addition to the prompts should also be considered to improve treatment adherence (La Greca & Schuman, 1995). For this study, we were specifically interested in using an antecedent prompting procedure due to its simplicity and relatively ease of being implemented in the context of a real-world medical setting. However, reinforcement-based procedures would likely increase patients' and families' participation in the study protocol. In addition, adding a reinforcement-based procedure (i.e., earn \$1 if a blood glucose check is completed in a timely manner) in addition to the prompts may produce more significant treatment outcomes. Withdrawal of the reward contingency, perhaps through a sequential-withdrawal design, would also allow direct examination of the effects of alternating the two treatment components (i.e., prompts versus reinforcement) on performance.

### Future Adaptations of Antecedent Prompting Intervention

One adaptation to consider in future studies is to use prompts, perhaps in the form of tactile prompts (i.e., vibrating), with youngsters in the school setting. For many younger patients with type 1 diabetes, there is often an important transition period in which responsibility for performing the blood glucose checks is transferred from school officials to the youngster. Before this transitional period, the onus often falls on school officials (i.e., school nurse, teachers) to provide reminders and ensure that the checks are being completed. In situations in which health care team members and families would like to transfer increased responsibility to the youngster, providing a supplemental stimulus in the form of a tactile prompt may facilitate a smoother transition period. Even with modest, short-term performance increases in blood glucose monitoring, prompts delivered through automated paging technology may be a time-efficient and portable intervention approach to promote increased independence during this transitional period. Adding a reinforcement-based contingency (i.e., teacher provides a small reward if the child completes the blood glucose check after receiving the prompt) may further help to increase and maintain independent blood glucose monitoring. In addition, attempts could be made to gradually reduce the prompts and/or reinforcement-based procedure to evaluate whether or not appropriate rates of blood glucose monitoring would be maintained over time.

Although this study assessed the impact of the intervention on patients diagnosed with type 1 diabetes, the intervention could also be adapted for use with other populations. For example, when expectant mothers are diagnosed with gestational diabetes, it is imperative that they continually monitor their blood glucose levels as this may lead to serious, immediate negative health consequences for the fetus. Since these



mothers are likely to be quite unfamiliar with an acute, short-term medical regimen, providing prompts to remind them to complete blood glucose checks in a timely fashion may be quite useful. Similarly, it may also be beneficial to apply the intervention in populations (i.e., elderly, traumatic brain injury) that respond less favorably to naturally occurring contingencies.

### Conclusions

Despite the limitations and methodological issues encountered, this study is the first to our knowledge to use automated paging technology to deliver prompts designed to increase adherence to an individual treatment component of the diabetes regimen. Also, relatively few studies to date have attempted to document the efficacy of interventions by presenting quantitative data (i.e., blood glucose levels) to assess for positive treatment health outcomes. Although preliminary findings are tentative and modest, this does not necessarily imply that even small performance changes are not clinically significant. Even with small changes in the frequency of blood glucose checking, significant improvements in the quality of diabetes management may be obtained. For example, adding only 1 extra blood glucose check per day may allow a patient to make a clinically important adjustment to the insulin level, which may in effect lower blood glucose levels for an extended period of time. If this check was not completed, blood glucose levels may have remained too high or low resulting in increased risk for negative health-outcomes such as hospitalization. The findings from this study are also novel in that this is the first known study to demonstrate that poor compliance to a specific component of a medical regimen can be improved in the short-term by delivering antecedent prompts through automated paging technology.

In conclusion, this study finds that extreme noncompliance to a specific treatment component of a chronic medical condition may be amendable to a simple antecedent prompting procedure (i.e., prompts) delivered through automated paging technology. For three participants studied, an antecedent prompting procedure was somewhat successful, albeit of limited duration, in increasing blood glucose checking. Two participants also demonstrated improved metabolic control (i.e., reduction in blood glucose levels). Although the prompts may have only improved blood glucose monitoring in the short-term, these improvements could be framed for families as temporary motivational conditions to increase treatment adherence to a point where natural reinforcers (i.e., improved health outcomes, praise from parents or health-care team members) begin to function as effective consequences for continued adherence.

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## Appendix A

Enrollment Criteria  
Physician Recruitment Script  
Informational Flyer

## Enrollment Criteria

Listed below, I have outlined the enrollment criteria that will be used in this study. For some of the criteria, I have provided a more in-depth explanation as needed. If the patient meets the enrollment criteria, please pass out an informational flyer inviting them to participate in this study. Potential participants that might be interested in this study can call me at the number provided on the informational flyer.

### Inclusion/Exclusion Criteria:

1. Adolescents aged 12-years-old and older will be eligible to participate in this study.
2. Adolescents who demonstrate an average compliance rate of 50% or less than the recommended frequency of blood glucose monitoring during the last 3 months will be eligible for participation. Generally speaking, it is assumed that the patient should be checking his or her blood glucose levels four times per day. To calculate the average compliance rate during the past 3 months, please divide the number of blood glucose checks performed by the total number recommended (for 3 months) and multiply by 100. Patients who demonstrate an average compliance rate of 50% or less during the last 3 months will be eligible.
3. Diagnosis of Insulin-Dependent Diabetes Mellitus (IDDM) for a duration of  $\geq 1$  year.
4. At least one annual visit to the diabetes clinic during the last year.
5. No other diagnosis of any serious medical conditions
6. No documented history of any newly diagnosed psychiatric conditions during the past 6 months.
7. No documented evidence of any serious psychiatric conditions (i.e., conduct disorder, schizophrenia, etc.)
8. No significant mental impairment or developmental delay.

## Physician Recruitment Script

I would like to tell you about a research project that is being conducted by a graduate student at Western Michigan University here in Kalamazoo. The purpose of this study is to help adolescents with Type 1 Diabetes to do a better job with checking their blood sugar levels. If you decide to participate in this study, the student investigator will give you a Motorola™ pager to carry around with you. The student investigator will send you pages every day to help you remember to check your blood sugar levels. You will also be allowed to use this pager with your family and friends. You will not be able to keep this pager after you complete the study. Here is an information flier that has the name of the student investigator, Steve Albrecht, and his telephone number. If you are interested in this study, you can call the student investigator to learn more about the study.

## **Research Participants Needed**

A clinical researcher at WMU is seeking adolescents diagnosed with Type 1 Diabetes to participate in a treatment study.

Are you having a difficult time remembering to check your blood sugar levels each day? If you are having this type of problem, this study might be for you!

If you decide to participate in this study, we will give you a Motorola™ pager to carry around with you. The student investigator in this study will send you pages every day to help you to remember to check your blood sugar levels.

You will also be able to use this pager to keep in touch with your family and friends. You will not get to keep this pager after you are done with this study.

If you are not checking your blood sugar levels every day, and would like to get some help, please contact  
Stephen J. Albrecht by calling him at  
(616) 337-6229.

When calling, please state that you are interested in the Albrecht Study and leave your name, phone number, and the times in which it is best to reach you by telephone.

**THANK YOU!!!**

**All information is private and confidential**

## Appendix B

### Initial Phone Contact Script

## Initial Phone Contact Script

“Hello, \_\_\_\_\_. My name is Stephen J. Albrecht and I am a graduate student from the Department of Psychology at Western Michigan University. I recently received a message from you that you might be interested in participating in my research study entitled, “Increasing Blood Glucose Monitoring in Adolescents with Type 1 Diabetes: Effects of a Prompt.” I am calling you today to ask if you would be willing to come to MSU/KCMS for a meeting with me to further discuss your participation in this study. If you and your adolescent decide to participate, this meeting should take 1 to 2 hours to complete. During this meeting, I will ask you and your teenager to read and sign a consent form and if you decide to participate, to complete several questionnaires. I will also provide your teenager with an electronic pager and will show them how to use it during this meeting. I will be available during this meeting to answer any questions or concerns that you might have regarding this study. Would you like to set up an appointment?”



## Appendix C

### Measures

## Demographic Questionnaire – Adolescent Version

Directions: Please answer the following questions by checking the box, filling in the blank, or circling the answer.

1. What is your present age?

- 01 12 years
- 02 13 years
- 03 14 years
- 04 15 years
- 05 16 years
- 06 17 years

2. What is your gender?

- 01 Male
- 02 Female

3. What best describes your race/ethnicity?

- 01 Asian/Pacific Islander
- 02 African American
- 03 Hispanic/Latino
- 04 Native American
- 05 White
- 06 Other

4. Are you currently going to school?

- 01 Yes
- 02 No

5. What is the name of your school? \_\_\_\_\_

6. What is your present grade level?

- 01 6<sup>th</sup> Grade
- 02 7<sup>th</sup> Grade
- 03 8<sup>th</sup> Grade
- 04 9<sup>th</sup> Grade
- 05 10<sup>th</sup> Grade
- 06 11<sup>th</sup> Grade
- 07 12<sup>th</sup> Grade

7. How long have you had diabetes?

- 01 1 to 3 Years
- 02 4 to 7 Years
- 03 8 to 11 Years
- 04 12 to 15 Years
- 05 16 to 19 Years
- 06 19 to 21 Years

8. Have you had any type of conflict or arguments with your parents about managing your diabetes?

- 01 Yes
- 02 No

9. If you answered "Yes" to question # 8 above, what did you argue about? Please circle all that apply.

- 01 Testing urine for Ketones
- 02 Checking blood sugar levels
- 03 Recording blood sugar levels in log book
- 04 Administering Insulin shots
- 05 Eating the proper foods
- 06 Exercising on a regular basis
- 07 Making doctor appointments
- 08 Remembering to take meter to school
- 09 Other

10. How many times do you usually test your blood sugar each week?

- 01 1-5 times
- 02 6-10 times
- 03 11-15 times
- 04 16-20 times
- 05 21-25 times
- 06 26-30 times
- 07 31-35 times
- 08 36-40 times
- 09 41 or more times

11. When do you most often forget to test your blood sugar levels? Please circle all that apply.

- |                          |  |
|--------------------------|--|
| 01 At school             | 08 When on a vacation or weekend trip  |
| 02 Before breakfast      | 09 At an evening party or dance        |
| 03 Before lunch          | 10 When feeling sick                   |
| 04 Before dinner         | 11 While hanging out with friends      |
| 05 Before bedtime        | 12 During the summer months            |
| 06 When I feel fine      | 13 When I feel embarrassed             |
| 07 I forgot my equipment | 14 When I do not want to know my level |

12. Do you ever need reminders from your parents to test your blood sugar levels?

- 01 Yes
- 02 No

13. If you answered "Yes" to question # 12 above, how many times during the last week did your parents remind you to check your blood sugar levels?

- 01 1-2 times
- 02 3-4 times
- 03 5-6 times
- 04 7-8 times
- 05 9-10 times
- 06 11-12 times
- 07 13-14 times
- 08 15-16 times
- 09 17-18 times
- 10 19-20 times
- 11 21 or more times

14. Do you ever need reminders from your parents to do your Insulin shots?

- 01 Yes
- 02 No

15. If you answered "Yes" to question # 14 above, how many times during the last week did your parents remind you to do your Insulin shots?

- 01 1-2 times
- 02 3-4 times
- 03 5-6 times
- 04 7-8 times
- 05 9-10 times
- 06 11-12 times
- 07 13-14 times
- 08 15-16 times
- 09 17-18 times
- 10 19-20 times
- 11 21 or more times

16. Do you ever get mad or angry with your parents when they tell you or remind you to complete a diabetes-related task?

- 01 Yes
- 02 No

17. Have you ever not checked your blood sugar levels when you are mad or angry with your parents?

- 01 Yes
- 02 No

18. On the lines below, please write down the times when you usually eat breakfast, lunch, and dinner, and your bedtime.

- 01 Breakfast Time: \_\_\_\_\_
- 02 Lunch Time: \_\_\_\_\_
- 03 Dinner Time: \_\_\_\_\_
- 04 Bedtime Time: \_\_\_\_\_

19. Are you currently seeing a counselor, therapist, psychologist, or psychiatrist for personal concerns?

- 01 Yes
- 02 No

20. If you answered "Yes" to question # 19 above, please indicate which personal concerns led you to seek counseling/therapy at this time?

- |                                  |                              |
|----------------------------------|------------------------------|
| 01 Depression                    | 09 Manic depressive disorder |
| 02 Anxiety                       | 10 Schizophrenia             |
| 03 Traumatic experience          | 11 Anger control problems    |
| 04 Relationship problems         | 12 Learning disability       |
| 05 Academic problems             | 13 Panic disorder            |
| 06 Obsessive/Compulsive disorder | 14 Agoraphobia/Other phobias |
| 07 Eating disorder               | 15 Career development        |
| 08 Alcohol or drug problems      | 16 Other:                    |

21. Have you ever attended a summer camp or training program to help you better manage your diabetes?

- 01 Yes
- 02 No

22. Do you have a computer with Internet access in your house?

- 01 Yes
- 02 No

## Demographic Questionnaire – Parent Version

Directions: Please answer the following questions by filling in the blank or circling the answer.

1. What is your present age? \_\_\_\_\_
2. What is your gender?
  - 01 Male
  - 02 Female
3. What best describes your race/ethnicity?
  - 01 Asian/Pacific Islander
  - 02 African American
  - 03 Hispanic/Latino
  - 04 Native American
  - 05 White
  - 06 Other
4. Did you graduate from high school?
  - 01 Yes
  - 02 No
5. How many years of school have you completed after college?
  - 01 0 years
  - 02 1 year
  - 03 2 years
  - 04 3 years
  - 05 4 years
  - 06 5 years
  - 07 6 or more years
6. What educational degrees do you hold? \_\_\_\_\_.
7. Are you currently employed?
  - 01 Yes
  - 02 No
8. Are you working full-time or part-time?
  - 01 Full-Time
  - 02 Part-Time
9. If you answered “Yes” to question # 8 above, what kind of work do you do? \_\_\_\_\_  
\_\_\_\_\_

10. What is your current family yearly income, before taxes?

- 01 \$15,000 or less
- 02 \$15,001 - \$25,000
- 03 \$25,001 - \$35,000
- 04 \$35,001 - \$50,000
- 05 \$50,001 - \$65,000
- 06 \$65,001 - \$75,000
- 07 \$75,001 - \$85,000
- 08 \$85,001 - \$100,000
- 09 Over \$100,000

11. Are you currently married?

- 01 Yes
- 02 No

12. Have you been married before?

- 01 Yes
- 02 No

13. Are you currently living with your spouse?

- 01 Yes
- 02 No

14. How many years has your son or daughter had diabetes?

- 01 1 to 3 Years
- 02 4 to 7 Years
- 03 8 to 11 Years
- 04 12 to 15 Years
- 05 16 to 19 Years
- 06 19 to 21 Years

15. Have you had any type of conflict or arguments with your son or daughter about the management of his or her diabetes?

- 01 Yes
- 02 No

16. If you answered "Yes" to question # 16 above, what did you argue about? Please circle all that apply.

- 01 Testing urine for Ketones
- 02 Testing blood sugar levels
- 03 Recording blood sugar levels in log book
- 04 Administering Insulin shots
- 05 Eating the proper foods
- 06 Exercising on a regular basis
- 07 Making doctor appointments
- 08 Remembering to take meter to school

17. How many times does your son or daughter test his or her blood sugar each week?

- 01 1-5 times
- 02 6-10 times
- 03 11-15 times
- 04 16-20 times
- 05 21-25 times
- 06 26-30 times
- 07 31-35 times
- 08 36-40 times
- 09 41 or more times

18. Does your son or daughter ever forget to check his or her blood sugar levels?

- 01 Yes
- 02 No

19. If you answered "Yes" to question # 19 above, how many times does your son or daughter forget to check his or her blood sugar levels each week?

- 01 1-5 times
- 02 6-10 times
- 03 11-15 times
- 04 16-20 times
- 05 21-25 times
- 06 26 or more times

20. When does your son or daughter most often forget to test his or her blood sugar levels? Please circle all that apply.

- |                     |                                       |
|---------------------|---------------------------------------|
| 01 At school        | 06 When on a vacation or weekend trip |
| 02 Before breakfast | 07 When at an evening party or dance  |
| 03 Before lunch     | 08 When feeling sick                  |
| 04 Before dinner    | 09 While hanging out with friends     |
| 05 Before bedtime   | 10 During the summer months           |

21. Do you ever have to remind your son or daughter to check his or her blood sugar levels?

- 01 Yes
- 02 No

22. If you answered "Yes" to question # 22 above, how many times during the week do you have to remind your son or daughter to check his or her blood sugar levels?

- 01 1-2 times
- 02 3-4 times
- 03 5-6 times
- 04 7-8 times
- 05 9-10 times
- 06 11-18 times
- 07 19-20 times
- 08 21 or more times



23. When does your son or daughter most often forget to check his or her blood sugar levels? Please circle all that apply.

- |                     |                                       |
|---------------------|---------------------------------------|
| 01 At school        | 06 When on a vacation or weekend trip |
| 02 Before breakfast | 07 When I go to evening part or dance |
| 03 Before lunch     | 08 When I am feeling sick             |
| 04 Before dinner    | 09 While hanging out with friends     |
| 05 Before bedtime   | 10 During the summer months           |

24. Have you ever had to remind your son or daughter to take his or her Insulin shots?

- 01 Yes  
02 No

25. If you answered "Yes" to question # 25 above, how many times each week do you have to remind your son or daughter to take his or her Insulin shots?

- 01 1-2 times  
02 3-4 times  
03 5-6 times  
04 7-8 times  
05 9-10 times  
06 11-12 times  
07 13-14 times  
08 15-16 times  
09 17-18 times  
10 19-20 times  
11 21 or more times

26. Has your teenager ever been made or angry with you after you tell or remind him or her to complete a diabetes-related task?

- 01 Yes  
02 No

27. Do you think that your teenager has ever purposely not check his or her blood sugar levels when they are mad or angry with you?

- 01 Yes  
02 No

28. On the lines below, please write down the times when your son or daughter usually eats breakfast, lunch, and dinner, and bedtime.

- |              |             |
|--------------|-------------|
| 01 Breakfast | Time: _____ |
| 02 Lunch     | Time: _____ |
| 03 Dinner    | Time: _____ |
| 04 Bedtime   | Time: _____ |

29. Is your son or daughter currently seeing a counselor, therapist, psychologist, or psychiatrist for personal concerns?

- 01 Yes
- 02 No

30. If you answered "Yes" to question # 30 above, please indicate which personal concerns led your son or daughter to seek counseling/therapy at this time?

- |                                  |                              |
|----------------------------------|------------------------------|
| 01 Depression                    | 09 Manic depressive disorder |
| 02 Anxiety                       | 10 Schizophrenia             |
| 03 Traumatic experience          | 11 Anger control problems    |
| 04 Relationship problems         | 12 Learning disability       |
| 05 Academic problems             | 13 Panic disorder            |
| 06 Obsessive/Compulsive disorder | 14 Agoraphobia/Other phobias |
| 07 Eating disorder               | 15 Career development        |
| 08 Alcohol or drug problems      | 16 Other:                    |

31. Has your teenager ever been diagnosed with a psychological disorder?

- 01 Yes
- 02 No

32. If you answered "Yes" to question #32 above, what was your son or daughter diagnosed with? \_\_\_\_\_

33. Have your son or daughter ever attended a summer camp or training program to help him or her to better manage the diabetes?

- 01 Yes
- 02 No

34. Has your teenager ever participated in a summer camp or some other training program to help him or her manage the diabetes?

- 01 Yes
- 02 No

35. On the lines below, please indicated several good days and times for when the student investigator can get a hold of you by telephone each week.

Day: _____	Time: _____
Day: _____	Time: _____
Day: _____	Time: _____
Day: _____	Time: _____

36. Do you own a computer with Internet access?

- 01 Yes
- 02 No

## SCI

Instructions: Please rate each of the items according to HOW WELL YOU FOLLOWED YOUR PRESCRIBED REGIMEN FOR DIABETES CARE in the past month. Then, using the rating scale below, please carefully read and answer each statement. If a statement does not apply to you, then rate it as "Not Applicable [NA]."

Ratings:

- 1 = Never
- 2 = Sometimes (about 25% of the time)
- 3 = About 50% of the time
- 4 = Often (about 75% of the time)
- 5 = Always (100% of the time)
- NA = Cannot rate this item (Not Applicable)

In the past month, how well have you followed the recommendations for:

1. Glucose Testing	1	2	3	4	5	NA
2. Glucose Recording	1	2	3	4	5	NA
3. Ketone Testing	1	2	3	4	5	NA
4. Administering Correct Insulin Dose	1	2	3	4	5	NA
5. Administering Insulin at Right Time	1	2	3	4	5	NA
6. Adjusting Insulin Intake Based on Blood Glucose Values	1	2	3	4	5	NA
7. Eating the Proper Foods; Sticking to the Meal Plan	1	2	3	4	5	NA
8. Eating Meals on Time	1	2	3	4	5	NA
9. Eating Regular Snacks	1	2	3	4	5	NA
10. Carrying Quick-Acting Sugar to Treat Reactions	1	2	3	4	5	NA
11. Coming in for Appointments	1	2	3	4	5	NA
12. Wearing a Medic Alert ID	1	2	3	4	5	NA
13. Exercising Regularly	1	2	3	4	5	NA
14. Exercising Strenuously	1	2	3	4	5	NA

### TADS – Adolescent

Instructions: This is a survey about how you have reacted to diabetes during the past month. Below you will read some statements, which may describe your behavior toward diabetes during that time. Next to each statement, please circle the number which best describes you during that time.

How often did you:

	<u>Never</u>	<u>Rarely</u>	<u>Sometimes</u>	<u>Usually</u>	<u>Always</u>
1. Eat exactly what was on the meal plan?	1	2	3	4	5
2. Eat meals on a strict schedule?	1	2	3	4	5
3. Pass up candy or sweets when they were offered?	1	2	3	4	5
4. Eat snacks as instructed?	1	2	3	4	5
5. Draw up insulin doses very carefully?	1	2	3	4	5
6. Take insulin about 30 minutes before meals?	1	2	3	4	5
7. Use many different places for shots?	1	2	3	4	5
8. Test blood sugar at least twice daily?	1	2	3	4	5
9. Write down every blood sugar test result immediately in a log book?	1	2	3	4	5
10. Do blood sugar test just before taking insulin shots?	1	2	3	4	5
11. Tell the truth to parents and doctors about diet, test results, etc.?	1	2	3	4	5
12. Enjoy learning about diabetes?	1	2	3	4	5

### TADS – Adolescent

Instructions: This is a survey about how you have reacted to diabetes during the past month. Below you will read some statements, which may describe your behavior toward diabetes during that time. Next to each statement, please circle the number which best describes you during that time.

	<u>Never</u>	<u>Rarely</u>	<u>Sometimes</u>	<u>Usually</u>	<u>Always</u>
13. Accept being different from others?	1	2	3	4	5
14. Express appreciation to doctors and nurses?	1	2	3	4	5
15. Feel there is hope for the future despite having diabetes?	1	2	3	4	5
16. Feel confident about taking shots, doing blood sugar tests, and eating a special diet?	1	2	3	4	5
17. Enjoy being around others with diabetes?	1	2	3	4	5
18. Wear diabetic identification?	1	2	3	4	5
19. Tell friends about diabetes and its treatment	1	2	3	4	5
20. Explain diabetes and its treatment to teachers, coaches, and other parents, etc.?	1	2	3	4	5
21. Seek help quickly when blood sugar got too high or there were ketones in your urine?	1	2	3	4	5

### TADS – Parent

Instructions: This is a survey about how your son or daughter has reacted to diabetes during the past month. Below you will read some statements, which may describe your son's or daughter's behavior toward diabetes during that time. Next to each statement, please circle the number which best describes your son or daughter during that time.

How often did your son or daughter:

	<u>Never</u>	<u>Rarely</u>	<u>Sometimes</u>	<u>Usually</u>	<u>Always</u>
1. Eat exactly what was on the meal plan?	1	2	3	4	5
2. Eat meals on a strict schedule?	1	2	3	4	5
3. Pass up candy or sweets when they were offered?	1	2	3	4	5
4. Eat snacks as instructed?	1	2	3	4	5
5. Draw up insulin doses very carefully?	1	2	3	4	5
6. Take insulin about 30 minutes before meals?	1	2	3	4	5
7. Use many different places for shots?	1	2	3	4	5
8. Test blood sugar at least twice daily?	1	2	3	4	5
9. Write down every blood sugar test result immediately in a log book?	1	2	3	4	5
10. Do blood sugar test just before taking insulin shots?	1	2	3	4	5
11. Tell the truth to parents and doctors about diet, test results, etc.?	1	2	3	4	5
12. Enjoy learning about diabetes?	1	2	3	4	5

### TADS – Parent

Instructions: This is a survey about how your son or daughter has reacted to diabetes during the past month. Below you will read some statements, which may describe your son's or daughter's behavior toward diabetes during that time. Next to each statement, please circle the number which best describes your son or daughter during that time.

	<u>Never</u>	<u>Rarely</u>	<u>Sometimes</u>	<u>Usually</u>	<u>Always</u>
13. Accept being different from others?	1	2	3	4	5
14. Express appreciation to doctors and nurses?	1	2	3	4	5
15. Feel there is hope for the future despite having diabetes?	1	2	3	4	5
16. Feel confident about taking shots, doing blood sugar tests, and eating a special diet?	1	2	3	4	5
17. Enjoy being around others with diabetes?	1	2	3	4	5
18. Wear diabetic identification?	1	2	3	4	5
19. Tell friends about diabetes and its treatment	1	2	3	4	5
20. Explain diabetes and its treatment to teachers, coaches, and other parents, etc.?	1	2	3	4	5
21. Seek help quickly when blood sugar got too high or there were ketones in your urine?	1	2	3	4	5

### Diabetes Responsibility Scale (DRC)

For each of the following parts of your child's diabetes care, circle the number that best describes the way you handle things at home.	Child all the time	Child most of the time	Parent and child half	Parent most of the time	Parent all the time
1. Who remembers what time to give your child's insulin?	1	2	3	4	5
2. Who measures/draws up the insulin dose?	1	2	3	4	5
3. Who give the injections?	1	2	3	4	5
4. Who checks the blood sugars?	1	2	3	4	5
5. Who keeps track of blood/urine records?	1	2	3	4	5
6. Who takes care of hypos?	1	2	3	4	5
7. Who decides what to eat at meals and snacks?	1	2	3	4	5
8. Who decides what to eat (away from home) at movies or birthday parties?	1	2	3	4	5
9. Who talks to the diabetes teams about diabetes care?	1	2	3	4	5
10. Who talks to adults about your child's diabetes (like teachers or the principal)?	1	2	3	4	5
11. Who talk to your child's friends about diabetes?	1	2	3	4	5
12. Who makes sure your child has insulin/syringes/supplies?	1	2	3	4	5
13. Who decides when your child exercises?	1	2	3	4	5
14. Who decides which people know your child has diabetes?	1	2	3	4	5



### Diabetes Responsibility Scale (DRC)

For each of the following parts of your child's diabetes care, circle the number which best describes how much you argue/hassle with your child about it.	Never	Some times	Half the time	Frequently	All the time
15. Who remembers what time to give your child's insulin?	1	2	3	4	5
16. Who measures/draws up the insulin dose?	1	2	3	4	5
17. Who give the injections?	1	2	3	4	5
18. Who checks the blood sugars?	1	2	3	4	5
19. Who keeps track of blood/urine records?	1	2	3	4	5
20. Who takes care of hypos?	1	2	3	4	5
21. Who decides what to eat at meals and snacks?	1	2	3	4	5
22. Who decides what to eat (away from home) at movies or birthday parties?	1	2	3	4	5
23. Who talks to the diabetes teams about diabetes care?	1	2	3	4	5
24. Who talks to adults about your child's diabetes (like teachers or the principal)?	1	2	3	4	5
26. Who talk to your child's friends about diabetes?	1	2	3	4	5
27. Who makes sure your child has insulin/syringes/supplies?	1	2	3	4	5
28. Who decides when your child exercises?	1	2	3	4	5
29. Who decides which people know your child has diabetes?	1	2	3	4	5

## Appendix D

### Informed Consent Documents

## **Parent Consent for Own Participation and for Son or Daughter To Participate**

An Office-Based Intervention Designed to Improve Blood Glucose  
Monitoring in Adolescents With Insulin-Dependent Diabetes Mellitus

Principal Investigator: Amy E. Naugle, Ph.D.

Student Investigator: Stephen J. Albrecht, M.A.

Western Michigan University

### Department of Psychology

You and your teenager have been invited to participate in a research study entitled “An Office-Based Intervention To Improve Blood Glucose Monitoring in Adolescents with Insulin-Dependent Diabetes Mellitus.” This study will help us learn more about a treatment designed to increase the number of times that adolescents with diabetes check their blood sugar levels. The goal of this study is to help your adolescent do a better job with monitoring your blood sugar levels. This study will also look at how well this treatment can be used in the diabetes clinic where your teenager is currently receiving his or her medical services. This study is Stephen Albrecht’s dissertation project.

*What is involved?* Your decision to participate and your permission for your teenager to participate in this project means that both you and your teenager will be asked to spend about 90 minutes in a meeting with the student investigator at Michigan State University/Kalamazoo Center for Medical Studies (MSU/KCMS). During this meeting, you and your teenager will be asked to complete several questionnaires. You and your teenager will be asked to share some personal information on these forms, such as age, racial identity, and level of education. These questionnaires will also ask questions about whether you have had any conflicts or arguments with each other about his or her diabetes. You will also be asked to report the number of times that your teenager usually checks his or her blood sugars and completes his or her Insulin injections each week. It will take you and your teenager about 30 to 45 minutes to complete these questionnaires.

If you and your adolescent agree to participate in this study, your teenager will be asked to participate in a 7-week paging treatment. You and your teenager will not be required to make any additional office-based visits during this treatment. If your teenager decides to participate, he or she will be provided with one electronic pager. Your teenager will not be able to keep this pager after they have completed the study. Your teenager will be provided with the pager number and will be allowed to give this number out to family and friends at no cost during the treatment period. Your teenager will be asked to carry this pager with them at all times, including those times when they are away from home or in school. Your teenager will be provided with a letter so that she or he has formal permission to use this pager while attending school. Before your teenager starts receiving pages, the student investigator will call your teenager every three days to find out how many times that they have been checking their blood sugar levels each day. When the student investigator calls your teenager, he or she will be asked to look at their reflectance meter to determine how many times that they checked their blood sugar levels. The student investigator will contact your teenager to let him or her know when their pager will be activated. Your teenager will start receiving the pages one day after the pager has been activated. During the treatment, the student investigator will send

several pages each day for a period of 7-weeks to remind your teenager to check his or her blood sugar levels. Your teenager will receive 4 pages per day for the first four weeks of the treatment, followed by 3 pages per day in Week 5, 2 pages per day in Week 6, and 1 page per day in Week 7.

After your teenager starts receiving pages, the student investigator will complete one 15-minute telephone call with your teenager at the end of each week to gather information on how well they have been following their diet, exercising, and completing their Insulin injections. During these telephone contacts, the student investigator will also ask your teenager to report how many times that they are checking their blood sugar levels each week.

At the end of the 7-week paging treatment, the student investigator will then contact you and your teenager by telephone at 3-months and 6-months following the completion of the treatment. During these one-time telephone contacts, you and your teenager will also be asked to complete several questionnaires over the phone. These are the same questionnaires that you will complete during today's meeting. Since you will not have a copy of these questionnaires, the student investigator will read the questions to you and your teenager. The student investigator will contact you and your teenager one-week before to let you that this information will be collected the following week.

*Potential Benefits* You and your teenager may benefit from participating in this study in several ways. The treatment that will be used in this study may increase the number of blood sugar checks that your teenager completes each week. By increasing the number of blood sugar checks, your teenager may obtain better control of his or her diabetes condition, which may help prevent the development of potentially serious medical problems. Another possible benefit may be that it helps your teenager to develop more independence and take more responsibility in managing his or her diabetes. Your teenager will also be provided with a free paging service and will be able to stay in contact with you, other family members, and friends by using the electronic pagers. This study may also help in the development of cost-effective interventions that can be used in the context of a medical setting. And finally, other children and adolescents with diabetes may benefit in the future from the knowledge that is gained from this research study.

*Risks of Participating in Study* As in all research, there may be unforeseen risks to the participant. If an accidental injury occurs, appropriate emergency measures will be taken; however, no compensation or treatment will be made available to your adolescent except otherwise specified in the consent form. There are minimal risks for you and your teenager in this study. The only risks anticipated for you and your teenager are the minor discomforts and inconveniences that may be experienced when asked to fill out questionnaires or participate in weekly telephone contacts. Another possible risk/inconvenience involves the time commitment required for the office-based visit at MSU/KCMS. This may pose a time commitment inconvenience and/or transportation difficulty. You and your teenager may also experience discomfort when asked to disclose personal information about yourselves on the questionnaires. Your son or daughter may also get tired of checking his or her blood sugar levels and talking to the student investigator on the telephone at the end of each week. Your son or daughter may also experience some distress or minor discomforts if school staff asks them why they are

carrying a pager with them on school property. We anticipate that this risk will be minimal. The student investigator in this study will provide a letter for your son and daughter in the event that school staff asks them why they have a pager in school. The student investigator and your physician at MSU/KCMS will sign this letter. Given that your adolescent will be allowed to use the pager for personal purposes, there is a risk that he/she will abuse or misuse their pager privileges. Such misuse may result in adverse consequences (e.g., getting in trouble at school). You have the right to implement consequences for any misuse. One additional risk is that you may begin to rely on the pager to remind your adolescent and therefore decrease how often you remind your teenager. This is not necessarily a bad outcome, if your teenager is able to increase their blood-glucose monitoring due to the pager intervention. However, it is possible that by decreasing your reminders, your teenager will decrease their blood-glucose monitoring. We are not asking you to change anything about your behavior or how you remind your teenager.

In the event that your teenager needs immediate medical attention for his or her diabetes, we will ask that you respond as you ordinarily would in an emergency situation by immediately seeking medical attention from your hospital and/or contacting your physician. If your adolescent is significantly distressed and it becomes clear that individual therapy may be more immediately useful, an appropriate referral to a competent mental health professional will be made.

*Confidentiality of Data* You and your teenager's responses and performance in this project will remain strictly confidential. That means that you and your teenager's name will not appear on any research questionnaires or forms completed during this study. No other person other than you and your teenager will have access to the pager number, unless your teenager decides to give out his or her number to other family members and friends. All forms and computer files with information regarding you and your teenager's performance will be coded with a unique number in order to ensure confidentiality. All information will be labeled with this research number and stored in a locked file cabinet in a laboratory at Western Michigan University. The student investigator will keep a separate master list with the names of the participants and the corresponding code numbers. Once the data are collected and analyzed, the master list will be destroyed, thus rendering you and your adolescent's information anonymous. All other questionnaires and forms will be saved for at least three years in a locked file in the primary investigator's laboratory. Information collected in this study will be disclosed in professional journals so as to assist clinicians, physicians, and other researchers in their understanding of how to improve the management of diabetes in adolescent populations. Information presented in such publications will be anonymous so as to ensure you and your teenager's confidentiality.

*Participation is Voluntary* You and your teenager's participation in this study is completely voluntary. You and your teenager may withdraw from this study at any time without any negative effect on services provided to you or your teenager. There will be no penalty if you and your teenager do not wish to be involved in this study, and you may withdraw at any time during the study and refuse to answer any of the questions. Your decision on whether or not to allow you and your teenager to participate in this study will not jeopardize your future relations with Western Michigan University or the medical

services provided at Michigan State University/Kalamazoo Center for Medical Studies (MSU/KCMS).

Questions? We invite you to ask any questions you may have. If you have any additional questions or concerns about this study, please feel free to contact Stephen Albrecht at 387-4485 or Dr. Amy Naugle at 387-4726. We will be happy to answer any of your questions. You may also contact the Chair of the Human Subjects Institutional Review Board (387-8293) or the Vice President for Research (387-8298) with any questions or problems that arise during this study. You will be given a copy of this form to keep for your records.

This consent document has been approved for use for one year by the Human Subjects Institutional Review Board (HSIRB) as indicated by the stamped date and the signature of the board chair in the upper right corner of all pages. Participants, including parents or legal guardians, should not sign this document if the corner of all pages does not show a stamped date and signature.

**Your signature below indicates that you, as parent or legal guardian, can and do give your permission \_\_\_\_\_ (child's name) to participate in this study.**

Date: \_\_\_\_\_

Time: \_\_\_\_\_

\_\_\_\_\_  
Signature of Parent or Legal Guardian

\_\_\_\_\_  
Date

\_\_\_\_\_  
Teenager's Name (Please Print Name)

\_\_\_\_\_  
Date

\_\_\_\_\_  
Signature of Student Investigator Obtaining Permission

\_\_\_\_\_  
Date

**You are also making a decision as to whether or not you would like to participate in this study. Your signature below indicates that you have read the information provided above and have decided to provide consent to participate in this study.**

Date: \_\_\_\_\_

Time: \_\_\_\_\_

\_\_\_\_\_  
Signature of Parent or Legal Guardian

\_\_\_\_\_  
Date

\_\_\_\_\_  
Signature of Student Investigator Obtaining Permission

\_\_\_\_\_  
Date

## Assent for Teenagers

An Office-Based Intervention Designed to Improve Blood Glucose Monitoring in Adolescents With Insulin-Dependent Diabetes Mellitus

Principal Investigator: Amy E. Naugle, Ph.D.

Research Associate: Stephen J. Albrecht, M.A.

Western Michigan University

### Department of Psychology

You and your parent(s) have been invited to participate in a research study entitled "An Office-Based Intervention To Improve Blood Glucose Monitoring in Adolescents with Insulin-Dependent Diabetes Mellitus." This study will help us learn more about a treatment designed to increase the number of times that adolescents with diabetes check their blood sugar levels. The goal of this study is to help you do a better job with monitoring your blood sugar levels. This study will also look at how well this treatment can be used in the diabetes clinic where you are currently receiving your medical services. This study is Stephen Albrecht's dissertation project.

What is involved? If you agree to participate in this study, you and your parent(s) will be asked to spend about 90 minutes in a meeting with the student investigator at Michigan State University/Kalamazoo Center for Medical Studies (MSU/KCMS). During this meeting, you and your parent(s) will be asked to complete several questionnaires. You and your parents(s) will be asked to share some personal information on these forms, such as age, racial identity, and level of education. These questionnaires will also ask questions about whether you have had any conflicts or arguments with your parent(s) about your diabetes. You and your parent(s) will also be asked to report the number of times that you check your blood sugar levels and complete your Insulin injections each week. It will take you about 30 to 45 minutes to complete these questionnaires.

If you decide to participate, you will be asked to participate in a 7-week paging treatment. You will not be required to make any additional office-based visits during this treatment. If you decide to participate, you will be provided with one electronic pager. You will not be able to keep this pager after you are finished with this study. You will be asked to carry this pager with you at all times, including those times when you are away from home or in school. You will be able to give out the pager number to your family and friends and may use the pager at no cost to you during the treatment period. You will be provided with a letter so that you can have permission to use this pager while going to school.

Before you start receiving pages on your pager, the student investigator will call you every three days to see how you are doing with your diabetes. The student investigator will ask you to report the number of blood sugar tests that you performed by looking at your reflectance meter. After a period of time, the student investigator of this study will contact you to let you know when your pager will start receiving pages. The student investigator will send several pages to you each day for a total of 7 weeks. These

pages will help you to remember to check your blood sugar levels each day. You will receive 4 pages per day for the first four weeks of the treatment, followed by 3 pages per day in Week 5, 2 pages per day in Week 6, and 1 page per day in Week 7. Since the pages will help you to remember to check your blood sugar levels, your parents will be asked to not remind you as much to check your blood sugar levels.

After you start receiving pages and throughout the 7-week treatment, the student investigator will complete one 15-minute telephone call with you at the end of each week to gather information on how well you have been following your diet, exercising, and completing your Insulin shots. The student investigator will also ask you to report how many times you have checked your blood sugar levels each day. You will determine how many blood sugar tests you have performed by looking at your reflectance meter.

At the end of the 7 weeks, the student investigator will then contact you and your parent(s) by telephone at 3-months and 6-months after you complete the treatment. During these one-time telephone calls, you will be asked to share the same information that was collected from you during the treatment. You will be asked to complete several questionnaires over the phone. These are the same questionnaires that you will complete during today's meeting. Since you will not have a copy of these questionnaires, the student investigator will read the questions to you. The student investigator will contact you one-week before this telephone call to help remind you.

*Potential Benefits* You may benefit from participating in this study in several ways. If you decide to participate in this study, it may help you to do a better job with checking your blood sugar levels each day. This will help you to better manage your blood sugar levels, which may help you from having other medical problems. This study may also help you to become more independent from your parents in managing your diabetes. You will also be provided with a free paging service during this study. This will allow you to stay in contact with your friends and family. This study may also be helpful to your doctors in providing similar interventions to other adolescents. Also, other adolescents with diabetes may benefit in the future from the knowledge that is gained from this research study.

*Risks of Participating in Study.* As in all research, there may be unforeseen risks to the participant. If an accidental injury occurs, appropriate emergency measures will be taken; however, no compensation or treatment will be made available to you except otherwise specified in the consent form. There are minimal risks for you in this study. You might feel uncomfortable when you fill out the questionnaires or complete the weekly telephone contacts. Also, the time it takes to complete the phone calls might be inconvenient for you. You may also get tired of checking your blood sugar levels and talking to the student investigator on the telephone at the end of each week. If school staff asks you why you are carrying a pager with you on school property, you might feel embarrassed or uncomfortable. The student investigator in this study will provide a letter for you in case school staff asks you why you have a pager in school. The student investigator and your physician at MSU/KCMS will sign this letter. Given that you will be allowed to use the pager for personal purposes, if you choose to abuse or misuse your



pager privileges, there may be negative consequences for you for doing so (e.g., getting in trouble at school or with your parents). If you do abuse these privileges, your parent(s) has the right to stop your participation in the study and to return the pager to us. One additional risk is that your parents may stop reminding you so often about checking your blood-glucose levels. This is not necessarily a bad outcome, if you are able to increase their blood-glucose monitoring due to the pager intervention. However, it is possible that by decreasing their reminders, you forget to check your blood-glucose levels or decrease your blood-glucose monitoring.

If you are feeling sick, you will be asked to tell your parents, call your doctor, or go to the hospital to get medical attention. If you become distressed or upset and would like to participate in therapy or counseling, you will be asked to tell your parents and a referral to a mental health professional will be made.

*Confidentiality of Data.* The information you provide and your answers on the questionnaires will be kept confidential. No one other than you and your parent(s) will be able to access this information. Your name will not be on any of the questionnaires or forms that you complete in this study. No one other than you and your parent(s) will have access to your pager number, unless you decide to give out your pager number to family and friends. The student investigator will use a code number on all questionnaires and forms. The student investigator will keep a list of names and code numbers locked up in a room. This list will be destroyed when you are done with the study. You will also not have to tell any of your friends why you are carrying a pager.

*Participation is Voluntary* Your participation in this study is completely voluntary. Even if you agree to participate in this study by signing this form, you can change your mind at any time and stop participating in this study. Your decision on whether or not to participate in this study will not jeopardize your future relations with Western Michigan University or the medical services provided at Michigan State University/Kalamazoo Center for Medical Studies (MSU/KCMS). You may also refuse to answer any of the questions. If you decide to stop, the doctors and other workers at the diabetes clinic will also not get mad at you.

*Questions?* We will be happy to answer any of your questions. If you have any additional questions or concerns about this study, you may call either Stephen Albrecht at 387-4485 or Dr. Amy Naugle at 387-4726. You may also contact the Chair of the Human Subjects Institutional Review Board (387-8293) or the Vice President for Research (387-8298) with any questions or problems that arise during this study. You will be given a copy of this form to keep for your records.

This consent document has been approved for use for one year by the Human Subjects Institutional Review Board (HSIRB) as indicated by the stamped date and the signature of the board chair in the upper right corner of all pages. Participants, including parents or legal guardians, should not sign this document if the corner does not show a stamped date and signature.

**YOU ARE MAKING A DECISION WHETHER OR NOT YOU WOULD LIKE TO PARTICIPATE IN THIS STUDY. YOUR SIGNATURE BELOW INDICATES THAT YOU HAVE READ THIS FORM, UNDERSTAND THE STUDY, AND HAVE DECIDED TO PARTICIPATE IN THIS STUDY.**

Date \_\_\_\_\_ Time \_\_\_\_\_

\_\_\_\_\_  
Please print name here Date

\_\_\_\_\_  
Sign name here Date

\_\_\_\_\_  
Signature of Student Investigator Obtaining Assent Date

## Consent for Own Participation

An Office-Based Intervention Designed to Improve Blood Glucose  
Monitoring in Adolescents With Insulin-Dependent Diabetes Mellitus

Principal Investigator: Amy E. Naugle, Ph.D.  
Research Associate: Stephen J. Albrecht, M.A.

Western Michigan University

### Department of Psychology

You and your parent(s) have invited to participate in a research study entitled “An Office-Based Intervention To Improve Blood Glucose Monitoring in Adolescents with Insulin-Dependent Diabetes Mellitus.” This study will help us learn more about a treatment designed to increase the number of times that individuals with diabetes check their blood sugar levels. The goal of this study is to help you do a better job with monitoring your blood sugar levels. This study will also look at how well this treatment can be used in the diabetes clinic where you are currently receiving your medical services. This study is Stephen Albrecht’s dissertation project.

What is involved? If you agree to participate in this study, you and your parent(s) will be asked to spend about 90 minutes in a meeting with the student investigator at Michigan State University/Kalamazoo Center for Medical Studies (MSU/KCMS). During this meeting, you and your parent(s) will be asked to complete several questionnaires. You and your parents(s) will be asked to share some personal information on these forms, such as age, racial identity, and level of education. These questionnaires will also ask questions about whether you have had any conflicts or arguments with your parent(s) about your diabetes. You and your parent(s) will also be asked to report the number of times that you check your blood sugar levels and complete your Insulin injections each week. It will take you about 30 to 45 minutes to complete these questionnaires.

If you decide to participate, you will be asked to participate in a 7-week paging treatment. You will not be required to make any additional office-based visits during this treatment. If you decide to participate, you will be provided with one electronic pager. You will not be able to keep this pager after you are finished with this study. You will be asked to carry this pager with you at all times, including those times when you are away from home or in school. You will be able to give out the pager number to your family and friends and may use the pager at no cost to you during the treatment period. You will be provided with a letter so that you can have permission to use this pager while going to school.

Before you start receiving pages on your pager, the student investigator will call you every three days to see how you are doing with your diabetes. The student investigator will ask you to report the number of blood sugar tests that you performed by looking at your reflectance meter. After a period of time, the student investigator of this study will contact you to let you know when your pager will start receiving pages. The student investigator will send several pages to you each day for a total of 7 weeks. These

pages will help you to remember to check your blood sugar levels each day. You will receive 4 pages per day for the first four weeks of the treatment, followed by 3 pages per day in Week 5, 2 pages per day in Week 6, and 1 page per day in Week 7. Since the pages will help you to remember to check your blood sugar levels, your parents will be asked to not remind you as much to check your blood sugar levels.

After you start receiving pages and throughout the 7-week treatment, the student investigator will complete one 15-minute telephone call with you at the end of each week to gather information on how well you have been following your diet, exercising, and completing your Insulin shots. The student investigator will also ask you to report how many times you have checked your blood sugar levels each day. You will determine how many blood sugar tests you have performed by looking at your reflectance meter.

At the end of the 7 weeks, the student investigator will then contact you and your parent(s) by telephone at 3-months and 6-months after you complete the treatment. During these one-time telephone calls, you will be asked to share the same information that was collected from you during the treatment. You will be asked to complete several questionnaires over the phone. These are the same questionnaires that you will complete during today's meeting. Since you will not have a copy of these questionnaires, the student investigator will read the questions to you. The student investigator will contact you one-week before this telephone call to help remind you.

*Potential Benefits* You may benefit from participating in this study in several ways. If you decide to participate in this study, it may help you to do a better job with checking your blood sugar levels each day. This will help you to better manage your blood sugar levels, which may help you from having other medical problems. This study may also help you to become more independent from your parents in managing your diabetes. You will also be provided with a free paging service during this study. This will allow you to stay in contact with your friends and family. This study may also be helpful to your doctors in providing similar interventions to other adolescents. Also, other adolescents with diabetes may benefit in the future from the knowledge that is gained from this research study.

*Risks of Participating in Study* As in all research, there may be unforeseen risks to the participant. If an accidental injury occurs, appropriate emergency measures will be taken; however, no compensation or treatment will be made available to you except otherwise specified in the consent form. There are minimal risks for you in this study. You might feel uncomfortable when you fill out the questionnaires or complete the weekly telephone contacts. Also, the time it takes to complete the phone calls might be inconvenient for you. You may also get tired of checking your blood sugar levels and talking to the student investigator on the telephone at the end of each week. If school staff asks you why you are carrying a pager with you on school property, you might feel embarrassed or uncomfortable. The student investigator in this study will provide a letter for you in case school staff asks you why you have a pager in school. The student investigator and your physician at MSU/KCMS will sign this letter. Given that you will be allowed to use the pager for personal purposes, if you choose to abuse or misuse your

pager privileges, there may be negative consequences for you for doing so (e.g., getting in trouble at school or with your parents). If you do abuse these privileges, your parent(s) has the right to stop your participation in the study and to return the pager to us. One additional risk is that your parents may stop reminding you so often about checking your blood-glucose levels. This is not necessarily a bad outcome, if you are able to increase your blood-glucose monitoring due to the pager intervention. However, it is possible that by decreasing their reminders, you may forget to check your blood-glucose levels or decrease your blood-glucose monitoring.

If you are feeling sick, you will be asked to tell your parents, call your doctor, or go to the hospital to get medical attention. If you become distressed or upset and would like to participate in therapy or counseling, you will be asked to tell your parents and a referral to a mental health professional will be made.

*Confidentiality of Data* The information you provide and your answers on the questionnaires will be kept confidential. No one other than you and your parent(s) will be able to access this information. Your name will not be on any of the questionnaires or forms that you complete in this study. No one other than you and your parent(s) will have access to your pager number, unless you decide to give out your pager number to family and friends. The student investigator will use a code number on all questionnaires and forms. The student investigator will keep a list of names and code numbers locked up in a room. This list will be destroyed when you are done with the study. You will also not have to tell any of your friends why you are carrying a pager.

*Participation is Voluntary* Your participation in this study is completely voluntary. Even if you agree to participate in this study by signing this form, you can change your mind at any time and stop participating in this study. Your decision on whether or not to participate in this study will not jeopardize your future relations with Western Michigan University or the medical services provided at Michigan State University/Kalamazoo Center for Medical Studies (MSU/KCMS). You may also refuse to answer any of the questions. If you decide to stop, the doctors and other workers at the diabetes clinic will also not get mad at you.

*Questions?* We will be happy to answer any of your questions. If you have any additional questions or concerns about this study, you may call either Stephen Albrecht at 387-4485 or Dr. Amy Naugle at 387-4726. You may also contact the Chair of the Human Subjects Institutional Review Board (387-8293) or the Vice President for Research (387-8298) with any questions or problems that arise during this study. You will be given a copy of this form to keep for your records.

This consent document has been approved for use for one year by the Human Subjects Institutional Review Board (HSIRB) as indicated by the stamped date and the signature of the board chair in the upper right corner of all pages. Participants, including parents or legal guardians, should not sign this document if the corner does not show a stamped date and signature.

**YOU ARE MAKING A DECISION WHETHER OR NOT TO YOU WOULD LIKE TO PARTICIPATE IN THIS STUDY. YOUR SIGNATURE BELOW INDICATES THAT YOU HAVE READ THIS FORM, UNDERSTAND THE STUDY, AND HAVE DECIDED TO PARTICIPATE IN THIS STUDY.**

Date \_\_\_\_\_ Time \_\_\_\_\_

\_\_\_\_\_  
Please print name here Date

\_\_\_\_\_  
Sign name here Date

\_\_\_\_\_  
Signature of Student Investigator Obtaining Assent Date

## Appendix E

### Office-Based Visit Instructional Script

## **Office-Based Visit Instructional Script**

### **Informed Consent:**

“Thank you for your interest in this research project. Before we get started, I will first need you to read these consent forms, which will more fully explain the purpose of this study and the amount of time it will take for you to complete this study. There are two separate consent forms that need to be read– one for your parents and one for you. Please carefully read the consent forms as I review it with you and, if you are satisfied with the conditions of the study, please sign and date both copies at the bottom. One copy of this consent form will be returned for our records and the second copy will be for your records. If you have any questions while reading these consent forms, I will be more than happy to answer them.”

### **Administration of Questionnaires:**

“Thank you for agreeing to participate in this study. Your involvement in this study is greatly appreciated. Before we get started, I will first need you to fill out these questionnaires. Please remember, all of your responses on these questionnaires will remain completely confidential. If you have any questions or concerns while filling these questionnaires out, please let me know.”

### **Introduction to Pagers:**

“During the rest of our meeting today, we are going to fully explain the study procedures and provide you with specific instructions and practice in how to use the pager that I will be giving you. Before you leave today, you will receive one Motorola™ pager, like the one that I am holding in my hand. You will not be able to keep this pager after you complete the study. I will be providing you with your pager number during this study. Please feel free to give your pager number out to your parents, other family members, and friends. I will ask you to carry this pager with you at all times, including those times when you are away from home, hanging out with friends, on trips, or in school. Here is a letter that gives you permission to use this pager while attending school. Many high schools do not allow students to have electronic pagers or cellular phones in school. However, since you will have this pager for medical reasons, I will be able to get permission for you to bring this pager to school. You will need to carry this letter with you just in case a teacher or other school staff asks you why you have a pager in school. Although you will be allowed to use the pager for personal reasons, we expect that you will not abuse or misuse the paging services. For example, it is inappropriate for you to be paged at school for reasons other than to remind you to check your blood-glucose levels. If you misuse the pager, there may be serious consequences with your parents or teachers. If your parents think you are misusing the pager, they have the right to stop your participation in the study and return the pager to me. Please do not abuse or misuse your pager privileges.”

“After you leave today, you will not receive pages right away. I will contact you by telephone to let you know when you can expect to start receiving pages on your pager. When I page you, you will receive a code number on your pager. Do not worry right now if you do not know how to check and delete the messages. I will talk about how to do



that in a few minutes. When you receive a page from me, the **code number \*\* 4444\*\* or text message \*\*\*Please check your blood sugar level\*\*\*** will be displayed on your message screen. This code number will serve as a reminder for you to remember to check your blood sugar levels 4 times per day. You might receive a page from me and have already checked your blood sugar levels. If this happens, that's great! You remembered to do it without the pager reminding you to check it. However, let's say, for example, that you receive a page around lunchtime and you haven't checked your blood sugar level yet. If this happens, then the page will remind you that you should check your blood sugar levels.

"One of the most important things that you need to do each day to control your diabetes is to closely check your blood sugar levels. We feel that it is very important for you to closely check your blood sugar levels at least 4 times per day. The doctors here in the diabetes clinic at MSU/KCMS have told me that you should be checking your blood sugar levels at least four times per day, usually once before breakfast, lunch, and dinner, and once before bedtime. You may actually have to check it more often, especially if you are exercising or not feeling well. By closely checking your blood sugar levels each day, you will now know how well your diabetes is going. By checking your blood sugar levels at least 4 times per day, you will be in better control of your diabetes. That's why we are giving you this pager. The pages that you will receive on this pager will help you to remember to check your blood sugar levels each day. The pages are very similar to when people write notes or reminders to themselves that they need to complete something. For example, in order to remember a doctor's appointment, some people might write a note and place it on the refrigerator or in a calendar to help them remember. In school, you may have written notes to help you remember to complete homework assignments.

#### **Schedule of Pages:**

"After you start receiving pages, I will page you everyday for about 7-weeks. Most of the time, you will receive 4 pages per day to remind you to check your blood sugar levels. We are going to page you once in the morning before breakfast, once before lunchtime, once before dinnertime, and once before bedtime. In one of the questionnaires that you completed in the beginning of our meeting today, I asked you to write down the times in which you usually eat breakfast, lunch, and dinner, and what time you usually go to bed each night. We will now spend a few minutes figuring out the best times for me to page you every day. Since the times that you eat or go to bed vary from week to week, we realize that we may not page you at the exactly right time. Towards the end of the 7 weeks, you might not receive 4 pages per day; rather, you might only get 1, 2, or 3 pages per day. That's OK. This does not mean that there is anything wrong with your pager. We still want you to remember to check your blood sugar levels at least 4 times per day"

#### **Practice Using the Pagers:**

"I will now teach you how to use your pager and give you an opportunity to practice checking and deleting pages. During this meeting, I will actually send several pages to this pager in my hand so that you can have some practice. I also want to make sure that you know how to answer and delete your messages. It is important to make sure that you know how to properly use the pager before you leave today. We will also go through the "User's Guide" manual for your pager today. I will provide you with a copy of this

manual in case you have any problems at home. You will also be able to contact me by telephone if you have any problems with your pager. My phone number is on your copy of the consent form and on the informational flier that you received in the diabetes clinic.”

“The good news is that I have already taken the time to set-up most of the features on your pager. However, I want to make sure that you know how to receive and read your messages, delete your messages, and set the different alert modes. Since you will be allowed to take this pager with you to school, we want to show you how to set the alert mode from the audible mode to the silent alert mode (i.e., vibrating mode). That way, your pager will not disrupt other students or make your teacher mad at school. If you set your pager to the silent alert mode, it will be very important for you to wear your pager with this clip or put it in your pocket. That way, you will know when you get a page.”

#### **User’s Guide Instructional Manual:**

“We will now go through this “User’s Guide Manual” [Hand Out Manual] together to teach you how to use this pager. One of the most important things to remember is that you should not turn off your pager at any time. Also, it is important that you remember to delete your messages from time to time so the memory doesn’t get filled up. If you have any questions while we go through this manual, please let me know.

1. Pager Symbols
2. Receiving and Reading Your Messages
3. Using the Function Menu
4. Setting the Alert Mode
5. Deleting Your Messages
6. Checking Your Battery Gauge

#### **Telephone Contacts:**

“Throughout this study, I will also be contacting you by telephone every three days or at the end of each week. Before you start receiving pages, I will call you every three days. At some point, I will then tell you when you will start receiving pages from me. When you start receiving pages from me, I will then only contact you once per week. These telephone contacts should only take about 15 to 20 minutes to complete. On one of the questionnaires that you filled out earlier, you indicated some days and times each week that I can get a hold of you by phone. We will now look at those times to see what you think are the best times and days for me to call. I will try to contact you on your more preferred day and time. If I am unable to reach you at this time and day, I will then try another time and day until I get a hold of you. If I leave a message for you, you can call me back and leave a message on my recorder to let me know when would be a good time to get a hold of you.”

“During these telephone contacts, I will ask you to answer several questions over the telephone. When I call you, you will need to have your reflectance meter with you. If you know the time and day when I am going to call, you can make sure that your meter is in a location where it is easy to find when I call you. If you are not home when I call

you, I will try to call you back at another time. During this phone call, I will ask you to check your reflectance meter while you talk with me on the phone. By looking at your meter, you will be able to tell me how many blood sugar checks you completed during that week. If you have more than one meter, I will need you to have both meters at home on the day that I call you.”

**3- and 6-Month Follow-Up Sessions:**

“After you stop receiving pages on your pager, I will ask you and your parents to mail the pager back to me in a box like this one. I will give you one of these boxes before you leave today. I have already paid the postage and handling for this box. All you have to do is place the pager in this box, seal it, and then drop it in your mailbox at home or in a post-office mailbox. I will contact you by telephone to remind you if you forget to mail me the pager.”

“I will also be contacting you by telephone 3 and 6 months after you finish this study. During this telephone call, I will ask you and your parents the same questions that I asked you while you were participating in the study. In addition, I will also ask you and your parents to complete the same questionnaires that you filled out earlier today at the beginning of this meeting. Because you and your parents will not have a copy of these questionnaires, I will read them to you over the phone and you will tell me the answers.”

**Wrap-Up:**

“We have finished everything that we need to cover today. Remember, I will be calling you in three days to talk with you on the telephone. I will let you know when you will start receiving the pages. Thanks again for your willingness to participate in this study. If you have any questions or concerns, you can call me at the phone number listed on your copy of the informed consent form. My number is also located on the flier that you received in the diabetes clinic.”

## Appendix F

### Weekly Telephone Contact Script

## Weekly Participant Phone Contact Script – Baseline and Intervention Phases

“Hello, \_\_\_\_\_. This is Steve Albrecht calling from MSU/KCMS. [Establish Rapport] I am calling you today because we agreed that I would contact you to find out how many times you checked your blood sugar levels [over the past three days] each week. I will also ask you some questions about how you are doing with other diabetes self-care activities. This should take only about 15 minutes to complete. Do you have your reflectance meter with you right now? Before we can get started, you will need your reflectance meter. If you don't have your reflectance meter, I can wait here on the phone while you go and find it.

O.K. Now that you have your meter, I will need you to report how many times you have checked your blood sugar levels [over the past three days] over the past week. I will need you to tell me the time and date of each test and the actual blood sugar reading for each test. Let's start at the beginning of the week [with the day of our last conversation] and we will go over each day one at a time. Please tell me the number of times that you checked your blood sugar levels and your readings on \_\_\_\_\_ (Date). O.K. Lets check the next day. [Repeat Procedure]

“I am now going to ask you several questions about how well you've completed certain diabetes self-care activities [during the past 3 days] during the past 7 days. When I ask you a question, please try to think about how well you have done [over the past 3 days] over the past 7 days. I will ask you to tell me how many days [over the past 3 days] this week you completed the activity. Please take your time and try to remember everything. If you have any questions, please let me know.”

“That is all the questions that I have for you today. Do you have any questions or concerns about the study? Please remember that I will be calling you again in \_\_\_\_\_ (days). Thanks for your time and I will talk with you again [in three days] next week. Have a great week!

## Appendix G

### Data Collection Forms

**Data Collection Form 1 – Blood Glucose Monitoring**

	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday	Sunday
Date							
Check # 1- Time							
Blood Glucose Reading							
Check # 2- Time							
Blood Glucose Reading							
Check # 3- Time							
Blood Glucose Reading							
Check # 4- Time							
Blood Glucose Reading							
Check # 5- Time							
Blood Glucose Reading							
Check # 6- Time							
Blood Glucose Reading							
Check # 7- Time							
Blood Glucose Reading							
Check # 8- Time							
Blood Glucose Reading							
Check # 9- Time							
Blood Glucose Reading							
Check # 10- Time							
Blood Glucose Reading							

## Data Collection Form 2 – Diabetes Self-Care Activities

<b>Diet Questions</b>	<b>Days (1-7)</b>
1. How many days this week did you choose to eat healthy foods?	
2. How many days this week did you eat five or more servings of fruits and vegetables?	
3. How many days this week did you eat foods that were high in fat or salt, such as red meat, pizza, fast food, or salad dressings?	
4. How many days this week did you follow your eating plan?	
5. How many days this week did you eat the right amount of food?	
6. How many days this week did you eat your meals at the right time?	
7. How many days this week did you eat six meals or snacks per day?	
<b>Exercise Questions</b>	
8. How many days this week did you participate in at least 30 minutes of physical activity, such as walking or working in the yard?	
How many days this week did you participate in a specific type of exercise, such as working out in the gym, jogging, swimming, or biking?	
<b>Insulin/Medication Questions</b>	
How many days this week did you take your recommended number of insulin injections?	
11. How many days this week did you take your insulin injections at the right time?	
12. How many days this week did you take your recommended pill medications?	
<b>Foot Care Questions</b>	
13. How many days this week did you check your feet?	
14. How many days this week did you wash your feet?	



### Data Collection Form 3 – Medical Chart Review

Subject Number:	
Baseline Start Date:	
Intervention Start Date:	
Week Number:	
Date:	

Current Age:	
Type of Diagnosis:	
Age of Diagnosis:	
Number of Hospitalizations: (Previous Year)	
Types of Medications:	
Insulin Dose:	

#### Average number of blood glucose checks performed at 3-month intervals

	M1	M2	M3	M4	M5	M6
Date Range:						
Average Number of Blood Glucose Checks:						

\* Note: M=Month

#### Available hemoglobin A<sub>1c</sub> levels at 3-month intervals

	3-Months	6-Months	9-Months	12-Months
Date Range:				
HbA <sub>1c</sub> Values:				

## Appendix H

### Letter to School

## Letter to School

Dear School Staff:

I am a graduate student in a doctoral program in clinical psychology at Western Michigan University. I am currently conducting my dissertation study entitled "An Office-Based Intervention to Improve Blood Glucose Monitoring in Adolescents with Insulin-Dependent Diabetes Mellitus." This study is investigating whether or not a treatment is effective in improving blood glucose monitoring in teenagers with diabetes. The Human Subjects Institutional Review Board (HSIRB) at Western Michigan University (WMU) has granted me permission to conduct this study.

We are providing participants in this study with an electronic pager. I will be paging participants four times daily to remind them to check their blood glucose levels throughout the day. We are asking all participants to carry this electronic pager with them at all times, including those times when they are in school. We are also asking all students to set their pager to the silent mode so that it does not disrupt the classroom environment.

Although current state laws restrict all students from carrying a pager, cell phone, or other electronic devices within the school setting, it also provides several exemptions for students with chronic medical conditions. This letter provides an explanation for why this adolescent is using the electronic pager within the school setting. If you have any questions or concerns, please feel free to contact me at (616) 337-6459. I would be more than happy to answer any questions or concerns that you might have.

Sincerely,

Stephen J. Albrecht, MA  
MSU/KCMS

Martin Draznin, MD  
MSU/KCMS

## Appendix I

### Figures

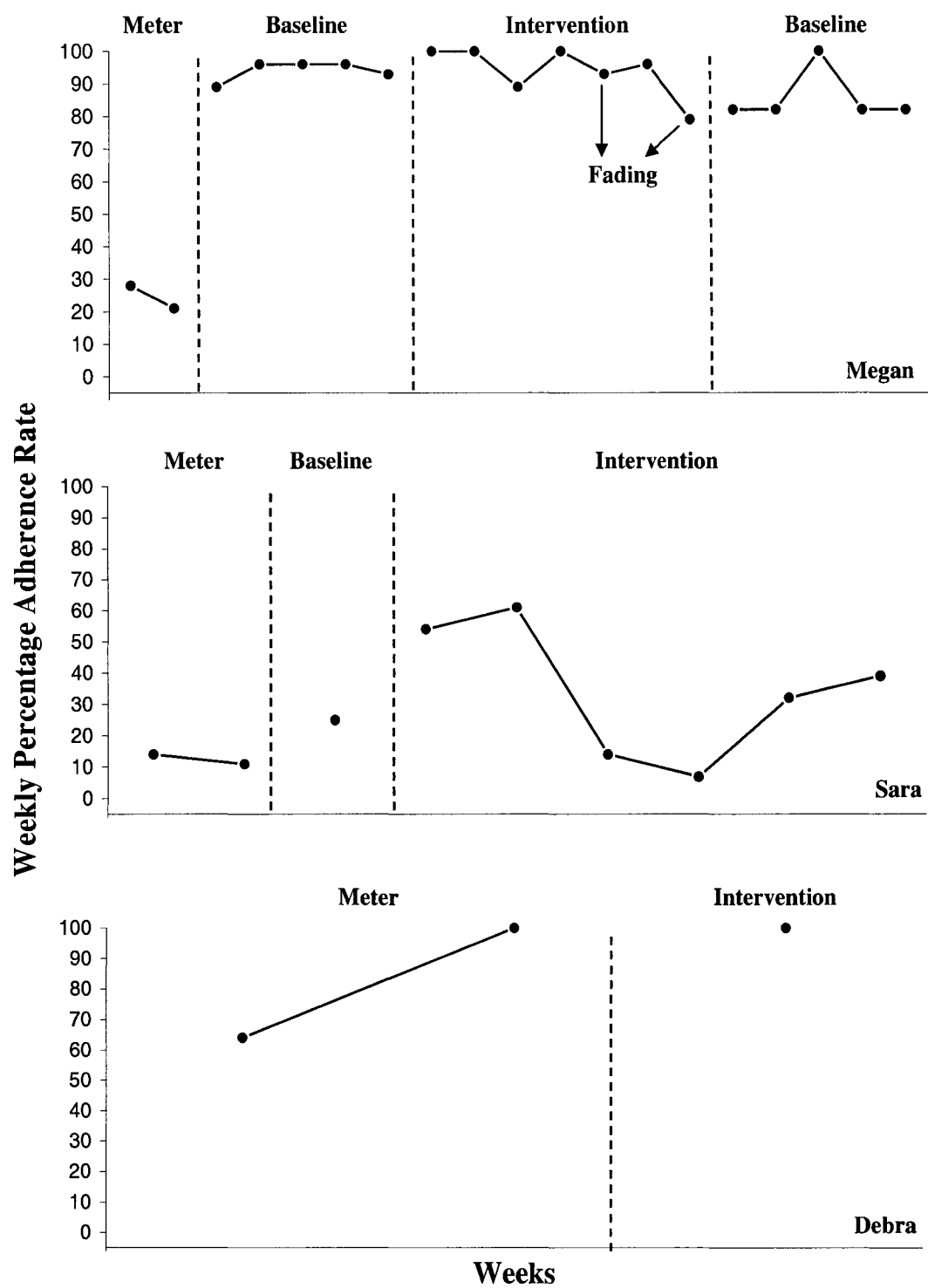


Figure 1. Percentage adherence to blood glucose monitoring checks across study conditions for Megan (top panel), Sara (middle panel), and Debra (bottom panel).

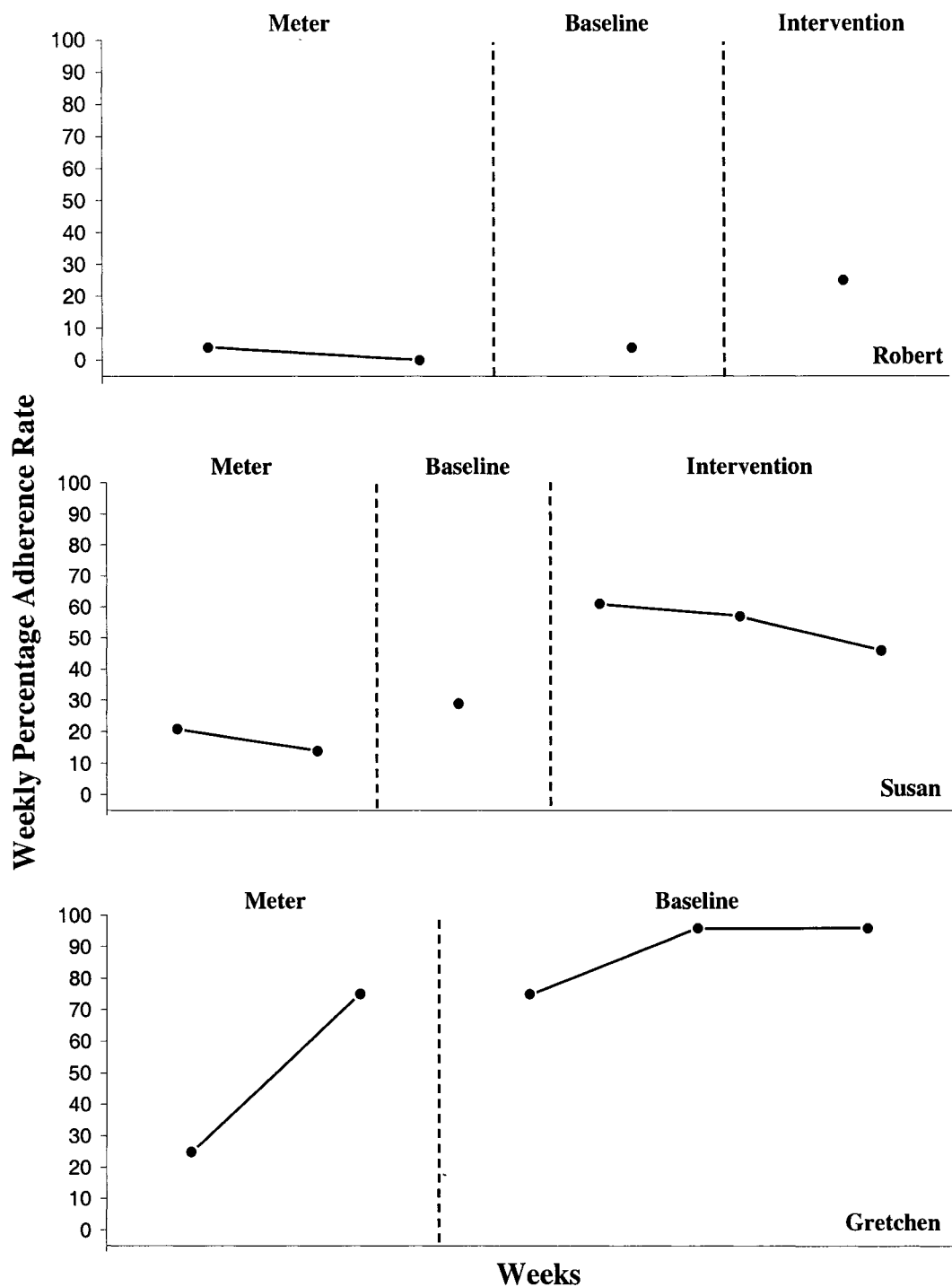


Figure 2. Percentage adherence to blood glucose monitoring checks across study conditions for Robert (top panel), Susan (middle panel), and Gretchen (bottom panel).

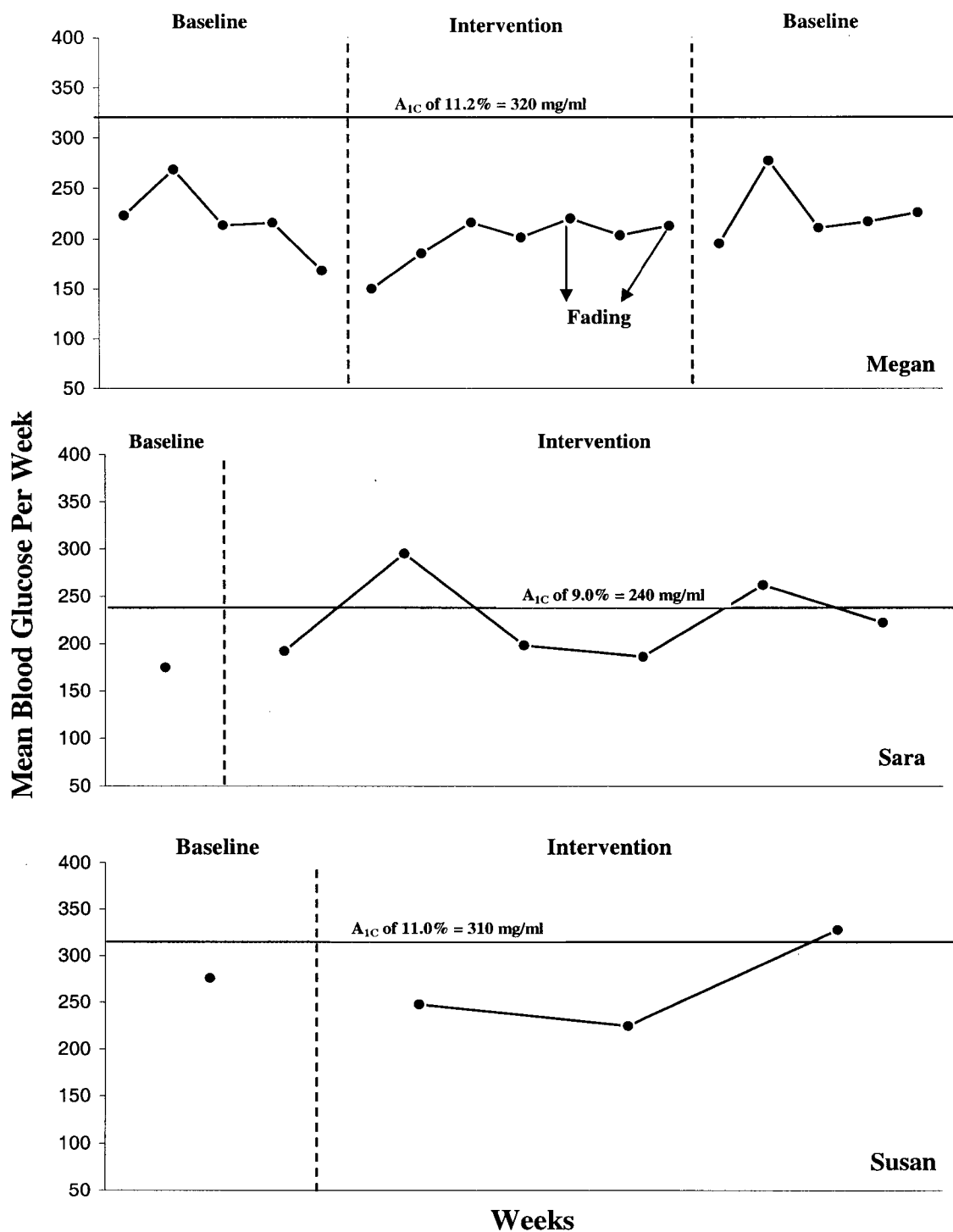


Figure 3. Mean 7-day blood glucose readings across study conditions for Megan (top panel), Sara (middle panel), and Susan (bottom panel). The horizontal line represents the participant's average blood glucose level (based on the participant's hemoglobin  $A_{1c}$  value) in the 2- to 3-months before study entry.

## Appendix J

### Approval Letter From the Human Subjects Institutional Review Board





Date: July 30, 2002

To: Amy Naugle, Principal Investigator  
Stephen Albrecht, Student Investigator for dissertation

From: Mary Lagerwey, Chair

A handwritten signature in dark ink, likely belonging to Mary Lagerwey, the Chair of the HSIRB.

Re: HSIRB Project Number: 02-07-04

This letter will confirm that your research project entitled "An Office-Based Intervention to Improve Blood Glucose Monitoring in Adolescents with Insulin-Dependent Diabetes Mellitus" has been **approved** under the **full** category of review by the Human Subjects Institutional Review Board. The conditions and duration of this approval are specified in the Policies of Western Michigan University. You may now begin to implement the research as described in the application.

Please note that you may **only** conduct this research exactly in the form it was approved. You must seek specific board approval for any changes in this project. You must also seek reapproval if the project extends beyond the termination date noted below. In addition if there are any unanticipated adverse reactions or unanticipated events associated with the conduct of this research, you should immediately suspend the project and contact the Chair of the HSIRB for consultation.

The Board wishes you success in the pursuit of your research goals.

Approval Termination: July 17, 2003