

THE DIETARY INTAKE OF YOUNG CHILDREN (2-7 YEARS) WITH TYPE 1
DIABETES COMPARED WITH THE NEW MYPLATE RECOMMENDATIONS.

By

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Abstract

Type 1 diabetes mellitus (T1DM) is estimated to be the third most common chronic disease in young people. Management of T1DM is complex, and if treatment is inadequate, a wide variety of complications may arise. Dietary management is crucial for maintaining near-normal blood sugar levels; however, there is currently no gold standard for measuring adherence to the American Diabetes Association's (ADA) recommendations. MyPlate is the United States Department of Agriculture's (USDA) new visual tool that serves as a guide for healthy eating at meal times; however, there are no published data to determine if people are meeting the goals MyPlate proposes. The purpose of this thesis was to determine if the dietary intake of young children with T1DM is meeting the new MyPlate recommendations.

Data for this study were compiled from one previously conducted study and two ongoing studies to generate a sample size of fifty-five young children (ages 2-7). Three-day diet records were obtained for each subject and analyzed using Nutrition Data Systems for Research (NDSR). Myplate Meal scores and USDA daily scores were calculated using a newly developed scoring system. The Healthy Eating Index (HEI), a validated measure of diet quality, was calculated for all subjects to compare to the new scoring systems.

Participants consumed 68% of the daily recommendation for fruit, 43% of the recommendation for vegetables, 59% of the recommendation for grains, 74% of the recommendation for dairy, and 60% of the recommendation for protein based on age-appropriate MyPlate recommendations. Moreover 89% of the children did not meet the recommendation to make half of their grains whole grains based on MyPlate. The

average HEI score was significantly correlated with percent calories from saturated fat intake ($p=.000$), and with the USDA daily score ($p=.000$), but not with the MyPlate Meal score. Both Body Mass Index (BMI) and Hemoglobin A1c were not significantly correlated with the Myplate Meal score, USDA Day score or HEI score; however, the correlations were trending in the negative direction. No significant relationship was found between fruit and vegetable intake and BMI percentile, and no significant relation was found between percent calories from saturated fat and protein intake. There was a significant positive relationship between dairy intake and percent calories from saturated fat intake ($p=0.04$), suggesting higher intake of dairy was associated with higher percent calories from saturated fat intake in children.

My research suggests that children with T1DM are not meeting the MyPlate recommendations. Adhering to the recommendations would be beneficial to reduce the risk of short and long-term complications. MyPlate could serve as an educational tool for health professionals to use in educating families and children with T1DM about healthy eating in a practical, diabetes specific manner.

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Table of contents

List of Tables and Figures.....	ix
Chapter 1: Introduction.....	1
Justification.....	1
Statement of Problem.....	3
Research Questions.....	3
Chapter 2: Review of Literature.....	5
Type One Diabetes Mellitus.....	6
Nutrition Recommendations.....	7
Adherence to Recommendations.....	7
Barriers to a Healthful Diet.....	11
T1DM Education.....	13
MyPlate.....	14
Conclusion.....	14
Chapter 3: Methods.....	16
Overview.....	16
Sample.....	16
Recruitment.....	17
Ethics.....	18
Anthropometrics.....	18
Demographics.....	19
Dietary intake.....	19
MyPlate Analysis.....	20

Food Group Percentages.....	24
MyPlate Total Adherence Score.....	24
Healthy Eating Index.....	25
Data Analysis.....	27
Chapter 4: Results.....	29
Subject Characteristics.....	29
Dietary Intake.....	30
Overall MyPlate Adherence.....	31
MyPlate Meal Adherence by Food Group.....	32
Comparison of MyPlate Meal Score, USDA Daily Score.....	33
HEI Score and Subcomponent Scores.....	33
MyPlate Meal and USDA Daily Scores Compared to HEI Score.....	34
Saturated fat Intake and Dietary Adherence.....	35
Hemoglobin A1c and Dietary Adherence.....	35
BMI Percentile and Dietary Adherence.....	36
Protein and Dairy Intake and Saturated fat.....	36
Chapter 5: Discussion.....	38
Sample.....	38
Dietary Intake.....	39
MyPlate Adherence.....	41
Healthy Eating Index.....	42
MyPlate Adherence Scores and HEI Scores.....	42
Saturated fat Intake and Dietary Adherence.....	43

Hemoglobin A1c and Dietary Adherence.....	44
BMI Percentile and Dietary Adherence.....	44
Limitations.....	45
Implications and Future Studies.....	46
Conclusion.....	48
Chapter 6: Summary.....	49
References.....	51
Appendix A: Questionnaires.....	54
Appendix B: Consent Forms.....	62

List of Tables and Figures

In-Text Tables:

Table 1: Dietary Guidelines for American’s Recommendations.....	24
Table 2. MyPlate Scoring System.....	25
Table 3. Socio-Demographic Characteristics of the Sample.....	29
Table 4. Subject Descriptive Statistics.....	30
Table 5. Dietary Characteristics of the Sample.....	31
Table 6. Food Groups Serving by Meal Period.....	32
Table 7. Subcomponent HEI scores.....	34
Table 8. Scaled Average Score by Dietary Adherence Scoring System.....	34
Table 9. Hemoglobin A1c compared to MyPlate Meal score, USDA Daily Adherence Score, and HEI score.....	36

In-Text Figures:

Figure 1. Daily Percent Adherence to Food Groups.....	32
Figure 2. The Healthy Plate for Type 1 Diabetes.....	48

Chapter 1: Introduction

Justification

Type 1 diabetes mellitus (T1DM) is estimated to be the third most common chronic disease in young people (1). The Centers for Disease Control and Prevention (CDC) estimates more than 13,000 young people are diagnosed each year (2).

Management of this disease is multifactorial, and a wide range of knowledge, skills and understanding of the disease process is needed for proper control. Unfortunately, if treatment is inadequate, a wide variety of complications may arise. Hypoglycemia and hyperglycemia (leading to diabetic ketoacidosis), both potentially fatal, are immediate complications of uncontrolled diabetes (1). Long-term complications include but are not limited to hypertension, cardiovascular disease (CVD), amputation and kidney disease (3). Research shows that mortality from CVD is increased two- to twenty-fold in T1DM patients (4-6). Establishing near-normal blood glucose is imperative to prevent all possible complications, and to achieve this goal, patients and families need multifactorial education.

Education for children and families with T1DM is intense and complex, and can be overwhelming. Educators should be good communicators, compassionate, sensitive, and they need to have an in-depth knowledge of childhood diabetes (7). Specifically, diet education is an essential component to achieve proper blood glucose control. In the 2005 position statement, the American Diabetes Association (ADA) recommends that children adhere to the recommendations from the Dietary Guidelines for Americans (DGA) for proper growth and development (7, 8). Due to the increased risk for developing CVD,

ADA recommends consuming less than 7% of daily calories from saturated fat, minimizing trans-fatty acid intake, and limiting daily dietary cholesterol to 200 milligrams per day (9). Several barriers may hinder children from consuming an overall healthful diet, yet while it is a difficult task, it is imperative to reduce possible complications that often arise. Data show that children with T1DM are not adhering to these recommendations (10-19). Research is needed to investigate other educational tools to translate the importance of meeting these recommendations to families and children with T1DM.

MyPlate is the United States Department of Agriculture's (USDA) newest visual tool that replaced MyPyramid in 2010 (20). MyPlate is based off of the Dietary Guidelines for Americans, and its purpose is to assist the general public at mealtimes, with the goal being to make half of their plate fruits and vegetables, one-fourth grains, one-fourth protein, and incorporate dairy. There is a lack of research regarding the extent to which Americans are meeting MyPlate's goals, as well as how many people understand the concept. A diabetes specific MyPlate tool emphasizing non-starchy vegetables, low fat dairy, and healthy fats as an alternative to high fat, carbohydrate free foods, would be extremely useful in educating young children with T1DM. It could also serve as a tool to measure adherence to the nutrition recommendations. More research is needed to investigate if young children with T1DM are meeting MyPlate's goals, and if there is a way to generate an adherence score based on deviation or achievement of MyPlate's recommendations.

Statement of Problem

Research has been conducted to evaluate the dietary intake of children with T1DM; however, there is currently no gold standard for measuring adherence to these recommendations. There are currently no published data to determine if people are meeting the goals outlined by MyPlate. Diabetes educators need to place a greater emphasis on the importance of healthy eating and meeting these dietary recommendations while maintaining near-normal blood glucose levels, so as to decrease the risk of complications. A simple visual cue could help educators communicate the benefits to adhering to the recommendations and help children with T1DM lead the healthiest life possible. Specifically, MyPlate could serve as a measure of adherence. MyPlate could also be modified to target diabetes education with the inclusion of more specific goals for plates including: non-starchy vegetables, low saturated fat/ healthy fat, lean proteins, whole grains, and low fat dairy.

Research Questions

Primary Question

1. To what extent do children with type 1-diabetes (2 to 7 years of age) meet the new MyPlate recommendations?

Secondary Questions

1. Do children with type 1-diabetes who have lower average HEI, MyPlate and USDA adherence scores have higher average saturated fat intake?

2. How does Body Mass Index (BMI) and hemoglobin A1c correlate in young children with type 1-diabetes who have higher MyPlate and USDA adherence scores?
3. Do young children with type 1-diabetes who have higher MyPlate and USDA adherence scores also have higher Healthy Eating Index (HEI) scores?
4. Is there a relationship between higher fruit and vegetable intake and young children's BMI?
5. Is there a relationship between protein and dairy intake and young children's percent calories from saturated fat intake?

Chapter 2: Review of Literature

Type 1-diabetes mellitus (T1DM) is a chronic disease that affects children and adults worldwide. It is estimated that it is the third most common chronic disease in young people (1, 21). The disease is characterized by the inability to make insulin, resulting in a need for chronic insulin injections to control the cellular uptake of glucose (1). Multifactorial management is necessary to ensure near-normal blood glucose control. According to the American Diabetes Association (ADA), for youth with T1DM, the goal is to provide adequate energy from healthy food choices to facilitate normal growth and development, and to integrate insulin regimens into the child's usual eating and physical activity habits for the purpose of delaying and managing complications that can present with diabetes (22).

The purpose of this literature review is to examine the current nutrition recommendations for young children with T1DM and assess to what extent they are meeting those recommendations, as well as the barriers they face in diabetes management. MyPlate is the United States Department of Agriculture's (USDA) newest tool for Americans to use as a healthful guide for mealtimes (20). Secondary aims of this review are to examine the tool MyPlate as a possible method for measuring adherence to nutrition recommendations and a new way for health professionals to implement better diabetes education. This search was conducted using PubMed and CINAHL databases. Search terms included: *Type 1 diabetes mellitus, young children, nutrition, education, nutrition recommendations, healthy eating, MyPlate, complications, barriers, nutrition guidelines, diabetes standards, nutritional requirements etc.* Limits of this search included: children and adolescents, and a time frame of 1990 to 2012.

It is important to evaluate the current nutritional status of children with T1DM and the barriers they face in accomplishing the recommended goals of healthy eating and blood sugar control. If children are not meeting the recommendations for these goals, education methods for teaching T1DM management need to be assessed, and the application of new adherence measures and/or educational tools, such as MyPlate, should be explored.

Type 1 Diabetes Mellitus

T1DM is characterized by a complete deficiency of insulin that most commonly results from an autoimmune destruction of insulin producing beta cells in the pancreas (23). Without insulin, the body cannot metabolize glucose, and it begins to build up in the blood (4). If left untreated, this can result in severe complications. The short-term complications of uncontrolled blood glucose include hypoglycemia and hyperglycemia (which can lead to diabetic ketoacidosis), which are both potentially fatal (1). Long-term complications include microvascular and macrovascular complications that can ultimately lead to hypertension, cardiovascular disease (CVD), amputation, and kidney disease (3). Research shows that mortality from CVD is increased two- to twenty-fold in T1DM patients (4). The main goal for children with diabetes is to establish near normal control of blood glucose (70–130 mg/dl) to prevent all possible complications. To reach this goal, multiple factors of diabetes management must be understood, and then carried out.

Nutrition recommendations

Diet is an essential component of diabetes management and proper control of blood glucose. The nutrition recommendations for children with T1DM are based on requirements for all healthy children and adolescents (7). The 2010 Dietary Guidelines for Americans recommends increasing the intake of fruits and vegetables, whole grains, and low-fat dairy (8). The ADA recommends adhering to the Recommended Dietary Allowance (RDA) for carbohydrate intake, which is 130 grams per day or 45 to 65 percent of total energy (9). The Dietary Guidelines (8) suggest young children (2 to 3 years old) should consume 30-35 percent of energy from fat, and older children (ages 4 to 18 years old) should consume 25-30 percent of energy from fat. The Dietary Guidelines also recommend children and adolescents consume less than 10% of daily calories from saturated fatty acids, avoid consuming trans-fatty acids, consume less than 300 milligrams of cholesterol per day, and reduce the intake of calories from solid fats and added sugars (8). Taking the Dietary Guidelines one step further, the ADA recommends that those with diabetes should limit saturated fat to less than 7% of daily calories, minimize trans-fatty acid intake, and limit daily dietary cholesterol to 200 milligrams to reduce the risk of cardiovascular disease (9). These recommendations can be difficult to adhere to for all people, and it may be especially hard to focus on healthy eating when several other factors need to be considered in diabetes management.

Adherence to recommendations

Healthy children in the United States are not meeting national recommendations, and instead choosing foods higher in fat and added sugars and lacking in some nutrients

(24). Children with T1DM follow a similar pattern to children without T1DM by not eating the recommended amount of fruits, vegetables, whole grains and dairy, and consuming more dietary fat, saturated fat, and added sugars than recommended (15). Macronutrient intake as well as intake of certain food groups have been studied and measured among T1DM children with the goal being to evaluate dietary intake and to generate ideas to promote healthful eating.

Dietary fat and saturated fat may be the nutrient of most concern for children with T1DM because of their predisposed risk of CVD. Virtanen et al (19) found that newly diagnosed children with T1DM ate an overall nutrient dense diet. The children in this study had daily percentages of energy from total fat within ADA recommendations, and also had intake of total fat less than the control group of children without T1DM (28% vs. 35%, respectively). Although the percent of energy from saturated fat was lower in the T1DM group than in the control group (11% vs. 15%, respectively), it still exceeded the ADA saturated fat recommendation. In contrast, several other studies examining the total percent of energy from fat consumed by youth and adolescents with T1DM have found that overall these children and adolescents exceed the recommendations for fat intake (11, 13, 14, 16, 17). Similar findings have also been reported for the percentage of energy from saturated fat (12, 14, 17, 19). It has been speculated that dietary management of diabetes focuses mainly on carbohydrates, and that fat containing foods may be appealing to avoid blood sugar fluctuations, and because insulin does not have to be given for carbohydrate-free, potentially high fat foods (18).

Adequate intake of carbohydrate has been reported in several studies of youths with T1DM (11-14, 16, 19). Although these children are consuming the recommended

amount of carbohydrate, the SEARCH for Diabetes in Youth study found that none of the children met recommendations for whole grain intake (13). Rather than focusing on incorporating whole grains and fruits into the child's carbohydrate allotment, parents and youths tend to focus on carbohydrate amount and portion size due to the ease of reading the nutrition label, which leads to a greater intake of processed foods over whole foods (25). Research also shows that children with T1DM are not consuming appropriate amounts of fiber, consuming only 50% of recommended amount (13, 14, 17). Data suggest that eating a high-fiber diet can reduce glycemia in people with T1DM; therefore, these individuals should strive to increase fiber and whole grain intake (9).

Protein foods are mostly carbohydrate-free, and studies have found that children with T1DM have an adequate protein intake that meets current recommendations (11-13, 16, 19). Other studies have found that children with T1DM actually consume more protein per day than the control group non-T1DM peers (11, 14, 19). The long-term effects of a high protein diet (greater than twenty percent of calories) and the resulting complications are unknown; therefore, the ADA recommends that children with T1DM who have normal renal function should consume the same amount of protein recommended for children without diabetes (9).

All children may experience difficulty in meeting the recommendations for fruits and vegetables due to taste and texture preferences, unwillingness to try new foods, convenience, or even appearance (26). The SEARCH study (13) found that less than 20% of children in the study met the recommendations for fruit and vegetable consumption, and similarly, Overby et al. (14) found that participants consumed 210 grams of fruits and vegetables per day, which is well under the recommended 500 grams per day. Fruits and

vegetables are an essential part of any healthy diet and the Dietary Guidelines for Americans recommends children and adolescents consume 1- 1 ½ cups of fruit and 1-2 cups of vegetables per day for optimal healthy growth and development (8).

Dairy and dairy products are an excellent source of calcium and consumption is encouraged to optimize bone health, which is especially important during childhood and adolescence when bone mass is being built (8). Higher intake of dairy is also associated with a lower risk of cardiovascular disease, as well as lower blood pressure in adults (8). Patton et al. (16) found that less than half of the children with T1DM met the recommended Dietary Reference Intake (DRI) for calcium, but alternatively the SEARCH study (13) found that 63.2% of the younger children (10-14 years old) and 54.9% of the older children (15 years and older) met the recommendation for calcium. A study from 2002 found that children with T1DM consumed low fat and fat free milk while the control group more often chose higher fat dairy products. Since low fat and fat free milk has less calories than full fat milk, children with T1DM consumed 20% of daily calories from dairy products as opposed to the control group of healthy children who consumed 30% (19). The current recommendations are that children two years to eight years should consume 2- 2 ½ cups per day and children nine and older should consume 3 cups per day (8). Not meeting these requirements could pose as a health risk for bone development in children.

The risk of immediate complications (hypo- and hyperglycemia) may dominate the long-term complications when it comes to dietary management (1). Instead of focusing on healthy eating and prevention of long-term complications, parents and children may become primarily focused on controlling blood sugar and neglect to follow

general dietary recommendations. These practices can become problematic regarding the child's growth and development, ability to form lifelong healthy habits, as well as the risk of long-term diabetes-related complications. The importance of promoting adherence to nutrition recommendations for youths with T1DM is imperative given both the potential benefit for blood sugar control and reducing the risk of long-term complications (26).

Barriers to a healthful diet

Parents of children with T1DM may encounter many barriers that prevent them from providing the ideal diet for their child. A possible explanation as to why children with T1DM do not consume the recommended amounts of dairy, fruits, vegetables, and whole grains may be due to the amounts of carbohydrate in these healthy foods. Geller et al. (26) found that in reference to "good diabetes management," children reported consuming high fat meat and cheese snacks because they are carbohydrate-free foods. The children deemed these foods as "free," however these foods are typically higher in saturated fat and cholesterol, which are not recommended for children with T1DM due to their already increased risk for CVD (26). Education is necessary to ensure that children are eating healthy foods, and choosing low fat or healthy fat options as part of their goal to achieve near-normal blood glucose control.

Along with the extreme focus on carbohydrate counting during education sessions, a lack of general healthy eating knowledge may be an obstacle to the child consuming the appropriate nutrition recommendations. Without proper education, a carbohydrate-free food may seem like a healthy option to feed a child with T1DM. While there are many healthful carbohydrate-free foods (non-starchy vegetables, low fat cheese,

etc.) there are also a lot of high fat, high cholesterol options that are low cost and convenient. Some parents report feeding their child foods that do not require additional insulin administration, and while this strategy could promote greater intake of vegetables, it could also encourage the consumption of sugar-free, high fat products (25).

Due to differing insulin regimens, some children must eat specific amounts of food at specific times, however most youths now have the flexibility to eat when and whatever they want based on their insulin to carbohydrate ratio (26). A flexible regimen can better accommodate a child's sporadic lifestyle and appetite uncertainty. This greater flexibility may also increase the opportunity to choose foods that are unhealthy and the opportunity to eat more often (25). While a flexible insulin regimen may be more convenient and less stressful for a family managing a child with diabetes, it presents a greater likelihood that the child will consume a less healthy diet. General healthful eating education is needed to help children and families make healthy meal and snack choices on a flexible insulin regimen.

Young children can be very unpredictable, and their ever-changing activity level and food preferences can result in stress and conflict when making insulin adjustments (1). The variability of a child's eating habits causes an even greater issue if the child is a picky eater. The uncertainty of children's behavior also affects how a parent manages the balance between carbohydrate intake and insulin administration. It has been reported that young children have a greater risk for experiencing hypoglycemia, which leads some parents to become worrisome and fearful. This fear of hypoglycemia can sometimes lead parents to "keep blood sugars high" in hopes that this will prevent an immediate complication, disregarding the risk of hyperglycemia and long term complications (7).

Maintaining near-normal control of blood glucose while eating a healthy diet can be extremely challenging and social and behavioral factors, such as food preferences and fear of hypoglycemia, need to be taken into consideration when educating young children with T1DM and their families.

T1DM Education

Nutrition education is an essential component of diabetes management. Upon diagnosis, the family and child must learn a multitude of information about the disease process, insulin administration, blood glucose monitoring etc. In addition, learning a child has a chronic disease that will encompass lifelong management can be overwhelming and stressful. Parents should discuss with a doctor what insulin regimen best fits into their child's current lifestyle, and because of the many insulin regimens available today, it can usually be adapted to the child's current meal routine, food preferences and activity schedule (9). After determining the amount of insulin required to cover the patient's usual meal carbohydrate amount, patients and/or parents can be taught how to match the insulin they inject with the carbohydrate they plan to eat commonly referred to as an insulin-to-carbohydrate ratio (27). Regardless of the insulin regimen, knowing the carbohydrate content of a food is a useful and necessary skill.

Following diagnosis, one of the first goals of diabetes education is to teach "survival" skills, such as learning how to adjust insulin based on the amount of carbohydrate the child plans to eat. Several methods can be used to estimate the carbohydrate content of meals, including carbohydrate counting and the exchange system. However, both systems require an expert diabetes team to educate, and the

patient and family's willingness to learn and accept the lifestyle (1). Often times, this segment of the education tends to dominate diet education throughout (25). If families are overly focused on learning to count carbohydrates, they may not think to ask about other nutrition recommendations, or learn the importance of eating healthfully to reduce the risk of possible diabetes related complications.

MyPlate

In 2011, the USDA launched a new visual dietary tool named MyPlate. It is a tool that serves to guide Americans during meal times, with a simple visual cue to remind the public to incorporate healthier choices among food groups and increase the intake of fruits and vegetables (20). Since this tool is relatively new, there is a gap in the literature regarding whether the public understands MyPlate, and to what extent they are meeting its proposed goals. Although this is still an unanswered question, developing a MyPlate tool specifically for diabetes would be extremely useful in educating young children with T1DM. A diabetes friendly MyPlate could be constructed to include more specific goals for their plates including: non-starchy vegetables, low saturated fat/ healthy fat proteins, whole grains, and low fat dairy. Developing this tool could assist in teaching children the importance of balanced food groups and healthy choices at mealtimes along with standard diabetes education.

Conclusion

The struggle to meet nutrition recommendations while managing a complicated disease is a difficult feat. This literature review shows that not all children with T1DM

are meeting the nutrition recommendations, and adhering to them is especially important due to the benefits children can achieve by eating healthfully with regards to the risk of short and long-term complications. Children and families that help manage their diabetes have an advantage when it comes to education because they already have a foundation of general nutrition knowledge (carbohydrate counting, measuring food intake etc.). Educators can build upon the skills that the children and families currently have, and go further than traditional diabetes education.

Data show that children are not consuming an overall healthful diet (10-19); therefore, the current education practices are insufficient and a new method of educating patients and their families needs to be evaluated. Although there are nutrition recommendations in place, there is still a lack of a gold-standard measure for assessing dietary adherence for children with T1DM (15). It would be interesting to investigate if MyPlate could serve as a measure of adherence, or determine a way to generate an adherence score based on deviation or achievement of MyPlate recommendations. The new MyPlate recommendations could serve as a baseline for health professionals to use in educating families and children with T1DM about healthy eating in a practical, diabetes specific manner. A diabetes-specific MyPlate would be a beneficial tool for teaching the importance of healthy eating, along with the proper balance of food groups at meal times.

Chapter 3: Methods

Overview

The purpose of this thesis was to determine if the dietary intake of young children with T1DM is meeting the new MyPlate recommendations. Data for this study were compiled from one previously conducted study and two ongoing studies to generate a sample size of fifty-five young children.

Sample

Participants were young children with T1DM between the ages of 2-7 years. The sample of children for this thesis comes from The Families Understanding Nutrition (FUN) study, the Behavior and Education Strategies That Make Eating Activities Less Stressful (BEST MEALS) study, and SNAP'd: A study of diet and parental feeding in young kids with type 1 diabetes (SNAP'd). The purpose and inclusion/exclusion criteria for each study are outlined below.

The FUN study was conducted at the Pediatric Diabetes Centers (PDC) at the University of Michigan Health System (UMHS) and Cincinnati Children's Hospital Medical Center (CCHMC) between 2007 and 2009. The primary objective of the study was to determine the impact of parent-child mealtime interactions on children's post-prandial blood glucose levels. To be eligible for the FUN study, children needed be between the ages of 2-7 years old, and needed to have a confirmed diagnosis of T1DM by the need for daily subcutaneous insulin injections to prevent diabetic ketoacidosis. They also were required to have had the diagnosis for 12 months, and to use English as their primary language. Subjects were excluded if they had a diagnosis of a developmental

delay (i.e. autism, cerebral palsy, or mental retardation), the presence of a disease or medication known to affect carbohydrate metabolism (other than thyroid hormone replacement), they had not come to the PDC at UMHS or CCHMC in the last twelve months, and if children and parents had had any severe psychopathology that required hospitalization. A total of 39 children were recruited in this study, and all participants were included in this master's thesis.

BEST MEALS is an ongoing study that aims to investigate if parent-based interventions focused on teaching new mealtime strategies will reduce parents' stress and improve mealtimes, promote better nutrition, and improve blood sugar levels. This study is currently underway at The University of Kansas Medical Center (KUMC). The eligibility requirements for BEST MEALS are virtually identical to FUN, with the exception of time since diagnosis; BEST MEALS accepted young children at least 6 months from diagnosis. Data from 4 participants from BEST MEALS were used for this master's thesis.

SNAP'd aims to quantify factors of food environment that impact parents' dietary management of their child with T1DM. The study is currently ongoing at KUMC, and 12 participants' data were used for this master's thesis. Eligibility criteria for SNAP'd were identical to those for BEST MEALS.

Recruitment

Letters were sent to all eligible families for the FUN study. A research assistant then attempted to contact families by telephone to recruit them into the study. Parents who agreed to participate scheduled a home visit to complete the informed consent. Fifty

one percent of eligible families were recruited for this study. Families who decided not to participate cited the videotaping and continuous glucose monitoring as their reasons for non-participation. Study information for BEST MEALS and SNAP'd were given to all eligible families at clinic appointments and followed up with a phone call from a research assistant to obtain verbal consent if they wish to participate. Parents who agreed to participate then scheduled a home visit to complete the informed consent.

Ethics

Informed consent from parents of participants were collected for all three studies. Families who participated received at least \$50 as compensation for their participation. The procedures for this Thesis project are covered under existing approved protocols; HSC #12327 (FUN), #12326 (BEST MEALS) and protocol #12695 (SNAP'd) by the University of Kansas Medical Center Human Subjects Committee for which Susana Patton, Ph.D. was the principal investigator.

Anthropometrics

Variables including height, body weight and hemoglobin A1c were collected from participant's medical records. For the FUN study, children were weighed and had their height measured according to a standardized protocol using portable equipment. The most recent height and weight measurements were collected as close as possible to the time of enrollment in the study for BEST MEALS and SNAP'd participants. BMI was calculated by dividing the child's weight in kilograms by height in meters squared. BMI

percentiles were calculated based on the CDC Growth Charts for males and females ages 2-20 years old (28).

Demographics

Demographic data for both children such as age, sex, race, and parent's socioeconomic status, were collected for all three studies using the same questionnaire (See Appendix A).

Dietary intake

During the first home visit for all research studies, parents were taught to keep a weighed diet diary of foods their child consumed during a 3-day recording period (two weekdays and one weekend). Parents were supplied with food scales and given written and verbal instructions on how to accurately measure and record their child's liquid and solid food intake. Parents were required to weigh all food and beverages pre- and post-feeding for the purposes of recording. If children attended daycare or school, they were asked to pack the child's lunch and instruct the child to bring any uneaten food home in order to accurately obtain a before and after weight. Parents were also asked to record the time, dose and type of insulin injections administered to their child on the diet record. Data for the FUN study were reviewed and analyzed by a trained research dietitian. Training was completed through the Bionutrition Section of the CTSA at UMHS. Dietary intake was analyzed using the Minnesota Nutrition Data Systems (NDSR; version 5.0) software system. Data for BEST MEALS and SNAP'd were reviewed and analyzed by a trained research dietitian at KUMC. Dietary intake was analyzed using NDSR version

2010. For all studies, data entry was double checked for red flags such as very high and very low calorie recordings, non-typical days or missed meals.

MyPlate Analysis

Data from the 55 three-day food records were compared to MyPlate recommendations. Each meal for each day was analyzed separately based on the percentage to which the child met the recommendations using a newly developed MyPlate adherence scoring system. Of the children in this sample with TIDM, 93% consumed at least one snack per day, and 45% of children consumed more than 2 snacks per day. For this reason, it was important to include snacks in this analysis. Thus, morning snacks were included in the breakfast MyPlate analysis, afternoon snacks were included in the lunch MyPlate analysis, and evening snacks were included in the dinner analysis.

All coding was based on the child's age at the time of data collection (1-3 years and 4-8 years). The meals were coded using the serving count output from NDSR to determine the amount of servings at each meal, and subsequently they were converted to the age appropriate portion size outlined below. Fruits, vegetables, grains (whole and refined), protein, and dairy were the food groups included in this analysis.

Fruits

MyPlate recommends making half the plate fruit and vegetables (29). For children 2 and 3 years old, the dietary guidelines recommend that children this age should be consuming 1 cup of fruit per day (8). This translates into 1/3 cup at each meal, and for

fruit to take up 1/4 of the child's plate. Children that are 4 to 8 years old should consume 1 to 1 ½ cups of fruit per day. This translates into a ½ cup at each meal. Any fruit or 100% fruit juice was counted within the fruit group. Types of fruits included are fresh, canned, frozen, dried, whole, cut-up, or pureed. The Dietary Guidelines state that 1 cup of fruit or 100% fruit juice, or 1/2 cup of dried fruit can be considered as 1 cup from the fruit group(8).

Vegetables

According to the Dietary Guidelines, children 2 and 3 years of age should consume 1 cup of vegetables per day (8), thus translating into 1/3 cup at each meal. For children 4 to 8 years of age, the dietary guidelines recommend children consume 1 to 1 ½ cups of vegetables per day (8). This translates into 1/2 cup of vegetables at each meal. Any vegetable or 100% vegetable juice counts as a member of the vegetable group. Vegetables may be raw or cooked; fresh, frozen, canned, whole, cut-up, or mashed. The Dietary Guidelines state that 1 cup of raw or cooked vegetables or vegetable juice, or 2 cups of raw leafy greens can be considered as 1 cup from the vegetable group (8).

Grains

The Dietary Guidelines recommend that children 2 or 3 years old should consume 3 ounce equivalents of grains per day (8). One ounce equivalent at each meal is the MyPlate goal for this age group. Children that are 4 to 8 years old should consume 5-ounce equivalents of grains per day. This translates into 1 2/3 ounce equivalents per meal to meet the MyPlate goal. Grain products can be any food made from wheat, rice, oats,

cornmeal, barley or another cereal grain (e.g. bread, pasta, oatmeal, breakfast cereals, tortillas, and grits). The Dietary Guidelines recommend consuming half of the grains as whole grains (8). Whole grains contain the entire grain kernel, the bran, germ, and endosperm (e.g. whole-wheat flour, bulgur, oatmeal, whole cornmeal, and brown rice). Refined grains have been milled, a process that removes the bran and germ (e.g. white flour, de-germed cornmeal white bread, and white rice).

Protein

Children 2 to 3 years of age should consume 2 ounce equivalents of protein foods per day according to the Dietary Guidelines (8). This translates into $\frac{2}{3}$ of an ounce equivalent per meal. Children 4 to 8 years old should consume 4-ounce equivalents per day, translating into $1\frac{1}{3}$ ounce equivalent per meal to meet the MyPlate goal. Protein foods are those made from meat, poultry, seafood, beans and peas, eggs, processed soy products, nuts, and seeds. One ounce of meat, poultry or fish, one-fourth cup cooked beans, one egg, one tablespoon of peanut butter, or one half an ounce of nuts or seeds can be considered as one ounce equivalent from the protein group (8).

Dairy

Children 2 to 3 years of age should consume 2 cups of dairy per day, based on the Dietary Guidelines (8). This translates into $\frac{2}{3}$ of a cup per meal to meet the MyPlate goal. Children who are 4 to 8 years old should consume $2\frac{1}{2}$ cups per day (8). This translates into a little over $\frac{3}{4}$ of a cup per meal to meet the MyPlate goal. The dairy group consists of all fluid milk products, foods made from milk that retain their calcium

content, as well as calcium-fortified soymilk. One cup of milk, yogurt, or soymilk, one and a half ounces of natural cheese, or two ounces of processed cheese can be considered as one cup from the dairy group (8). Foods made from milk that have little to no calcium such as cream cheese, cream, and butter are not counted as a part of this group.

Solid Fats and Added Sugars

The first USDA food pyramid included sweets, oils, and fats in a small triangle at the top of the pyramid with the message “use sparingly”. The updated MyPyramid in 2005 had vertical bands representing each of the food groups including a band for oils from fish, nuts, and plant sources. Discretionary calories were represented by the narrow tip of each colored band including items such as candy, alcohol, or additional food from any other group (8). Unlike these two previous nutrition icons from USDA, MyPlate does not include a symbol for fats, or any distinction between heart healthy and unhealthy fats. Information is available on the USDA MyPlate website regarding the message to include essential oils into the diet and advises individuals to cut back on foods containing saturated fats, trans fats, and cholesterol, but this message is not represented within the pictorial MyPlate image (8).

It is important to note the amount of solid fats and added sugars (SoFAAS) that children are consuming especially since consuming SoFAAS contribute to a further increased risk of chronic disease (30). However, since MyPlate does not have a specific recommendation for consumption of SoFAAS, the amount in servings will be added for each child for each meal and will be reported as a mean \pm standard deviation. The types of foods included in this category will be the same as those used in the Healthy Eating

Index (HEI), which is a validated measurement of healthy eating and will be discussed further in the methods (31).

Food Group Percentages

For each of the 5 food groups, a score was calculated to determine whether the child met the individual food group recommendations at each meal. The food group percentage was calculated by dividing the actual amount of food consumed by the recommended amount for each food group on MyPlate. The current recommendations are outlined in **Table 1**. The meals were then averaged for the entire day to determine the percent to which the child met the specific MyPlate food group goals overall for that day. Since multiple 24-hour diet records were collected, percentages for each day of intake were averaged. If a child exceeded the recommendation for a food group they were counted as meeting the recommendations (e.g. 100% is the highest score possible).

Table 1: Dietary Guidelines for American's Recommendations

	Fruit	Vegetable	Grains	Whole Grains	Protein	Dairy
Ages 1-3	1 cup	1 cup	3 oz	1.5 oz	2 oz	2 cups
Age 4-8	1.5 cup	1.5 cup	5 oz	2.5 oz	4 oz	2.5 cups

MyPlate Total Adherence Score

For the purpose of measuring how a child adhered to the overall MyPlate recommendations, points were awarded for the extent to which the child did not meet, met, or exceeded the goals for each food group based on their age from the NDSR

serving count output (see **Table 2**). The highest possible score for each food group was 6 points and the highest possible score for each meal was 30 points.

Table 2. MyPlate Scoring System

	Grains	Protein	Fruits	Vegetables	Dairy
Met	6	6	6	6	6
¼ over	4.5	4.5	6	6	4.5
½ over or more	3	3	5	5.5	3
¼ under	4.5	4.5	4.5	4.5	4.5
½ under	3	3	3	3	3
¾ under	1.5	1.5	1.5	1.5	1.5

No points were deducted for a child consuming ¼ of a serving over the fruit and vegetable category since these are healthy choices, and only 1 point and half of a point were deducted for consuming ½ of a serving over the fruit and vegetable categories, respectively. If a child consumed more than ¾ of a serving under the recommended amount, or the food group was not present on the plate they received a score of zero for that specific food group. MyPlate recommends making half of the grains whole grains. If the child did not meet this recommendation one point was deducted from the total score.

Healthy Eating Index

The Healthy Eating Index-2005 (HEI) is a scoring system developed by the USDA to assess adherence to the DGA (31). This validated tool measures twelve individual components corresponding to the DGA recommendations: total fruit, whole fruit, total vegetables, dark green and orange vegetables and legumes, total grains, whole grains, milk, meat and beans, oils, saturated fat, sodium and energy from solid fat,

alcoholic beverages and added sugars (SoFAAS). Solid fats are considered sources of both saturated and trans fat (31). Originally, the USDA used a different nutrient database to calculate HEI scores, and recently Miller et al. introduced a method to calculate an HEI score using NDSR (32). The HEI was calculated using three separate NDSR output files: serving counts, intake property, and component ingredient. The serving count food file was used to create scores for nine of the components: total fruit, whole fruit, total vegetables, dark green and orange vegetables, total grains, whole grains, milk, meat and beans, and oil. The intake property food file was used to calculate the total calories consumed, sodium and saturated fat components, as well as the added sugar and grams of alcohol subcomponents of the SoFAAS. The component ingredient file was used to create scores for the solid fat subcomponent of the SoFAAS (31).

To obtain the final HEI score, each component was converted from the NDSR serving to an ounce or cup equivalent per 1000 calories. Once all servings per 1000 calories were calculated for each HEI component, a score value was assigned. The USDA provides a grading system with points awarded for the amount of servings consumed in each category. Point values for each category were summed to give the final HEI score, with 100 points serving as the maximum score. A score of 80-100 is considered “good”, a score of 51-79 is considered “needs improvement”, and less than 50 points is “poor”. This methodology was used in calculating the HEI scores for this sample to compare relationships between the HEI, MyPlate Meal score, and USDA daily score.

Data Analysis

For each child, a serving ratio score for each food group was calculated for each meal. The meals were then averaged for the entire day to determine the percent to which the child met each MyPlate goal overall for that day based on the food group. Since multiple 24-hour records were collected, the percentage to which they met the guidelines for each day of intake was also averaged.

The total MyPlate Meal score was calculated for each meal. The meals were then summed to determine an overall daily meal score out of 90 points (30 points per meal). The total MyPlate Meal scores were then averaged again since multiple 24-hour recalls were conducted. Many children may not consume the recommended serving of a food group at each meal, but consume the recommended serving throughout the course of the day. For this reason, total servings of food groups per day were analyzed using the same MyPlate adherence scoring system, but for the entire day of intake (30 points possible). This scoring methodology is referred to as the USDA daily adherence score. The USDA daily adherence score was then averaged since multiple 24-hour records were collected to determine a daily score out of 30 points. Using the same concept of the HEI scoring categories, MyPlate Meal Score considered a score of 70 or greater as “good”, 45-69 as “needs improvement” and 44 or less as “poor”. Similarly, for the USDA daily adherence score, a score over 25 was considered “good”, 15-24 was considered “needs improvement” and less than 15 was considered “poor”. These data were analyzed and entered into SPSS (version 18). The significance level was set at a p-value of <0.05. Descriptive statistics provided baseline characteristics of the children. Pearson correlations were used to determine associations between several variables. Food group

percentages were analyzed to determine if there was a relationship with the food group and a specific outcome (e.g. Fruit and Vegetable group with BMI).

Chapter 4: Results

The primary objective of this thesis was to determine the percentage to which young children with T1DM meet the new MyPlate recommendations. The secondary objectives were to a) examine if those children with lower HEI, MyPlate Meal and USDA daily adherence scores have higher saturated fat intake, b) examine how BMI and hemoglobin A1c correlate in those children with higher MyPlate Meal adherence scores and USDA daily adherence scores, c) determine if children with higher MyPlate Meal and USDA daily adherence scores also have a higher Healthy Eating Index (HEI) score, and d) examine if there is a relationship between higher fruit and vegetable intake and BMI, as well as if there is a relationship between higher protein and dairy intake and percent calories from saturated fat.

Subject Characteristics

Fifty-five participants were included in the analyses. Participants ranged in age from 2 to 6 years, and 52.7% were female. The majority (83.6%) of the sample was Caucasian. A summary of the socio-demographic characteristics of the total sample is provided in **Table 3**.

Table 3. Socio-Demographic Characteristics of the Sample (n=55)

Characteristic	n (%)
Age (y) ¹	5.04 ± 1.0
Gender	
Male	26 (47.3%)
Female	29 (52.7%)
Race	
Caucasian	46 (83.6%)
African American	4 (7.3%)
Mixed Race	5 (9.1%)

¹mean ± SD

Height, weight and BMI for two subjects were missing from the data set. The average weight in kilograms for this population was 21.22 ± 3.98 . The average BMI percentiles are outlined in **Table 4**. Average hemoglobin A1c was 8.33 ± 1.29 mg/dL, with values ranging from 5.7 mg/dL to 12.7 mg/dL. The ADA recommends hemoglobin A1c targets of less than 8.5% for children younger than 8 years old (7).

Table 4. Subject Descriptive Statistics

Characteristic	Mean \pm SD
Weight (kg)	21.22 \pm 3.98
Height (cm)	111.95 \pm 9.34
BMI Percentile ¹	
5-84 Healthy Weight	28 (52.3 %)
85-94 Overweight	20 (36.7%)
>95 Obese	5 (9.4 %)
Hemoglobin A1c (mg/dL)	8.33 \pm 1.29

¹n(%)

Dietary Intake

From the 55 subjects, 133 dietary recalls were analyzed. No recalls were deemed unreliable. The average energy intake was 1377.66 ± 387 kcal. The average percent of daily calories from carbohydrates, protein and fat was $48.20 \pm .09$, $14.51 \pm .04$, and $33.42 \pm .07$, respectively. The average percent of daily calories from saturated fat was 13.07 ± 3.39 , which is higher than the “less than 7 percent” ADA recommendation for children with T1DM (9). These data are shown in **Table 5** below.

Table 5. Dietary Characteristics of the Sample

Characteristic	Mean \pm SD (n=55)
Energy (kcal)	1377.66 \pm 387
Carbohydrate (g)	163.82 \pm 48.19
Protein (g)	49.22 \pm 19.06
Fat (g)	50.06 \pm 14.52
Fiber (g)	11.22 \pm 5.62
% kcal from Carbohydrate	48.20 \pm .09
% kcal from Protein	14.51 \pm .04
% kcal from Fat	33.42 \pm .07
% kcal from Saturated Fat	13.07 \pm 3.39

Overall MyPlate Adherence

The primary research question was to investigate to what extent children with T1DM (2 to 7 years of age) meet the new MyPlate recommendations. **Figure 1** outlines the food group percentages, which are based on the amount of food consumed within each food group divided by the daily recommended amount for each food group. Based on the current dietary recommendations for this age group, on average subjects had the lowest intake of vegetable and grain groups, and the food group they adhered to the most was dairy. Of this sample, 49 (89%) of the children did not meet the recommendation to make half of their grains whole grains.

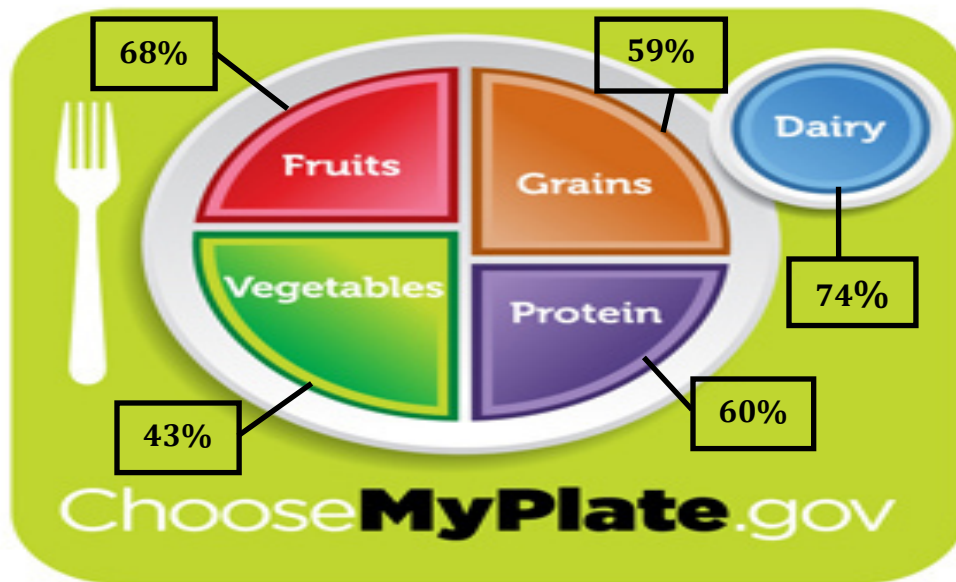


Figure 1. Daily Percent Adherence to Food Groups

MyPlate Meal Adherence by Food Group

To better understand the types of foods these children are consuming at mealtimes, the average servings consumed from each food group during breakfast, lunch, and dinner were analyzed and reported in **Table 6**. Although MyPlate does not provide specific guidelines for the amount of solid fat and added sugars (SoFAAS) at each meal, the same types of foods included when calculating the HEI subcomponent score for SoFAAS were summed to provide an estimate of the amount consumed at each meal, and this is included within the MyPlate Meal Adherence table.

Table 6. Food Group Servings by Meal Period¹

	Fruit	Vegetable	Grain	Protein	Dairy	SoFAAS ²
Breakfast	0.29 ± .44	0.02 ± 0.12	1.06 ± .51	0.28 ± .42	0.76 ± .57	0.56 ± .65
Lunch	0.66 ± .61	0.22 ± 0.37	1.05 ± .66	1.16 ± .96	0.65 ± .54	0.91 ± .60
Dinner	0.52 ± .69	0.48 ± 0.40	0.91 ± .59	1.21 ± .98	0.86 ± .61	1.10 ± 1.0

¹ Servings reported as mean ± SD

² SOFAAS = Solid Fats and Added Sugars (sugary drinks, desserts, high fat meats, processed foods)

Comparison of MyPlate Meal Score and USDA Daily Adherence Score

MyPlate recommends consuming a variety of foods and encourages including foods from each food group at every meal. The MyPlate Meal scoring system was used to assess how well the child conformed to the MyPlate recommendations at each meal. Out of 30 possible points per meal, the average score for breakfast was 8.95 ± 4.03 , lunch was 12.36 ± 5.07 , and dinner was 13.33 ± 4.50 . The breakfast, lunch and dinner scores were combined to obtain an average total MyPlate Meal score of 34.61 ± 9.08 out of 90 points possible.

While children may not meet the MyPlate recommendation at each meal, they may achieve the recommended number of servings for each food group throughout the course of the day. Thus, a USDA daily adherence score was calculated to determine if the overall daily intake met USDA recommendations. Using the same scoring system as the MyPlate Meal Score, the average USDA daily adherence score was 16.78 ± 4.56 out of 30 points possible.

HEI Score and Subcomponent Scores

The average total HEI score for children with T1DM in this sample was 62.95 ± 10.17 , which indicates the diet “needs improvement.” The average subcomponent score for fruits, vegetables and SoFAAS are provided in **Table 7**.

Table 7. Subcomponent HEI scores

	Score (Mean ± SD)
Fruit ¹	3.75 ± 1.65
Vegetable ¹	2.42 ± 1.75
SoFAAS ²	12.31 ± 5.67

¹ Scale= 0-5

² Scale= 0-20

MyPlate Meal and USDA Daily Scores Compared to HEI Scores

To compare scores between the three different scoring systems, scores were converted to a scale of 0.0-1.0 by dividing each average score by the total points possible.

The mean score for each scoring system is located in **Table 8**.

Table 8. Scaled Average Score by Dietary Adherence Scoring System

Scoring System	Scaled Score ¹ (Mean ± SD)
MyPlate Meal Score	0.38 ± 0.08
USDA Daily Adherence Score	0.56 ± 0.15
HEI Score	0.63 ± 0.10

¹Scale = 0.0-1.0

To examine the differences between the MyPlate Meal score, USDA Daily adherence score and HEI score, a series of paired sample T-tests were conducted. The results indicated that the mean MyPlate Meal score was significantly lower than both the mean USDA Daily adherence score ($t(54) = -11.91, p < .000$) and the mean HEI score ($t(54) = -16.50, p < .000$). Additionally, the mean USDA Daily adherence score was significantly lower than the mean HEI score ($t(54) = -0.0329, p = .000$).

A correlation analysis was conducted to determine if there was a relationship between the scores obtained using the newly developed MyPlate Meal and USDA daily adherence systems and those from the previously validated HEI scoring system. There was a statistically significant positive relationship between the HEI score and USDA daily adherence score ($r = 0.520$, $p=0.000$). Similarly, there was a positive relationship between the HEI score and MyPlate Meal score ($r = .262$, $p=0.054$), but the relationship was not statistically significant.

Saturated fat Intake and Dietary Adherence Scores

In partial support for my hypothesis related to young children's saturated fat intake, there was a significant negative correlation between children's total HEI score and percent saturated fat intake ($r = -0.554$, $p=0.000$), such that as HEI scores increased there was a reduction in percent saturated fat intake. However, no relation was found between young children's MyPlate Meal score and their intake of saturated fat ($r= 0.262$, $p=0.431$). There was also no relation between children's USDA Day score and their intake of saturated fat ($r= -0.172$, $p=0.210$).

Hemoglobin A1c and Dietary Adherence

A Pearson correlation was conducted to determine the relationship between hemoglobin A1c and each of the three dietary adherence scoring systems. As shown in **Table 9**, no significant relations were found.

Table 9. Hemoglobin A1c compared to MyPlate Meal score, USDA Daily Adherence Score, and HEI score.

	Pearson's Correlation	P Value**
MyPlate Meal Score	-0.237	0.095
USDA Daily Adherence Score	-0.142	0.321
HEI Score	-0.171	0.229

**All correlations were 2 Tailed

BMI Percentile and Dietary Adherence

Separate Pearson product-moment correlations were run to determine the association between young children's BMI percentile and each of the three dietary adherence scoring systems. However, no significant correlations were found (BMI percentile and the Myplate Meal score $r = -0.081$, $p < 0.563$; USDA daily score $r = -0.015$, $p < 0.917$; and HEI score $r = -0.025$, $p < 0.860$, respectively).

Pearson product-moment correlation coefficients were computed to assess the association between children's fruit and vegetable intake and BMI percentile. However, no significant relation was found between fruit intake and BMI percentile ($r = 0.088$, $p = 0.523$) or vegetable intake and BMI percentile ($r = -0.032$, $p = .816$).

Protein and Dairy Intake and Saturated fat

Lastly, Pearson product-moment correlation coefficients were computed to assess the relations between saturated fat, protein and dairy consumption. No significant relation was found between percent calories from saturated fat and protein intake ($r = -.031$, $p = .820$). However, there was a significant positive correlation between dairy intake and

percent calories from saturated fat ($r= 0.238$, $p=0.04$), suggesting higher intake of dairy was associated with higher percent saturated fat intake in children.

Chapter 5: Discussion

I am unaware of any other studies in the literature comparing dietary intake to the new MyPlate recommendations. For this reason, it is important to create a system to measure adherence to the MyPlate recommendations and possibly make improvements to the existing recommendations based on this research. MyPlate could serve as a measure of dietary adherence for children with and without T1DM, and creating a diabetes specific MyPlate would be instrumental in healthy eating education for patients and their families.

Sample

Fifty-five participants were included in the analyses. The majority of the sample was Caucasian, and participants ranged in age from 2 to 6 years, though most participants fell into the age range of 4-6 years. Data from the National Health and Nutrition Examination Survey (NHANES) reported that among children and adolescents in the United States, 16.9% were obese in 2009-2010 and 14.9% overweight (28). While the majority of subjects in this sample were a healthy weight based on the BMI percentiles (52.3 %), the prevalence of overweight and obesity (36.7% and 9.4%, respectively) was higher within this sample than that reported by the 2009-2010 NHANES data (28). The higher prevalence of overweight and obesity within this population is not surprising given the results of the SEARCH study, which found that the overall prevalence of overweight among youth with T1DM was higher than children without diabetes (33). The increasing prevalence of obesity among youth in the US is beginning to affect children with T1DM. It is critical to develop interventions for youth with T1DM due to their predisposed risk

for long term complications. The mean hemoglobin A1c was within the ADA recommended target of less than 8.5% for children younger than 8 years old (7) suggesting the children in this sample generally had good glycemic control.

Dietary Intake

From the 55 subjects in the sample, the mean energy intake, carbohydrate intake and protein intake all fell within the USDA recommendations for children with and without T1DM (8). The mean fat intake was higher than the recommendation of 25-30% of daily calories from fat (8). Similarly, the average percent of daily calories from saturated fat was 13.07 ± 3.39 , which is higher than the “less than 7 percent” ADA recommendation for children with T1DM (9). These results are similar to previous findings (12, 14, 17, 19) and suggest that children with T1DM consume a higher percentage of energy from saturated fat than recommended.

It was expected that the children would not meet the goals of MyPlate based on several previous studies examining the diets of children with T1DM (13, 15, 18), which showed intake below USDA daily guidelines for fruit and vegetable intake. In the current study, no subject was able to meet all of the recommendations by meal or by day for food group intake. Subjects were closest to meeting the daily MyPlate recommendations for fruit, dairy, and protein. On average, subjects consumed 74% of the daily recommendation for dairy, 68% of the daily recommendation for fruit, 60% of the daily recommendation for protein, 43% of the daily recommendation for vegetables, and 59% of daily grain intake. However, 89% of the children did not meet the recommendation to make half of their grains whole grains. The SEARCH for Diabetes in Youth study found

that none of the children met recommendations for whole grain intake (13). Rather than focusing on incorporating whole grains into the child's carbohydrate allotment, parents and youths may limit carbohydrates, or only focus on carbohydrate amount and portion size due to the ease of reading the nutrition label, which leads to a greater intake of processed foods over whole foods (25). Thus, our data suggest that vegetables and whole grains are the food groups children with T1DM struggle with most, which is similar to previous data reporting low whole grain and vegetable intake among all children in the United States (13, 34).

It was expected that children may have difficulty meeting the recommendation for vegetables during breakfast since they are not typically consumed at breakfast. In this sample, only an average of 0.02 ± 0.12 servings of vegetables were consumed at breakfast, but this number increased to 0.22 ± 0.37 and 0.48 ± 0.40 servings at lunch and dinner, respectively. Fruits were consumed in highest amounts during lunch (0.66 ± 0.61) and lowest amounts at breakfast (0.29 ± 0.44). Meat is not always consumed during breakfast; so as expected, the average protein serving at breakfast (0.28 ± 0.42) was much lower than the servings at lunch and dinner (1.16 ± 0.96 and 1.21 ± 0.98 , respectively). Dairy consumption was highest at dinner (0.86 ± 0.61), closely followed by breakfast and lunch (0.76 ± 0.57 and 0.65 ± 0.54 , respectively). Since a popular breakfast choice for children is cereal and milk, it was surprising that dinner had the highest intake of this food group. Since most people eat dessert after dinner, it was expected that the amount of SoFAAS (solid fats and added sugars) consumed would be highest at dinner (1.10 ± 1.0), closely followed by the amount at lunch (0.91 ± 0.060), which was supported by the data.

These data portray the barriers to eating a well-rounded plate at each meal. Meeting the goals at every meal is extremely difficult, but especially for children who tend to be picky eaters and lack variety in their food choices, especially in regards to fruits and vegetables. It is useful to know this information when counseling families to help them generate strategies to reduce potentially problematic behaviors during the day such as low vegetable and protein intake at breakfast, and high SoFAAS intake at lunch and dinner. Incorporating a vegetable into the mid-morning snack, or having a vegetable omelet for breakfast are a few examples of the direction that nutrition education should focus on given the results of this study.

MyPlate Adherence

Out of 30 possible points per meal, the daily average score for breakfast was the lowest (8.95 ± 4.03), and dinner was highest (13.33 ± 4.50). The average daily MyPlate meal score was 34.61 ± 9.08 on a 90-point scale, falling into the category of “poor”. Since it is difficult for children to meet the MyPlate recommendation at each meal, they may consume the recommended amount throughout the course of the day. Thus, USDA daily adherence scores were calculated to determine if the overall daily intake met MyPlate recommendations. Examining an average of the USDA daily adherence score for the 3-day reporting period, families earned a score of 16.78 ± 4.56 out of 30 points possible. This score falls into the “needs improvement” category suggesting that while children may not meet the goals at every meal, they may consume a better approximation of their daily intake goals over the course of a day. This could be because most children

snack between meals, or simply because consuming the recommended serving of every food group in one meal is difficult.

Healthy Eating Index

As reported, the average HEI-2005 score for this sample was 62.95 ± 10.17 , which also falls into the category of “needs improvement”. The average HEI score for the current study was higher than what had previously been reported by Nansel et al., which was a mean HEI score of 53.4 ± 11.0 in children and adolescents with T1DM (35). The average vegetable subcomponent score was 2.42 ± 1.75 , so it was not surprising that the total HEI score was low. This sample’s mean SoFAAS score fell below the middle at 12.31 ± 5.67 out of 20 points possible, meaning they are consuming about 32% of total daily calories from SoFAAS. These data suggest they are consuming a diet that may include too many desserts and non-nutritive foods. While unhealthy eating is consistent with data of same age peers, most young kids with T1DM have the unique opportunity to improve their diet via regular nutritional counseling. Thus, these findings suggest more focus needs to be placed on counseling parents of young kids with T1DM on how to reduce intake of non-nutritive foods.

MyPlate Adherence Scores and HEI Scores

The MyPlate Meal score was significantly lower than the USDA daily adherence score and the HEI score and USDA daily adherence score was significantly lower than the HEI score. It was expected that the mean MyPlate meal score would be the lowest of the three scoring systems since it was the “strictest” in terms of recommendations.

Interestingly, the HEI score was the highest of the scoring systems, even though SoFAAS were factored into the HEI score, and were not a factor of the MyPlate scoring systems. The HEI score may have been the most lenient scoring system used, as it does not deduct points for over consuming a food group recommendation. Over consuming the recommended intake of foods may lead to increased calories, fat and saturated fat, especially if the food groups being over consumed are high fat protein, high fat dairy, or refined grains. For this reason, the newly developed MyPlate meal scoring system deducted points for over consuming food groups, with the exception of non-starchy vegetables and may offer a more conservative evaluation of healthful eating than the HEI-2005.

Saturated fat Intake and Dietary Adherence

The HEI score was significantly correlated with percent calories from saturated fat intake, suggesting that as HEI scores increased there was a reduction in percent saturated fat intake. This association is likely because the HEI score takes into account SoFAAS intake, and the amount consumed would directly affect the overall HEI score. It was hypothesized that if children are not meeting the MyPlate goals and have lower adherence scores, they would have higher intakes of unhealthy foods, which are often high in saturated fat, and therefore the MyPlate meal score would be a predictor of saturated fat. However, the MyPlate meal scoring system was not a significant predictor for percent of calories from saturated fat. Therefore, future adaptations to the MyPlate Meal scoring system may want to include intake of SoFAAS to determine if this

modification improves the sensitivity of the MyPlate meal score to account for the healthy and unhealthy foods children consume.

Hemoglobin A1c and Dietary Adherence

Previous research has shown that children who have better dietary adherence are also more likely to have better glycemic control (36). In this sample, hemoglobin A1c was not significantly correlated with Myplate Meal score, USDA daily adherence score or HEI score; however, the correlations were trending in the negative direction, suggesting a relation that is consistent with the existent literature (as hemoglobin A1c increases, the dietary adherence scores tended to decrease).

BMI Percentile and Dietary Adherence

If children meet the dietary guidelines, it could be assumed that they are consuming a healthful diet with good incorporation of fruits, vegetables, dairy, grains and protein at each meal. Previous data show that children with poor diet quality have a higher BMI (37). However, in this study, no relations were found between children's BMI percentile and their Myplate Meal score, USDA daily adherence score or HEI score. There was also no relation found between children's BMI percentile and their MyPlate meal or USDA daily adherence scores for intake of fruits and vegetables.

Foods within the protein and dairy food groups can be high in fat and saturated fat depending upon the food processing and preparation. Children with diabetes tend to eat a higher protein diet than their peers because protein has a minimal effect on blood glucose (11, 14). No significant relationship was found between percent calories from saturated

fat and protein intake; however, there was a significant positive relationship between dairy intake and percent calories from saturated fat intake ($p=0.04$), suggesting higher intake of dairy was associated with higher percent saturated fat intake. These findings were similar to a previous study, which found that children consumed 22 percent of saturated fat from protein sources, and consumed 48 percent from dairy sources (14). Without nutrition education, children and families may not know that some dairy foods (such as milk, cream, butter and cheese) can be high in fat and saturated fat. Thus, it is essential to recommend lean sources of protein and low fat or fat free dairy during nutrition education if we expect children with T1DM to adhere to the ADA's recommendation of consuming less than 7% of calories from saturated fat.

Limitations

One limitation to this study is that the data were retrospective; therefore, the materials and methods could not be altered and there were some missing food records. While most children reported three full days of dietary data, 20 of the participants only reported two days. Thus, to keep results consistent, the analyses used the average intake from the number of available records.

Another limitation is that the methods used to collect dietary intake were not consistent. During the FUN study, dietary intake was weighed and recorded by the parents and was not reviewed by a dietitian until after families had completed the study, making it harder to follow-up on missing or incomplete records. In contrast, SNAP'd and BEST MEALS required the families to weigh and record intake, and then a trained registered dietitian called the family to verify the brand, amount, and preparation method

while families were actively involved in the research in an effort to minimize missing data. The two on-going studies use a better methodology than the FUN study in efforts to reduce missing data and maximize the accuracy of the child's actual intake. The small sample size in this study was also a limitation. If the sample size had been larger, the power of the study would have increased, and some additional significance may have been found.

A major limitation of the MyPlate Scoring system and the USDA daily adherence score was that they did not take into consideration SoFAAS. Other researchers have criticized the USDA's MyPlate for not including any information about healthy and unhealthy fats, and have proposed new ideas to make the plate more specific without added confusion (38). Unfortunately, MyPlate also does not show that whole grains are a better choice than refined grains, or that beans, fish, and chicken are healthier choices than red meat. Likewise, it does not encourage consumption of low-fat or fat-free dairy. Arguably, MyPlate's greatest limitation is that ignores those foods that tend to be a significant portion of the American diet: sugary drinks, high fat sweets, and salty processed foods. If MyPlate had a clear message about SoFAAS, it could have been included within the scoring system, potentially leading to different results.

Implications and Future Studies

Since MyPlate is a relatively new tool, there are no data comparing its proposed goals to the public's actual dietary intake. Specifically, it will be beneficial to compare MyPlate to the diets of older children with T1DM since there is such a great deal of education and emphasis placed on eating in T1DM management. Also, knowing which

mealtimes are most difficult to achieve MyPlate recommendations (i.e. breakfast) is helpful knowledge when educating these young children and their families.

Understanding the extent to which children with T1DM are meeting MyPlate's goals would be beneficial in targeting new educational practices.

Based on the results from this study, a MyPlate targeted for a diabetes population should be constructed to include more specific goals for their plates including: an emphasis on non-starchy vegetables; low saturated fat/ healthy fat proteins such as lean chicken, turkey, fish and beans; increased whole grains; and low-fat or fat –free dairy. There should also be a clear message such as “limit sugary drinks, cut back on foods containing saturated and trans fats to reduce the risk of cardiovascular disease”. Developing this tool could assist in teaching children the importance of balanced food groups and healthy choices at mealtimes along with standard diabetes education such as carbohydrate counting. **Figure 2** is a proposed example of what this tool might look like.

The Healthy Plate for Type 1 Diabetes!

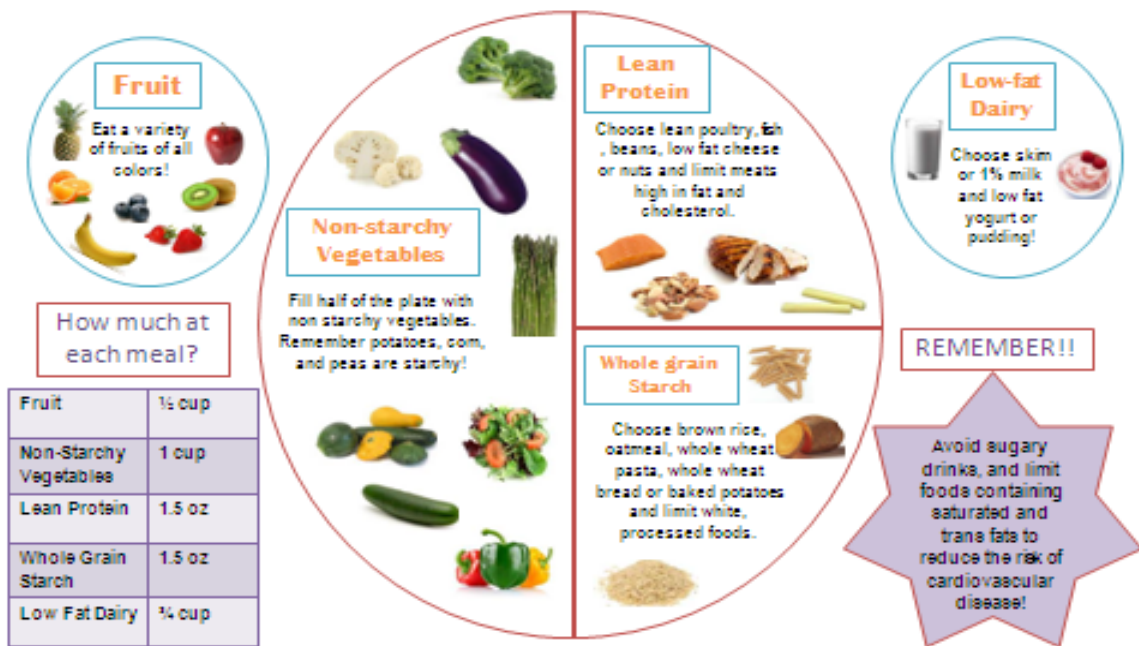


Figure 2. The Healthy Plate for Type 1 Diabetes

Conclusion

The findings from the current study suggest that children with T1DM are not consuming the MyPlate recommendations at each meal or throughout the day. Adhering to the recommendations would be beneficial to reduce the risk of short and long-term complications. Since children with T1DM often receive nutrition counseling at clinic visits, educators have the unique opportunity to share the recommendations and teach them strategies to adhere to the recommendations. The new MyPlate recommendations could serve as a baseline for health professionals to use in educating families and children with T1DM about healthy eating in a practical, diabetes specific manner. A diabetes-specific MyPlate would be a beneficial tool for teaching the importance of healthy eating, along with the proper balance of food groups at meal times.

Chapter 6: Summary

The purpose of this thesis was to a) determine the percentage to which young children with T1DM meet the new MyPlate recommendations, b) examine if those children with lower HEI, MyPlate Meal and USDA daily adherence scores have higher saturated fat intake, c) examine how BMI and hemoglobin A1c correlate in those children with higher MyPlate Meal adherence scores and USDA daily adherence scores, d) determine if children with higher MyPlate Meal and USDA daily adherence scores also have a higher Healthy Eating Index (HEI) score, and e) examine if there is a relationship between higher fruit and vegetable intake and BMI, as well as if there is a relationship between higher protein and dairy intake and percent calories saturated fat intake.

Data from fifty-five young children (ages 2-7) were compiled from one previously conducted study and two ongoing studies. Three-day diet records were obtained for each subject and analyzed using NDSR. Myplate Meal scores and USDA daily scores were calculated using a newly developed scoring system and scores were compared to the validated Healthy Eating Index score.

Subjects in this sample were closest to meeting the MyPlate recommendations for fruit, dairy, and protein. Subjects met 43% of the recommendation for vegetables, and 89% of the children did not meet the recommendation to make half of their grains whole grains. The average HEI score was significantly correlated with percent calories from saturated fat intake, and with the USDA daily adherence score, but not with the MyPlate Meal score. BMI was not significantly correlated with the MyPlate Meal score, USDA daily adherence score or HEI score; and Hemoglobin A1c was not significantly correlated with the MyPlate Meal score, USDA daily adherence score or HEI score; however, the

correlations were trending in the negative direction. No significant relationship was found between fruit and vegetable intake and BMI percentile, and no significant relation was found between percent calories from saturated fat and protein intake. There was a significant positive relationship between dairy intake and percent calories from saturated fat intake ($p=0.04$), suggesting higher intake of dairy was associated with higher percent calories from saturated fat intake in children.

These data suggest that children with T1DM are not consuming the MyPlate recommendations at each meal or throughout the day. Adhering to the recommendations would be beneficial to reduce the risk of short and long-term complications. A diabetes-specific MyPlate could serve as an educational tool for health professionals to use in educating families and children with T1DM about healthy eating in a practical, diabetes specific manner.

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APPENDIX A

Questionnaires

<h2 style="margin: 0;">Parent Demographic Information</h2>
--

Today's Date: _____ / _____ / _____

Please fill out the following information on your child

Child's Age: _____
 Child's Date of Birth: / _____ / _____

Child's Ethnicity: Caucasian African American Hispanic
 Asian Other

Child's gender boy girl

Child's Age at diagnosis: _____

Please fill out the following information on yourself:

Your relationship to the child: Mother Father Grandparent
 Other

Your Age: _____
 Your Marital Status: Married Single Divorced
 Engaged/Living with partner Separated Widow

What is the highest grade of school completed by:

Father	Mother
<input type="checkbox"/> Less than 7 th grade	<input type="checkbox"/> Less than 7 th grade
<input type="checkbox"/> Junior High School (8 th or 9 th grade)	<input type="checkbox"/> Junior High School (8 th or 9 th grade)
<input type="checkbox"/> Some High School (10 th or 11 th grade)	<input type="checkbox"/> Some High School (10 th or 11 th grade)
<input type="checkbox"/> High School Graduate	<input type="checkbox"/> High School Graduate
<input type="checkbox"/> Trade School Graduate	<input type="checkbox"/> Trade School Graduate
<input type="checkbox"/> Some College	<input type="checkbox"/> Some College
<input type="checkbox"/> College Graduate	<input type="checkbox"/> College Graduate
<input type="checkbox"/> Graduate School	<input type="checkbox"/> Graduate School

Are you currently employed? Yes No

If yes,
 What is your job? _____
 Full-time Part-time

If you are married, is your spouse employed? Yes No
If yes,
What is his/her job? _____
 Full-time Part-time

How many children do you have? _____

Does anyone else in your household (besides your child) have diabetes?
 Yes No

Family Income: What is the total annual income of your household (combined income of all living in your house now)? [This question is used strictly for research purposes to describe the socioeconomic status of the subjects as a whole. No individual information will be reported and all data will be kept strictly confidential].

- | | | |
|--|--|---|
| <input type="checkbox"/> \$0-\$9,999 | <input type="checkbox"/> \$40,000-\$49,999 | <input type="checkbox"/> \$80,000-\$89,999 |
| <input type="checkbox"/> \$10,000-\$19,999 | <input type="checkbox"/> \$50,000-\$59,999 | <input type="checkbox"/> \$90,000-\$99,999 |
| <input type="checkbox"/> \$20,000-\$29,999 | <input type="checkbox"/> \$60,000-\$69,999 | <input type="checkbox"/> \$100,000 or above |
| <input type="checkbox"/> \$30,000-\$39,999 | <input type="checkbox"/> \$70,000-\$79,999 | |

Who are you currently living with?

Adults: first name: _____ relationship: _____
first name: _____ relationship: _____
first name: _____ relationship: _____

Children: first name: _____ relationship: _____ Age: _____
first name: _____ relationship: _____ Age: _____
first name: _____ relationship: _____ Age: _____

Medical/Health Information

1. How does your child manage his/her diabetes? (select all that apply)
 - a. Insulin pump
 - b. ≥ 3 injections per day (multiple daily injections or basal/bolus)
 - c. ≤ 2 injections per day (conventional management)
 - d. Use continuous glucose monitor

2. How often has your child experienced a low blood sugar (hypoglycemic) episode?
Circle One
 - a. once a day
 - b. 1-2 times/week
 - c. 3-5 times/week
 - d. once a month
 - e. once every few months
 - f. never

3. Has your child ever experienced hypoglycemic seizures? Yes or No
If yes, how often?
 - a. once a day
 - b. Few times/week
 - c. once a month
 - d. once every few months
 - e. once

4. How many days a week does your child with diabetes eat breakfast?
 - a. 7 days
 - b. 5-6 days
 - c. 3-4 days
 - d. 2 or fewer days

5. How many meals each week does your family eat at home together?
 - a. More than 7 meals a week
 - b. 5-6 meals a week
 - c. 2-4 meals a week
 - d. Less than 2 meals a week

6. How many meals each week does your child eat from a fast food place or restaurant (e.g., McDonald's, Denny's, etc)?
 - a. More than 7 meals a week
 - b. 5-6 meals a week
 - c. 2-4 meals a week
 - d. Less than 2 meals a week

7. How much time (outside of school and work) does your child with diabetes spend watching a screen (e.g., TV, computer, videogames, GameBoy®, etc)?
 - a. Less than 1 hour a day
 - b. 1-2 hours a day
 - c. 3-4 hours a day
 - d. More than 4 hours a day

8. How many hours a day is your child with diabetes physically active (e.g., walking, running, playing, riding a bike, dancing, playing sports, etc)?
 - a. More than 2 hours a day
 - b. 1-2 hours a day
 - c. ½-1 hour a day
 - d. Less than ½ hour a day

9. How many hours of sleep does your child with diabetes get each night?
 - a. 8-10 hours a night
 - b. 6-7 hours a night
 - c. 5 hours a night or less

Child's Initials: _____ Subject #: _____ Date: _____ Site: _____

FOOD RECORD

REMEMBER: Please measure liquids in fluid ounces (floz); use scale to weigh foods in grams (g); use spoons or cups for measuring foods: teaspoon (t), Tablespoon (Tbsp), & cups (C). If your child asks for second helpings, please include these measurements also.

BREAKFAST: Time at start of meal _____ Time at end of meal _____ Location _____
 Meal eaten with _____ Blood glucose check: Time of check: _____ Result: _____
 Insulin Given: Before During After (circle all that apply) Insulin type: _____ Insulin dose: _____

Food Eaten	Brand	How Prepared	Amount served	-	Amount left	=	Amount consumed	Carbs (g)
				-		=		
				-		=		
				-		=		
				-		=		
				-		=		
				-		=		
							TOTAL=	

SNACK: Time at start of meal _____ Time at end of meal _____ Location _____ Meal eaten with _____ Blood glucose check: Time of check: _____ Result: _____
 Insulin given: Before During After (circle all that apply) Insulin type: _____ Insulin dose: _____

Food Eaten	Brand	How Prepared	Amount served	-	Amount Left	=	Amount consumed	Carbs (g)
				-		=		
				-		=		
				-		=		
				-		=		
							TOTAL=	

LUNCH: Time at start of meal _____ Time at end of meal _____ Location _____
 Meal eaten with _____ Blood glucose check: Time of check: _____ Result: _____
 Insulin given: Before During After (circle all that apply) Insulin type: _____ Insulin dose: _____

Food Eaten	Brand	How Prepared	Amount Served	-	Amount Left	=	Amount consumed	Carbs (g)
				-		=		
				-		=		
				-		=		
				-		=		
				-		=		
				-		=		
							TOTAL=	

Type of Vigorous Exercise/Activity	Time (morning)	How long?

Date: _____

SNACK: Time at start of meal _____ Time at end of meal _____ Location _____ Meal eaten with _____

Blood glucose check: Time of check: _____ Result: _____

Insulin given: Before During After (circle all that apply) Insulin type: _____ Insulin dose: _____

Food Eaten	Brand	How Prepared	Amount Served	-	Amount Left	=	Amount consumed	Carbs (g)
				-		=		
				-		=		
				-		=		
				-		=		
							TOTAL=	

DINNER: Time at start of meal _____ Time at end of meal _____ Location _____ Meal eaten with _____

Blood glucose check: Time of check: _____ Result: _____

Insulin given: Before During After (circle all that apply) Insulin type: _____ Insulin dose: _____

Food Eaten	Brand	How Prepared	Amount Served	-	Amount left	=	Amount consumed	Carbs (g)
				-		=		
				-		=		
				-		=		
				-		=		
				-		=		
				-		=		
							TOTAL=	

SNACK: Time at start of meal _____ Time at end of meal _____ Location _____ Meal eaten with _____

Blood glucose check: Time of check: _____ Result: _____

Insulin given: Before During After (circle all that apply) Insulin type: _____ Insulin dose: _____

Food Eaten	Brand	How Prepared	Amount Served	-	Amount left	=	Amount consumed	Carbs (g)
				-		=		
				-		=		
				-		=		
				-		=		
							TOTAL=	

VITAMINS TAKEN (when?): _____

Type of vigorous exercise/activity	Time (afternoon/evening)	How long?

DAILY NOTES:

Add'l Carbs/Insulin given?	Time	Reason
<i>Example: 1.5U Novolog</i>	<i>3:15pm</i>	<i>Treating BS level of 380 mg/dl</i>

APPENDIX B

Consent Forms

The University of Kansas Medical Center

Human Research Protection Program

August 27, 2010

Project Number: 12327
Project Title: Assessment of parent-child mealtime interactions and their relationship to post-prandial glycemic control in young children with type 1 diabetes: The FUN Study (Families Understanding Nutrition)
Sponsor: National Institutes of Health
Protocol Number: DK076921
Primary Investigator: Susana Patton, PhD
Meeting Date: 9/7/2010
Approval Date: 8/27/2010
Expiration Date: 8/26/2011
Type of Approval: Expedited f(5) with a Waiver of Consent

Dear Investigator:

This is to certify that your research proposal involving human subject participants has been reviewed and **approved** by the KU Human Subjects Committee. In this project, the Committee approved your request for a Waiver of Consent, pursuant to 45 CFR 46.116(d), **because (1) the retrospective data review procedures involved present no more than minimal risk of harm to subjects, (2) the subjects rights and welfare will not be adversely affected, (3) written informed consent would is not practicable because many of the subjects are lost to follow-up and it is not possible to remove the identifiable information from the videotapes, and (4) this study will not result in any information that would be pertinent to the individual subjects..**

This approval is based upon the assurance that you will protect the rights and welfare of the research participants, employ approved methods of securing informed consent from these individuals, and not involve undue risk to the human subjects in light of potential benefits that can be derived from participation.

Approval of this research is contingent upon your agreement to:

- (1) Adhere to all KUMC Policies and Procedures Relating to Human Subjects, as written in accordance with the Code of Federal Regulations (45 CFR 46).
- (2) Maintain copies of all pertinent information related to the research study including, but not limited to, video and audio tapes, instruments, copies of written informed consent agreements, and any other supportive documents in accordance with the KUMC Research Records Retention Policy.
- (3) Report potentially serious events to the KUMC HSC by completing the KUMC HSC "Adverse Event Report".
- (4) Submit deviations from previously approved research activities which were immediately necessary to eliminate apparent and immediate dangers to the subjects.
- (5) Submit Amendments to the KUMC HSC for any proposed changes from the previously approved project. Changes may not be initiated without prior HSC review and approval.
- (6) Submit a Summary Progress Report (SPR) to the KUMC HSC before the expiration date. Federal regulations and HSC policies require continuing review of research at intervals appropriate to the degree of risk, but not less than once per year.

If you have any questions regarding the human subject protection process, please do not hesitate to contact our office.

Very truly yours,



Daniel J. Voss, M.S., J.D.
IRB Administrator

RESEARCH CONSENT FORM AND PARENTAL PERMISSION FORM
BEST MEALS: Behavioral and Educational Solutions that Make Eating Activities
Less Stressful
Protocol #12326

You are being invited to participate in a research study. You are also being asked to give permission to allow your child to participate in this study. This study is examining how to better assist parents of young children with type 1 diabetes (ages 2-7 years) in planning meals and managing their child's eating. It will be performed at the University of Kansas Medical Center. The investigator in charge of the study is Dr. Susana Patton. If you decide to participate, you will be 1 of 16 families to be recruited for the present study.

You and your child do not have to participate in this research study. It is important that before you make a decision to participate, you read the rest of this form. You should ask as many questions as needed to understand what will happen to you and your child if you participate in this study.

BACKGROUND

For many young children with type 1 diabetes, studies demonstrate that mealtimes can present a unique challenge because they involve multiple aspects of diabetes care, including blood sugar monitoring, insulin, and meal planning. Previous research suggests that in some young children with type 1 diabetes, mealtimes are difficult for families not because children act differently at meals than kids without type 1 diabetes, but because how they behave at mealtimes may impact how fast and how much they eat at mealtimes and their daily blood sugar levels. There are no interventions developed to help parents of young children with type 1 diabetes with the challenges they may encounter in caring for and raising their child. This study seeks to test one parent-focused intervention which targets mealtimes and looks to see if this helps with diabetes management.

PURPOSE

By doing this study, researchers hope to learn if a parent-based intervention focused on teaching new mealtime management strategies will reduce parenting stress, improve mealtime functioning and nutrition, improve quality of life, and improve children's blood sugar levels.

PROCEDURES

If you and your child are eligible and you decide to participate in this study and give permission for your child to participate, your participation will last approximately 4 months. Your participation will involve:

- 3 Study assessment visits- Study assessment visits will occur at the beginning of the study (baseline), at about 6-8 weeks after your first study visit (pre-treatment), and at the end of the study or about 12-14 weeks after your first study visit (post-treatment). Study visits can be completed at your home. Study visits should last about 1- 1 ½ hours. During each study visit, we will ask you to

fill out surveys, for you to videotape a family meal, and we will download your child's blood sugar meter. During the first study visit, you will be trained to complete a 24-hour food record for your child. We will ask you to complete the food record for the 24-hours immediately following each study visit (total of 3 food records). We will give you a stamped self-addressed envelope to return your completed food record.

- Videotaped family meals- to test our treatment we ask you to videotape a family meal at each of the three study visits. We ask for your permission to videotape you, your child with diabetes, and any minor-aged at these meals, if this is typical for your family. The research team will provide a digital camera and tripod to film the meal. These meals will be filmed at the time of the study visit. While you are filming the meal the researcher will leave your house and wait in their car outside until you are done. Meal videos will be stored in a locked file cabinet and kept for the duration of the study.
- 6 group treatment sessions- Group treatment sessions will occur weekly for 6 weeks around the middle of the study (weeks 8-14). These group sessions will be for parents. Group sessions will be held at the KU Pediatrics Diabetes Clinic located in Mission, KS. Each group will last about 50-60 minutes. Each group will have a session topic which will include handouts covering the main points for that session. During groups, parents will have the time to ask questions, share with other parents of young children, and learn a new topic related to mealtime management.
- Permission to the research team to look at your child's diabetes medical record to record your child's average blood sugar level (A1c) and most recent height/weight.

Your child's participation will involve:

- Videotaped family meals- to test our treatment we ask for your child to participate in videotaping a family meal at each of the three study visits (same meals you are consenting to). The research team will provide a digital camera and tripod to film the meal. These meals will be filmed at the time of the study visit. During the filming the researcher will leave your house and wait in their car outside until you are done. Meal videos will be stored in a locked file cabinet and kept for the duration of the study.
- You may choose to bring your child to the groups. Children who attend groups with their parents will have activities to do that are age-appropriate and educational. These activities are not a focus of the intervention.

RISKS

Parents' Risks:

1. We are collecting information about parent and child eating and feeding behaviors, quality of life, and stress. You might be embarrassed by some of the questions the researchers ask you. You are free not to answer any questions.

We will provide a list of resources for further mental health treatment if you would like.

2. We are collecting information about you and your child that you may not want anyone else to find out. We will use an identification number that is unique to this study to code all of the information that you provide. You or your child's name will not appear on any lists that are immediately recognizable to someone outside of the research team and could link you to the information you provide.
3. We will record at least 3 videotaped meals during the study. We will use these videotaped meals to help us evaluate the treatment program. We will not disclose the videotaped meals to anyone outside of the research team without additional written consent from you. Meal videos will be stored based on a unique study identification number and locked in a file cabinet.

Child Risks:

1. The risks to your child for participating in this study is that someone will learn that your child participated by viewing a videotaped meal. We will not disclose the videotaped meals to anyone outside of the research team without additional written consent from you. Meal videos will be stored based on a unique study identification number and locked in a file cabinet.

There may be other risks of the study that are not yet known.

NEW FINDINGS STATEMENT

You will be told about anything new that might change your decision to be in this study. You may be asked to sign a new consent and parental permission form if this occurs.

BENEFITS

You and your child may not receive any personal benefits from being in this study.

However, families who participate in the study will have the opportunity to learn information specific to diabetes and parenting a young child, which could help with their own management.

Researchers hope that the information from this research study may be useful in creating effective and age-specific interventions for families of young children with type 1 diabetes to help them to maintain healthy blood sugar levels in their young kids.

ALTERNATIVES

Participation in this study is voluntary. Deciding not to participate will have no effect on the care or services you or your child receive at the University of Kansas Medical Center. Families who choose not to participate in this study can still seek individual diabetes education from the Diabetes Clinic staff.

COSTS

There is no cost for being in the study.

Rev. June 2008

HSC #: 12326
Approval Date: 06/12/11 to 08/11/12
Assurance #: FWA00003411

PAYMENT TO SUBJECTS

You will receive \$20 after completing the study materials for each study assessment visit 1 and study assessment visit 2. You will receive \$30 after completing the study materials for study assessment visit 3. To help you to complete the food records, you will receive a digital scale. This scale is yours to keep after the study ends. If you choose to withdraw before the end of the study, you will be paid for the study assessment visits you have already completed. You will receive free parking for study visits completed at KUMC.

The KUMC Research Institute will be given your name, address, social security number, and the title of this study to allow them to write checks for your study payments. Study payments are taxable income. A Form 1099 will be sent to you and to the Internal Revenue Service if your payments are \$600 or more in a calendar year.

IN THE EVENT OF INJURY

If you have been injured or experience any other problem during the study, you should immediately contact Dr. Susana R. Patton at 913-588-6323. If it is after 5:00 p.m., a holiday or a weekend, you should call 913-917-4278. A member of the research team will decide what type of treatment, if any, is best for you at that time. If you have routine questions related to your child's diabetes treatment or management, please call 913-588-6326.

INSTITUTIONAL DISCLAIMER STATEMENT

If you think you **or your child** have been harmed as a result of participating in research at the University of Kansas Medical Center (KUMC), you should contact the Director, Human Research Protection Program, Mail Stop #1032, University of Kansas Medical Center, 3901 Rainbow Blvd., Kansas City, KS 66160. Under certain conditions, Kansas state law or the Kansas Tort Claims Act may allow for payment to persons who are injured in research at KUMC.

CONFIDENTIALITY AND PRIVACY AUTHORIZATION

The researchers will protect your information and your child's information, as required by law. Absolute confidentiality cannot be guaranteed because persons outside the study team may need to look at your study records. The researchers may publish the results of the study. If they do, they will only discuss group results. Yours and your child's name will not be used in any publication or presentation about the study.

Your child's health information is protected by a federal privacy law called HIPAA. By signing this consent form, you are giving permission for KUMC to use and share your child's health information. If you decide not to sign the form, you and your child cannot be in the study.

The researchers will only use and share information that is needed for the study. To do the study, they will collect health information from the study activities and from your

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Assurance #: FWA00003411

child's medical record. You and your child may be identified by information such as name, address, phone, date of birth, social security number, or other identifiers. Your child's health information will be used at KU Medical Center by Dr. Susana Patton, members of the research team, the University of Kansas Hospital Medical Records Department, the KUMC Research Institute and officials at KUMC who oversee research, including members of the KUMC Human Subjects Committee and other committees and offices that review and monitor research studies.

All study information that is sent outside KU Medical Center will have your name, your child's name, and other identifying characteristics removed, so that your identity and your child's identity will not be known. Because identifiers will be removed, yours and your child's health information will not be re-disclosed by outside persons or groups and will not lose its federal privacy protection.

Your permission to use and share your child's health information remains in effect until the study is complete and the results are analyzed. After that time, researchers will remove personal information from study records.

QUESTIONS

Before you sign this form, Dr. Susana Patton or other members of the study team should answer all your questions. You can talk to the researchers if you have any more questions, suggestions, concerns or complaints after signing this form. If you have any questions about your rights as a research subject, or if you want to talk with someone who is not involved in the study, you may call the Human Subjects Committee at (913) 588-1240. You may also write the Human Subjects Committee at Mail Stop #1032, University of Kansas Medical Center, 3901 Rainbow Blvd., Kansas City, KS 66160.

SUBJECT RIGHTS AND WITHDRAWAL FROM THE STUDY

You may stop being in the study at any time. You can take back your permission for your child to be in the study at any time. Your decision to stop or take back permission for your child will not prevent you or your child from getting treatment or services at KUMC. The entire study may be discontinued for any reason without your consent by the investigator conducting the study.

You have the right to cancel your permission for researchers to use your child's health information. If you want to cancel your permission, please write to Dr. Susana Patton. The mailing address is Susana Patton, PhD, CDE, University of Kansas Medical Center, 3901 Rainbow Boulevard, MS 4004, Kansas City, KS 66160. If you cancel permission to use your health information, you will be withdrawn from the study. The research team will stop collecting any additional information about you. The research team may use and share information that was gathered before they received your cancellation.

CONSENT

Rev. June 2008

HSC #: 12326
Approval Date: 08/12/11 to 08/11/12
Assurance #: FWA00003411

BEST MEALS: Behavioral and Educational Solutions that make Eating Activities Less Stressful

Dr. Patton or the research team has given you information about this research study. They have explained what will be done and how long it will take. They explained any inconvenience, discomfort or risks that may be experienced during this study.

By signing this form, you say that you freely and voluntarily consent to participate in this research study and you give permission for your child to participate in this study. You give consent to be audiotaped during the group treatment sessions. These tapes will be used primarily to evaluate the group leader and not your participation in the group. You give consent to the videotaping of your child and family for recording mealtime behaviors. You have read the information and had your questions answered.

You will be given a signed copy of the consent form to keep for your records.

Print Participant's Name

Signature of Participant

Time

Date

Print Name of Person Obtaining Consent

Signature of Person Obtaining Consent

Date

HSC #: 12326 Approval Date: 08/12/11 to 08/11/12 Assurance #: FWA00003411

RESEARCH CONSENT FORM

SNAP'd: A Study of Diet and Parental Feeding in Young Kids with Type 1 Diabetes Protocol

You are being invited to participate in a research study. This study is examining some of the factors and concerns that you may think about when you plan meals for your young child with type 1 diabetes (ages 1-7 years), including things from the food environment (e.g., television, school menu influences). It will be performed at the University of Kansas Medical Center. The investigator in charge of the study is Dr. Susana Patton. If you decide to participate, you will be 1 of 25 families to be recruited for the present study.

You do not have to participate in this research study. It is important that before you make a decision to participate, you read the rest of this form. You should ask as many questions as needed to understand what will happen to you if you participate in this study.

BACKGROUND

For many children and teenagers with type 1 diabetes, studies demonstrate that they are not eating a daily diet that includes foods from multiple food groups, such as fresh fruits and vegetables, and foods that have other nutritional benefits (e.g., fiber, lower fat). Moreover, parents and teenagers with type 1 diabetes frequently cite challenges in blood glucose control and carbohydrate counting related to dietary planning. We do not currently have any information concerning the specific challenges families of young children with type 1 diabetes may encounter with meal planning and without this information, we cannot go forward in designing a targeted education program for nutrition. This study seeks to learn from parents of young children with type 1 diabetes about the factors they consider when planning meals for their child with diabetes as well as their feelings and perceptions of how the food environment (e.g., television, school menus, food availability) may affect their choices in dietary planning.

PURPOSE

By doing this study, researchers hope to learn what parents of young children with type 1 diabetes are thinking about when planning meals for their child, including the parents' concerns about their child's diet and nutrition, their concerns about the messages kids learn from television about diet, the impact of school and day care on children's daily diet, and the effect of the kinds of foods available and the cost of foods in local stores.

PROCEDURES

If you are eligible and you decide to participate in this study and give permission for your child to participate, your participation will last approximately 1 month. Your participation will involve:

- 2 Study assessment visits- Study assessment visits will occur at the beginning of the study (Visit 1) and at the end of the study (Visit 2). Study visits can be completed at your home. Study visits should last about 1- 1 ½ hours. During study visit 1, we will train you to complete a 24-hour food record for your child,

we will ask you to complete some questionnaires, and we will ask you to complete an interview to learn about your child's diabetes regimen. During study visit 2, we will pick up all completed study forms and ask you to complete an interview specific to what you think about when planning meals for your child.

- Between the two study visit appointments, we will ask you to complete at least 3 24-hour recall interviews by telephone. We expect each of these telephone calls will last no longer than 20 minutes and we will schedule these calls at times of the day that are convenient for you. We will ask you to complete a 24-hour recall interview for at least 2 weekdays and 1 weekend day between our two study visits.
- Permission to the research team to contact someone from your child's school or day care (if applicable) to learn more about their school/day care nutrition and physical activity programming.
- Permission to the research team to look at your child's diabetes medical record to record your child's average blood sugar level (A1c) and most recent height/weight.

RISKS

Parents' Risks:

1. We are collecting information about eating and feeding behaviors, nutrition, and your beliefs related to meal planning. It is possible you might be embarrassed by some of the questions the researchers ask you. You are free not to answer any questions.
2. We are collecting information about you and your child that you may not want anyone else to find out. We will use an identification number that is unique to this study to code all of the information that you provide. You or your child's name will not appear on any lists that are immediately recognizable to someone outside of the research team and could link you to the information you provide.
3. We will audio record our interviews with you. We will use these audio recordings to obtain a written transcript of our interview and the information that you shared with us during the interview. We will not disclose the contents of the written transcripts generated from your interviews to anyone outside of the research team without additional written consent from you. We will destroy the audio recordings once we have obtained a written transcript from the recordings. The written transcripts will not contain any identifying information for you or your family.

There may be other risks of the study that are not yet known.

NEW FINDINGS STATEMENT

You will be told about anything new that might change your decision to be in this study. You may be asked to sign a new consent form if this occurs.

BENEFITS

You may not receive any personal benefits from being in this study.

However, the researchers hope that the information gained from this research study may be useful in creating effective and age-specific nutrition education programs for families of young children with type 1 diabetes.

ALTERNATIVES

Participation in this study is voluntary. Deciding not to participate will have no effect on the care or services you or your child receive at the University of Kansas Medical Center. Families who choose not to participate in this study can still seek individual diabetes education from the Diabetes Clinic staff.

COSTS

There is no cost for being in the study.

PAYMENT TO SUBJECTS

You will receive \$50 at the end of the study to reimburse you for your participation. You will receive free parking for study visits completed at KUMC.

The KUMC Research Institute will be given your name, address, social security number, and the title of this study to allow them to write checks for your study payments. Study payments are taxable income. A Form 1099 will be sent to you and to the Internal Revenue Service if your payments are \$600 or more in a calendar year.

IN THE EVENT OF INJURY

If you have been injured or experience any other problem during the study, you should immediately contact Dr. Susana R. Patton at 913-588-6323. If it is after 5:00 p.m., a holiday or a weekend, you should call 913-917-4278. A member of the research team will decide what type of treatment, if any, is best for you at that time. If you have routine questions related to your child's diabetes treatment or management, please call 913-588-6326.

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CONFIDENTIALITY AND PRIVACY AUTHORIZATION

The researchers will protect your information and your child's information, as required by law. Absolute confidentiality cannot be guaranteed because persons outside the study team may need to look at your study records. The researchers may publish the results of the study. If they do, they will only discuss group results. Yours and your child's name will not be used in any publication or presentation about the study.

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Your child's health information is protected by a federal privacy law called HIPAA. By signing this consent form, you are giving permission for KUMC to use and share your child's health information. If you decide not to sign the form, you and your child cannot be in the study.

The researchers will only use and share information that is needed for the study. To do the study, they will collect health information from the study activities and from your child's medical record. You and your child may be identified by information such as name, address, phone, date of birth, social security number, or other identifiers. Your child's health information will be used at KU Medical Center by Dr. Susana Patton, members of the research team, the University of Kansas Hospital Medical Records Department, the KUMC Research Institute and officials at KUMC who oversee research, including members of the KUMC Human Subjects Committee and other committees and offices that review and monitor research studies.

All study information that is sent outside KU Medical Center will have your name, your child's name, and other identifying characteristics removed, so that your identity and your child's identity will not be known. Because identifiers will be removed, yours and your child's health information will not be re-disclosed by outside persons or groups and will not lose its federal privacy protection.

Your permission to use and share your child's health information remains in effect until the study is complete and the results are analyzed. After that time, researchers will remove personal information from study records.

QUESTIONS

Before you sign this form, Dr. Susana Patton or other members of the study team should answer all your questions. You can talk to the researchers if you have any more questions, suggestions, concerns or complaints after signing this form. If you have any questions about your rights as a research subject, or if you want to talk with someone who is not involved in the study, you may call the Human Subjects Committee at (913) 588-1240. You may also write the Human Subjects Committee at Mail Stop #1032, University of Kansas Medical Center, 3901 Rainbow Blvd., Kansas City, KS 66160.

SUBJECT RIGHTS AND WITHDRAWAL FROM THE STUDY

You may stop being in the study at any time. You can take back your permission for your child to be in the study at any time. Your decision to stop or take back permission for your child will not prevent you or your child from getting treatment or services at KUMC. The entire study may be discontinued for any reason without your consent by the investigator conducting the study.

You have the right to cancel your permission for researchers to use your child's health information. If you want to cancel your permission, please write to Dr. Susana Patton.

SNAP'd: A Study of Diet and Parental Feeding In Young Kids with Type 1 Diabetes

The mailing address is Susana Patton, PhD, CDE, University of Kansas Medical Center, 3901 Rainbow Boulevard, MS 4004, Kansas City, KS 66160. If you cancel permission to use your health information, you will be withdrawn from the study. The research team will stop collecting any additional information about you. The research team may use and share information that was gathered before they received your cancellation.

CONSENT

Dr. Patton or the research team has given you information about this research study. They have explained what will be done and how long it will take. They explained any inconvenience, discomfort or risks that may be experienced during this study.

By signing this form, you say that you freely and voluntarily consent to participate in this research study. You give consent to be audiotaped when completing the interviews during study visits 1 & 2 and the 3- 24 hour recall interviews (completed by telephone). These tapes will be used to generate written transcripts of the interview and will be destroyed once these written transcripts are available. You have read the information and had your questions answered.

You will be given a signed copy of the consent form to keep for your records.

Print Participant's Name

Signature of Participant

Time

Date

Print Name of Person Obtaining Consent

Signature of Person Obtaining Consent

Date

HSC #: 12695
Approval Date: 5/31/11 to 5/30/12
Assurance #: FWA00003411