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CHILDREN AND ADOLESCENTS DIAGNOSED WITH TYPE 2 DIABETES IN PEDIATRIC AND ADULT ENDOCRINOLOGY CLINICS IN MICHIGAN, GLYCEMIC CONTROL AND ASSOCIATED FACTORS

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CHILDREN AND ADOLESCENTS DIAGNOSED WITH TYPE 2 DIABETES IN PEDIATRIC AND ADULT ENDOCRINOLOGY CLINICS IN MICHIGAN, GLYCEMIC CONTROL AND ASSOCIATED FACTORS

By

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ABSTRACT

CHILDREN AND ADOLESCENTS DIAGNOSED WITH TYPE 2 DIABETES IN PEDIATRIC AND ADULT ENDOCRINOLOGY CLIINICS IN MICHIGAN, GLYCEMIC CONTROL AND ASSOCIATED FACTORS

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Type 2 diabetes (T2DM) in children and adolescents is a “newly recognized” pediatric disease, for which childhood overweight/obesity has been shown to be a strong predictor. The prevalence of overweight/obesity in youth is a serious concern in Michigan and there is no data on T2DM in this vulnerable age group. The purpose of this study was to: 1) estimate the proportion of diagnosed T2DM among youth (6-19 yr) with either Type 1 (T1DM) or T2DM at endocrinology specialty clinics in Michigan; 2) to determine glycemic control and associated factors in cases of T2DM compared to T1DM; and 3) to determine the ecological factors that influence glycemic control in a sample of youth with T2DM. A two-phase study was conducted using an in-depth medical chart review for youth (6-19 yr) diagnosed with diabetes (Phase 1), and in-depth qualitative interviews and surveys of youth diagnosed with T2DM (Phase 2).

Of 2,018 subjects diagnosed with either Type 1 or Type 2 diabetes, 220 (11%) had T2DM. Among those 10-19 yr, the proportion of children with T2DM increased significantly (14%). Based on the census data for 2002 and study results, it was estimated that the minimum prevalence of T2DM in the lower peninsula of Michigan was 11.03/100,000. The mean (±SD) age and body mass index (BMI) for those with T2DM were 13 ± 2.8 yrs and 35 ± 12.5 kg/m^2, respectively. The mean age of onset for T2DM

was significantly higher than for T1DM (13 yr vs 8.7 yr, $p<0.01$) with the majority at Tanner stage 3 or higher for puberty (83% vs 28%, $p<0.01$). T2DM was also significantly higher among African Americans (52%) compared to Caucasians (15%) and Hispanics (12%). Based on body mass index (BMI) percentiles, 78% of youth with T2DM had BMI >95^{th} %tile (overweight), the BMI percentile for youth with T1DM was between the 5^{th}-85^{th} %tile (normal) for 81%. Sixty five percent of youth with T2DM were living in single parent families compared to 40% of youth with T1DM ($p<0.01$). There was a significantly higher prevalence of metabolic risk factors in youth with T2DM compared to those with T1DM: low HDL-C (48% vs 12%), elevated serum triglyceride (33% vs 9%), and hypertension (85% vs 74%). Compared to youth with T1DM, youth with T2DM were less likely to follow a prescribed diet (80% vs 42%, $p<0.01$) or exercise recommendations (64% vs 38%, $p<0.01$). The key findings of the qualitative interviews were that dietary recommendations were difficult to adhere to, and that family support as well as friends and institutions were important facilitators of self-management in general.

The results of this multi-clinic study indicated that T2DM among youth in Michigan is high, mimicking the national estimates, and concomitant with the high obesity rates. The higher metabolic aberrations may be additional compounding factors that have serious long-term implications. Therefore, appropriate screening and targeted interventions are critical for effective diabetes management in this vulnerable population.

Dedicated to my parents and family

and

all those youth who have Type 2 diabetes

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CHAPTER 1

Introduction

Type 2 diabetes in children is a "newly recognized" pediatric disease. Historically diabetes mellitus occurring in children and adolescents was believed to be primarily Type 1. There are two major classes of diabetes: Type 1 (requiring exogenous insulin), which typically begins in those under 30 years of age; and Type 2 (may or may not require exogenous insulin depending on severity). Type 2 is the more predominant form of the disease (90%) and mainly occurs in adults (Centers for Disease Control and Prevention (CDC), 2002). An initial report of high occurrence of Type 2 diabetes in children came from the Pima Indians, who have the world's highest prevalence of Type 2 diabetes in adulthood (Savage et al., 1979; Fagot-Campagna, 1999). Savage et al. (1979) reported that >1% of 15-24 year old Pima Indians had diabetes associated with obesity and long-term diabetes complications (Savage et al., 1979; Fagot-Campagna, 1999). In a longitudinal study by Dabelea et al. (1998), in the Gila River Indian Community in Arizona, which is dominated by Pima Indians, it was observed that the prevalence of Type 2 diabetes in Pima Indian children had increased over a 30-year period. The results demonstrated that in boys 10-14 years, the prevalence of Type 2 diabetes increased from 0% in 1967-1976 to 1.4% in 1987-1996. In the 15-19 year old age group of boys, it increased from 2.43% to 3.78%. In girls 10-14 years of age, it increased from 0.72% in 1967-1976 to 2.88% in 1987-1996 and from 2.73% to 5.31% for the 15-19 year old age group (Dabelea et al., 1998).

More recently, several clinical reports have published an increasing incidence of Type 2 diabetes among African American children in Cincinnati and Arkansas (Pinhas-Hamiel et al., 1996; Pihoker et al., 1998); first nation (American Indian) children in Manitoba (Dean, 1998; Dean et al., 1992); Native Americans in Ontario (Harris et al., 1996); Hispanic children in California (Fagot-Campagna et al., 2001); and Japanese children in Tokyo (Kitagawa et al., 1994; Kitagawa et al., 1998).

Children and adolescents diagnosed with Type 2 diabetes are generally between 10 to 19 years old (usually at or close to puberty) (Pinhas-Hamiel et al., 1996; Henry, 1998). However, there have been reported cases as young as 6 years of age (Henry, 2001; Cicinelli-Timm, 2002). The primary distinguishing characteristics observed are obesity, insulin-resistance, a strong family history of Type 2 diabetes, and ethnicity with higher prevalence rates in Native American, African American or Hispanic Americans (Henry, 1998).

A recent study by Weatherspoon et al., (2000) showed that for children (12-19 years) from the National Health & Nutrition Examination Survey III, established risk factors for Type 2 diabetes as well as some family factors were associated with a glycated hemoglobin (GHB) >90^{th} percentile (upper limit of average blood sugar for past 3 months) as follows: ethnicity (odds ratio = 3.43), family history (odds ratio = 1.53), gender (odds ratio = 1.81), Body Mass Index (BMI- calculated as weight in kilograms divided by height in meters squared) (odds ratio = 2.82), poverty income ratio (odds ratio= 1.50 and 1.46) and domicile area (odds ratio= 0.55 for rural compared to urban dwellers). These data suggest that glycated hemoglobin >90th percentile might be a useful indicator for Type 2 diabetes in children, but findings also demonstrated a need to recognize the importance of including diabetes screening tests in youth < 18 in such national survey data. In addition, more convenient and reliable screening tools for Type 2 diabetes in children and adolescents at the national level, will allow the health professional to better address this growing health issue.

The spiraling rate of childhood obesity in America, which was declared an epidemic by Dr. David Satcher, former Surgeon General of the US in November 1998, is believed to be the most significant factor in the escalating numbers of children with Type 2 diabetes. Reports by the CDC illustrated that approximately 80% of youth with Type 2 diabetes are overweight (CDC, 1998). Moreover, obesity rates also are higher in African American and Hispanic populations (Kuczmarski et al., 1994). Most recent data from NHANES 1999 to 2000 and 2000 to 2004 indicated that among children aged 6-19 years in 1999–2002, 31.0% were at risk for overweight or overweight and 16.0% were overweight (Headley et al., 2004). Obesity prevalence over the past 20 to 30 years has doubled for children 2-5 years and almost tripled for those 6 to 19 years (Liu et al., 2004). In a Cincinnati clinic study to determine the rise in diagnosis of Type 2 diabetes among adolescents, 92% of subjects were obese and in a similar study in Arkansas, 96% were obese (Pinhas-Hamiel et al., 1996; Pihoker et al., 1998). Studies on obesity in Michigan have shown that in children 4 to 17 years of age, among boys, 38% were above the 85th percentile (at risk of overweight) and 16% above 95th percentile (overweight) for weight.

Of the girls, 33% were above the 85th percentile and 13% were above the 95th percentile for weight (Gautheir et al., 2000).

Several other factors that are associated with the prevalence and may be major contributors to the increase in Type 2 diabetes during childhood and adolescence include: (1) a condition called acanthosis nigricans characterized by dark irregular folds of skin around the neck, under the arms or behind the knees (Dean, 1998; Stuart et al., 1998). Acanthosis nigricans is a marker of insulin resistance and is associated with many different conditions and symptoms that include insulin resistance and compensatory insulin secretion (Liu et al., 2004); (2) socio-demographic and family factors (Jones, 1998; Dean, 1998); (3) family history of diabetes (Neufeld et al., 1998; Pinhas et al., 1996); (4) low level of physical activity (Ludwig et al., 2001; American Diabetes Association, 2000); (5) weight at birth (Dabelea et al., 1998); (6) pubertal status (Pinhas-Hamiel et al., 1996; Arslanian, 2000); as well as (7) exposure to diabetes in utero (Dabelea et al.,1998).

In addition to diagnosing diabetes, disease management is important for control and hence prevention of complications. Typically assessed as glycemic control, glycosylated hemoglobin (GHB) is currently considered the best indicator of a patient's average blood glucose over the past 120 days period (Lenzi et al., 1987; ADA, 2000). Treatment modalities for Type 2 diabetes are based on the belief that early diagnosis and careful control of blood sugar and related atherosclerosis risk factors (e.g. blood lipids, weight, diet and activity level) can reduce, delay or prevent complications or early mortality

(Anderson and Svardsudd, 1995; Ohkubo et al., 1995; Diabetes Control & Complications Trial Group, 1993; Turner et al., 1998). Lifestyle factors such as diet, exercise as well as medication compliance, regular medical assessments, and self-monitoring of blood glucose are critical components of diabetes care. Generally, children and adolescents with Type 2 diabetes may have poor glycemic control (GHB= 10%-12%), and hence an increased likelihood of developing complications of poorly controlled diabetes at a substantially younger age than the older person with Type 2 diabetes (CDC, 1998). Glycemic control is difficult to manage among Type 2 diabetes cases because the insidious nature of this condition makes it difficult for individuals to believe they actually have a serious problem. Type 2 diabetes cases are less likely to exhibit noticeable signs and symptoms if they initially fail to adhere to their recommended regimens. Therefore, self-care behaviors might be less likely to be practiced in the individual with Type 2 diabetes. In contrast, Type 1 cases become very ill if they omit their medication because the body response is immediate and serious. Aberrations in plasma glucose, in people with diabetes, may result in abnormal lipid metabolism, and elevated plasma cholesterol and triglycerides could increase the possibility of atherosclerosis (American Diabetes Association, 2000). Thus, serum lipid values are also a good indicator of diabetes management.

The ability of children and adolescents diagnosed with diabetes to comply with recommended behaviors is influenced by many ecological factors. Besides physiological influences, children are also vulnerable to influences of culture, family and economics (United States Department of Health and Human Services (DHHS), 2002). Meal preparation and food choices can be influenced by cultural beliefs and practices (Keith and Doyle, 1998). Economic status also plays a role in food choices, access to food and food preparation materials that might make it difficult for families to follow healthy eating habits (DHHS, 2002). Evidence from studies with families with a member with diabetes, indicates that diabetes and control may also be linked with cohesion and adaptability in families (Anderson et al., 198q). Families, which have extremely high or low cohesion, are associated with poor diabetes control. Tubiana-Rufi et al., (1998) demonstrated that children from less cohesive families had a significantly higher number of hypoglycemic episodes and had 6 times as many episodes of ketoacidosis than the children from more cohesive families (Tubiana-Rufi et al., 1998). An individual's susceptibility to intense emotional processes within the family and subsequent situational depression in response are also linked with diabetes and diabetes control (Lustman et al., 1998).

As the problem of Type 2 diabetes in children and adolescents continues to be defined and described, there remains a vast scope for research. Medical scientists recognize that inadequate research efforts and resources have been directed to Type 2 diabetes in children and adolescents, and insufficient public health and research data exist even to adequately describe the pathology of the disease in children and adolescents in the USA (Henry, 1998). According to Rosenbloom et al., (1999) many leading scientists advocate the necessity for both cross sectional and longitudinal studies to accurately document prevalence and incidence of Type 2 diabetes and its wide realm of associative factors in children and adolescents. Furthermore, it is not clear if the increased incidence of diabetes among African American, Hispanic American and Native American adolescents is due to greater reporting or improved discrimination between Type 2 and Type 1 diabetes (CDC, 1998). Lack of sufficient data on the prevalence and incidence of Type 2 diabetes and associated factors, as well as how well the diagnosed disease is being managed in children and adolescents in Michigan, and in the general US population, makes it difficult to plan interventions to delay onset or manage the disease.

Theoretical/ Knowledge Framework: This study is exploratory in nature. The ecological model (Bubolz and Sontag, 1993) best describes the approach, which encompasses both biomedical and environmental factors in the identification of risk factors for both prevalence and glycemic control in a defined population sample. The ***long term goal*** is to better understand the prevalence and risk factors for Type 2 diabetes in children and adolescents as well as determine efficacy of disease management including barriers and facilitators in order to design and implement effective strategies for the prevention and treatment of this disease. The objective of this study is to determine the magnitude of the problem of Type 2 diabetes in children and adolescents as depicted by medically diagnosed cases at endocrinology clinics in Michigan and the extent to which this disease is being effectively treated. Weatherspoon et al., (2001) investigated the risk for Type 2 diabetes in children and adolescents in Primary Care and Family Practice Clinics in Michigan. Data obtained were inconsistent and limited. Therefore, specialty endocrinology clinics were used in this study because of the anticipated greater likelihood for keeping complete and accurate medical records and the fact that Primary

Care and Family Practice clinics were shown (Weatherspoon et al., 2001) to have minimal patients with this disease.

There is a ***critical need*** for information on the magnitude of Type 2 diabetes in youth and management. Increased awareness about the disease occurrence and early identification of poor control and compliance-related issues will result in more timely and effective efforts to intervene in an appropriate manner and delay or prevent debilitating outcomes at a young age. Because this is a topical area of research, there is a paucity or very limited data, both nationally and for Michigan. True prevalence is difficult to determine, since there is undoubtedly an undiagnosed population similar to the situation, which exists for adults. However, the proportion of those who have been recognized as having the disease and who are being treated at endocrinology clinics will provide useful information. The fact that Type 2 diabetes in children is strongly linked to obesity and Michigan was recently ranked number three in the country for adult obesity, and one city Detroit, was classified as the "fattest city", warrants the importance of this study (Michigan Department of Community Health, 2004). Moreover, many debilitating complications like cardiovascular or renal diseases or retinopathy of uncontrolled diabetes may occur at a younger age if early diabetes onset is not recognized and/or controlled through treatment compliance during the teenage years. This study allowed us to estimate the number of children and adolescents (6-19 years) who have diagnosed Type 2 diabetes among those who have either Type 1 or Type 2 diabetes at endocrinology clinics in Michigan. Review of clinic data systems and medical chart reviews helped achieve this objective. In addition useful information was obtained for professionals who diagnose or counsel Type 2 diabetes children on glycemic control differences between Type 2 and Type 1 diabetes and associated biomedical, family, and health behaviors factors.

Specific Objectives were :

1) To estimate the proportion of diagnosed Type 2 diabetes among children and adolescents (6-19 years) who have either Type 1 or Type 2 diabetes at endocrinology specialty clinics in Michigan.
2) To determine glycemic control and associated factors (including biomedical, socio-demographic and family factors) in this population compared to Type 1 cases.
3) To determine the ecological factors that influence glycemic control in the population of children and adolescents with Type 2 diabetes.

1.1 Organization of the dissertation

This dissertation is organized into six chapters. Chapter one presents the general introduction of the problem and the rationale for this study. Chapter two provides a review of literature on the concepts of pathophysiology and types of diabetes, prevalence of Type 2 diabetes in children and adolescents, assessment of control of diabetes, and determinants of Type 2 diabetes. Chapter three presents the methods used to achieve the objectives of this study. This study is organized into 2 Phases: Phase 1 involved an in-depth medical chart reviews; and Phase 2 encompassed an in-depth qualitative interview study. This chapter also discusses the rationale for conducting a qualitative study for the second phase of this study. Chapter four presents article number one titled "Proportion of children and adolescents diagnosed with Type 2 diabetes in Michigan". This article addresses objective one of the study. Chapter five presents article number two titled "Glycemic control and associated factors in youth (6-19 years) with Type 2 or Type 1 diabetes in Michigan". This article compares Type 2 and Type 1 diabetes cases in terms of associated factors and self-care behaviors. It addresses objective two of this study. Chapter six presents article three titled "Ecological factors influencing adherence to self-care behaviors among children and adolescents with Type 2 diabetes". This is the qualitative part of the study trying to study the influence of social and institutional factors on self-care behavior for Type 2 diabetes. This chapter addresses objective three of the study.

Chapter seven provides an overall summary of the three studies and presents some conclusions. This chapter also presents recommendations for future research. This report is mainly targeted for nutrition and health professionals and others concerned with nutrition, health, and quality of life of children in US. The discussion and conclusions in this report focus on the prevalence of Type 2 diabetes in Michigan, the associated factors with Type 2 diabetes, and views of youth regarding their Type 2 diabetes.

CHAPTER 2

Review of Literature

The literature reviewed includes a description of diabetes mellitus and Type 2 diabetes in children and adolescents. A general description of epidemiology, diagnosis, associated factors, treatment, and diabetes control are also examined. Finally, reviewed are socio-demographic, biomedical, and self-care behaviors as they relate to diabetes control.

1) Diabetes Mellitus

Diabetes mellitus is a group of diseases characterized by high levels of blood glucose resulting from defects in insulin production, insulin action, or both. Diabetes can be associated with serious complications that are costly to manage and premature death, but steps to control the disease and lower the risk of complications can be taken. There are two main types of diabetes, Type 1 diabetes (insulin-dependent diabetes mellitus) and Type 2 diabetes (non-insulin-dependent diabetes).

Type 1 diabetes develops when the body's immune system destroys pancreatic beta cells, the only cells in the body that make the hormone insulin that regulates blood glucose. This form of diabetes usually strikes children and young adults, who need external insulin to survive. The typical age for onset ranges from 3 to 30 years of age. Type 1 diabetes may account for 5 to 10% of all diagnosed cases of diabetes. Risk factors for Type 1 diabetes includes autoimmune, genetic, and environmental factors (Centers for Disease Control and Prevention (CDC), 2004).

Type 2 diabetes occurs as a result of the body's inability to make enough insulin or properly use insulin. The primary underlying problem is believed to be insulin resistance, with some degree of insulin deficiency. The typical age of onset for Type 2 diabetes is over 45 years. Often Type 2 diabetes can be controlled with weight loss, healthy eating behaviors and exercise alone, but sometimes these are not enough and either oral medications and/or insulin must be used (CDC, 2002).

Prevalence of diagnosed diabetes for US adults ≥ 20 years of age is estimated to be 5.1% (10.2 million people when extrapolated to the 1997 US population) (Harris et al., 1998). According to data from CDC, the prevalence of diabetes among US adults ≥ 20 years of age is 8.7% (18 million) as of 2002 (CDC, 2004). Results from Behavioral Risk Factor Surveillance System (BRFSS) study between 1990 and 1998 demonstrated that prevalence of diabetes rose from 4.9% in 1990 to 6.5% in 1999, an increase of 33% (Mokdad et al., 2000).

Of the nearly 18.2 million Americans with diabetes, 90-95% of them have Type 2 diabetes (CDC, 2004). Of these, roughly a third are unaware they have the disease (CDC, 2004). People with Type 2 diabetes usually develop the disease after the age of 45 years, but often are not aware they have diabetes until severe symptoms occur or they are treated for one of its serious complications. The risk for Type 2 diabetes increases with the age. Nearly 31% of the United States population aged 65 and older has diabetes and more likely Type 2 diabetes (CDC, 2004). In 2002, the prevalence of diagnosed diabetes among people aged 65-74 (16.8%) was almost 14 times that of people less than 45 years of age (1.2%) (CDC, 2004). Studies indicate that diabetes is generally under-reported on death certificates, particularly in the cases of older persons with multiple chronic conditions such as heart disease and hypertension (Gu et al., 1998). Therefore, the toll of diabetes is believed to be much higher than officially reported (CDC, 2002). Besides the toll on health, diabetes also sets a toll on economy. The total cost of diabetes per year in US is $ 132 billion (indirect = $ 40 billion & direct = $ 92 billion)(CDC, 2004). Type 2 diabetes was typically known as the disease of adults and was previously considered rare in the pediatric population. Over the last decade, however, there has been a disturbing trend of increasing cases of Type 2 diabetes in youth, particularly adolescents, with a greater proportion being minority.

2) Type 2 diabetes in children and adolescents

2.1) Epidemiology

Epidemiologic data for Type 2 diabetes in children and adolescents is sparse. This limited information is in large part due to the relatively recent recognition of the emergence of the disease in this age group. There are currently no nationwide epidemiological data focusing on Type 2 diabetes in children. However, clinic-based reports and regional studies consistently emphasize the increasing prevalence of this clinical entity. Table 1 summarizes the studies to date and reports that provide estimates of the frequency of occurrence of Type 2 diabetes in children. Pima Indians in Arizona, known to have a high prevalence of Type 2 diabetes, have been extensively studied. Results from a 1992 to 1996 analysis of Pima Indians in Arizona revealed a prevalence of

22.3 per 1000 for Type 2 diabetes among 10 to 14 year olds and 50.9 per 1000 in the 15 to 19 year old age group (Dabelea et al., 1998).

Table 1: Estimates of the magnitude of Type 2 diabetes in children and adolescents.

Study types	Years	Race/Ethnicity	Age (Years)	Estimates
Population-based studies				**Prevalence per 1000**
Arizona, USA	1992-1996	Pima Indians	10-14	22.3
			15-19	50.9
Manitoba, Canada	1996-1997	First Nations	10-19	36.0 (girls)
NHANES III, USA	1988-1994	Whites, AA, MA	12-19	4.1*
Clinic-based studies				
Indian Health Services (all U.S.)	1996	American Indians	0-14	1.3*
Manitoba, Canada	1998	First Nations	15-19	4.5*
			5-14	1.0
			15-19	2.3
Clinic-based studies				**Incidence per 100,000/year**
Cincinnati, OH	1994	Whites, AA	10-19	7.2
Case series				**% of Type 2 DM among new cases of DM [Type 2(n)/ Type 1(n) +Type 2(n)]**
Cincinnati, OH	1994	Whites, AA	0-19	16 (20/119)
			10-19	33 (19/58)
Charleston, SC	1997	Blacks	0-19	46**
San Diego, CA	1993-1994	Whites, AA, Hispanics, Asian Americans	0-16	8 (13/160)
San Antonio, TX	1990-1997	Hispanics, Whites	0-17	18
Ventura, CA	1990-1994	Hispanics		45 (14/31)

*Estimates include Type 1 and Type 2 diabetes; ** percentages of Type 2 diabetes among non-incident cases of diabetes. Adapted from Fagot-Campagna et al., 2001.
AA = African American
MA = Mexican American

The National Institute of Diabetes and Digestive Kidney Diseases (NIDDK) and National Institute of Child Health and Human Development (NICHD) estimates a rise in diagnosed Type 2 diabetes from less than 5% in 1994 to 20-30% of all the cases of childhood diabetes after 1994 (NIDDK/NICHD, 1999). Data assessment from National Health And Nutrition Examination Survey (NHANES) III demonstrated that among 2,867 individuals aged 12-19 years between 1988 and 1994, thirteen of those sampled had diabetes (Fagot-Campagna et al., 2001). Of these 13, nine were based on insulin treatment and two on treatment with oral agents, and two on elevated fasting or random blood glucose levels. National prevalence estimates for all types of diabetes of 4.1 per 1000 in this age group were hence calculated (Fagot-Campagna et al., 2001). NHANES III has no actual diagnosis classification for diabetes among <18 year old, hence these parameters were used as indicators to calculate estimates.

Additional evidence of an increase in prevalence comes from reports of diagnosed cases in different states of the U.S. For example, in Cincinnati, Ohio, medical charts of diagnosed diabetes cases from 1982 to 1995 were reviewed, and the incidence of Type 2 diabetes in 10 to 19 year old subjects increased from 0.7/100,000 in 1982 to 7.2/100,000 in 1994 (Pinhas-Hamiel et al., 1996). Evidence suggesting increases in Type 2 diabetes in children and adolescents in U.S is accumulating. Data from Indian Health Service (1988 to 1996), also documented a 54% increase in prevalence of reported diabetes in 15-19 year old adolescents (Fagot-Campagna et al., 2002). Case studies in Ohio, South Carolina and a few other states have shown increasing percentages of incident pediatric cases of diagnosed diabetes, with fewer than 4% reported before 1990s and up to 45% in recent studies (Pinhas-Hamiel et al., 1996; Willi et al., 1997; Fagot-Campagna et al., 2000). Those believed to be at greatest risk are minority children (Native, African, and Mexican-Americans) who are obese, inactive, and genetically predisposed to the development of Type 2 diabetes (Dabelea et al., 1999).

This emergence of Type 2 epidemic is not limited to North America. Increases in Type 2 diabetes in children and adolescents have been detected in Tokyo (Kitagawa et al., 1998 & 1994), Libya (Kadiki et al., 1996), and aboriginal children in Australia (Daniel et al., 1999) and Canada (Dean, 1998). In Tokyo, the annual incidence of Type 2 diabetes among junior high school children, increased from 7.3 per 100,000 in 1976-1980 to 12.1/100,000 in 1981-1985, and to 13.9/100,000 in 1991-1995 (Kitagawa et al., 1998 & 1994). The age-specific prevalence of Type 2 diabetes in 5-14 year old in the First Nations population in Canada is 765/100,000 (Dean, 1998). Researchers from Taiwan reported an estimated rate of Type 2 diabetes as 6.5/100,000. In this study a total of 253 school children aged 6-18 years, registered in schools in Taiwan Province, were identified with newly diagnosed diabetes, 24 (9.5%) had Type 1 diabetes, 137 (54.2%) had Type 2 diabetes, and 22 (8.7%) had secondary diabetes (Wei et al., 2003). Among newly diagnosed diabetic children and adolescents in Bangkok, Type 2 diabetes increased from 5% of all cases during 1986-1995 to 17.9% during 1996-1999 (Likitmaskul et al., 2003).

2.2) Diagnosis

In the pediatric population, the huge variability in disease presentation and symptomatology has made distinguishing the diagnosis of diabetes more difficult without sophisticated laboratory evaluation. This has created confusion over the criteria that should be used to classify Type 2 diabetes in children. Obesity is perhaps the best and most strongly associated clinical criterion for risk of Type 2 diabetes in youth followed by a family history of Type 2 diabetes. The age of onset is believed to be usually over 8 years of age, often in the range of 12-14 years, coinciding with middle to late puberty (American Diabetes Association, 2000). However, as the childhood population becomes increasingly more obese, Type 2 diabetes may be expected to occur in younger children (American Diabetes Association, 2000). Indeed, cases as young as 6 years of age have been reported in some clinics (Henry, 2001; Cicinelli-Timm, 2002).

Many cases of Type 2 diabetes are undiagnosed due to the absence of specific symptoms early on in the disease process, or subjects are misdiagnosed due to a long-standing view by health-care professionals that diabetes in the young is usually Type 1 (Hale et al., 1998; Rosenbloom et al., 1999). Further complicating the difficulty of accurate diagnosis of Type 2 diabetes is the presence of ketoacidosis sometimes, a primary feature of Type 1 diabetes (Sellers and Dean, 2000; Tan et al., 2000; Tanaka et al., 1999; Thai et al., 1997; Scott et al., 1997; Pinhas-Hamiel et al., 1997; Yamada et al., 1996).

A clinical feature commonly found in children and adolescents with Type 2 diabetes is acanthosis nigricans, a dermatological disorder associated with obesity and insulin resistance (Stuart et al., 1998; Stuart et al., 1997; Stuart et al., 1994). Acanthosis nigricans is a velvety, dark thickening of the skin, typically found on the nape of the neck, axilla, and medial thighs. Some estimates suggest that it can be found in 90% of children with Type 2 diabetes and 7% in all school-aged children (Callahan and Mansfield, 2000; Hale and Danney, 1998; Glaser and Jones, 1998; Pinhas-Hamiel et al., 1996). It is rare in patients with Type 1 diabetes. Obese children and adolescents who present this clinical symptom, but are not overt, diabetes should be evaluated to exclude the possibility of undiagnosed hyperglycemia (Pinhas-Hamiel and Zeilter, 2001). Hence, the triad of obesity, a strong family history of Type 2 diabetes, and acanthosis nigricans should provide justification to screen these youth for Type 2 diabetes.

The American Diabetes Association has put forward diagnostic criteria as well as population selection criteria for the diagnosis of Type 2 diabetes in children and adolescents (Table 2)(American Diabetes Association, 2000).

Table 2: American diabetes association criteria for the diagnosis of Type 2 diabetes in children and adolescents.

Biochemical Parameters	Description
Classic symptoms of diabetes and casual plasma glucose ≥200 mg/dl (11.1 mmol/l) **OR**	Classic symptoms of diabetes: polyuria, polydipsia, & unexplained weight loss Casual = any time of the day without regard to time since last meal
Fasting plasma glucose ≥126 mg/dl (7.0 mmol/l) **OR**	Fasting= no caloric intake for at least 8 hrs
2-hour plasma glucose ≥ 200 mg/dl (11.1 mmol/l) during an OGTT	Glucose dosage= equivalent of 75 gm anhydrous glucose dissolved in water

As shown in Table 2 above, three key considerations are proposed for the diagnosis of Type 2 diabetes in children and adolescents. The Oral Glucose Tolerance Test (OGTT) for these tests should be performed as described by the World Health Organization (WHO, 1985), using a glucose load containing the equivalent of 75 gm anhydrous glucose dissolved in water. Population selection criteria in the studies cited included (a) Overweight (BMI >85th percentile for age and sex, weight for height >85th percentile, or weight >120 % of ideal for height) plus (b) any of the following risk factors: (i) family history of Type 2 diabetes in first or second degree relative (ii) Race/ethnicity and (iii) Signs of insulin resistance or conditions associated with insulin resistance (acanthosis nigricans, hypertension, dyslipidemia, polycystic ovarian syndrome (PCOS)). (c) Age of onset: age 10 years or at onset of puberty if puberty occurs at a younger age.

(d) Frequency of all the above mentioned three points (a,b, and c) as well as Fasting Plasma Glucose (FGP).

Table 3 outlines some general features useful in distinguishing between Type 1 and Type 2 diabetes. Presence of obesity, elevated C-peptide, belonging to minority ethnicity, strong family history of Type 2 diabetes, and the presence of acanthosis nigricans would suggest the diagnosis of Type 2 diabetes rather than Type 1 diabetes in the child or adolescent with diabetes. Obesity is perhaps the best clinical criterion for the diagnosis of Type 2 diabetes versus Type 1 diabetes in children and adolescents. In these children effects of chronic hyperglycemia on the β-cell may result in decreased insulin secretion and relative insulin deficiency resulting in an apparent clinical presentation of insulinopenia and ketosis or ketoacidosis and the diagnosis of Type 1 diabetes. Decreased β-cell responsiveness or premature β-cell death may be attributed to effects of chronic hyperglycemia on the β-cell resulting in glucose desensitizing or glucose toxicity respectively (Robertson et al., 1994). Therefore, changes in β-cell function over time may account for the variability of clinical presentations in children with Type 2 diabetes but after β-cell recovery with improved metabolic control are determined to have Type 2 diabetes (Clark et al., 2001)(Figure 1).

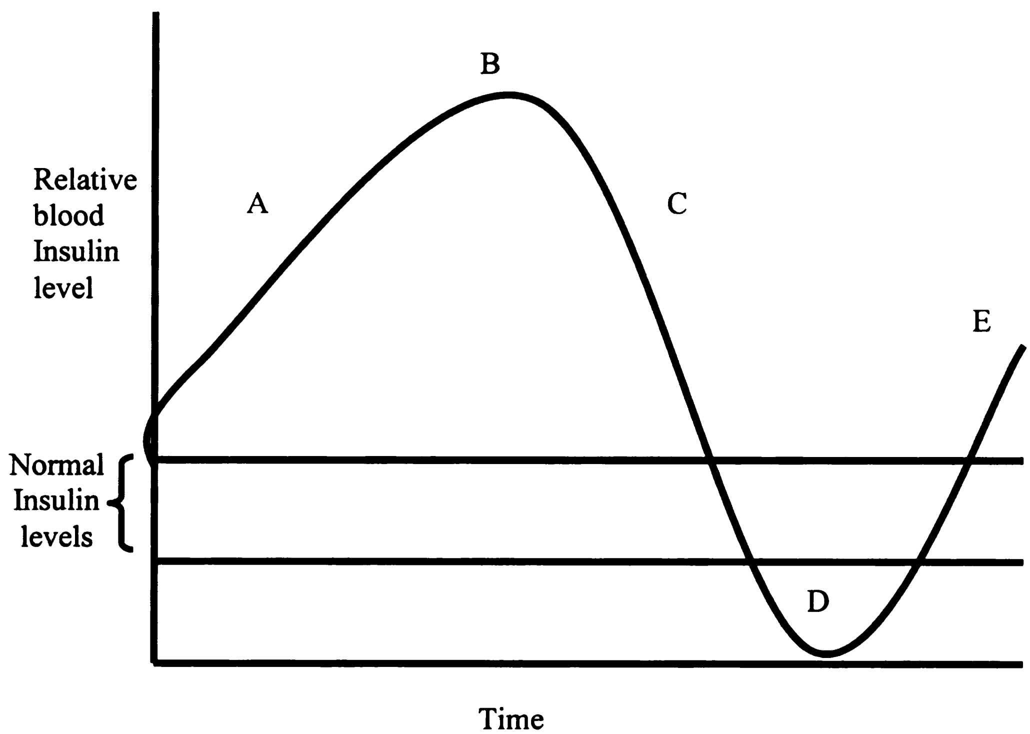
Table 3: Differentiating Type 1 from Type 2 diabetes in children and adolescents.

	Type 1	Type 2
Demographics		
Family History	3% - 5%	74% - 100%
Age or pubertal status	All ages but mostly young children	mostly >10 year and mostly after puberty
Gender	Females = Males	Females > Males
Presentation		
Symptom duration	Days or weeks	Weeks or months
Weight	All ranges	Obese
Weight loss	Common	Uncommon
Physical Findings		
BMI at diagnosis	<20kg/m^2	>27kg/m^2
Acanthosis Nigricans	Rare	Common
Hirsutism	Rare	Common
Biochemical Parameters at Diagnosis		
Hyperglycemia	Variable	Variable
Ketosis and ketonuria	Common	Common
Acidosis	Common	Variable
Other Markers		
GHB	Elevated	Elevated
Insulin	Low	High
Autoimmune markers	Common	Uncommon

Source: NIDDK/NICHD, 1999

Figure 1: Postulated clinical presentation

(A) Insulin resistance with hyperinsulinism, (B) Glucose intolerance, (C) Diabetes mellitus with hyperinsulinemia, (D) Insulinopenia with ketosis or Ketoacidosis, (E) Hyperinsulinsm after metabolic stabilization and recovery of beta cell function



Source: Clark et al., 2001.

2.3) Associated Factors

Relationship to Obesity

Among adults, numerous studies document a significant correlation between the prevalence of Type 2 diabetes and relative weight for height (Mokdad et al., 2000 and 2001). Ford et al., (1997) demonstrated that for every 1 kg increase in measured weight the risk of diabetes increased by 4.5% in a national sample of adults. A significant majority (85%) of children with Type 2 diabetes are overweight or obese at the time of diagnosis (American Diabetes Association, 2000; Pinhas-Hamiel et al., 1996; Pihoker et al., 1988). Obesity is perhaps the best clinical criterion for the diagnosis of Type 2 diabetes versus Type 1 diabetes in children and adolescents. The increase in diagnosis in the last few years coincides with the increasing prevalence of obesity among American children (NIDDK/NICHD, 1999).

Data on childhood and adolescent obesity levels between the 1960s and 1990s show a steady increase (Gortmaker, 1987; Campaigne, 1994; Webber et al., 1994). This raises a special concern, as obesity is usually also associated with other deleterious health outcomes such as high blood pressure, coronary artery disease and stroke (National Center for Health Statistics, 1987). Current data from NHANES III (1998-1994) of a nationally representative sample of children, aged 6-11 years and adolescents, aged 12-17 years and the National Longitudinal Study of Adolescent Health (Add Health) (National Center for Health Statistics (NCHS) 1994, Flegal et al., 2001) indicate that approximately 14% of children and 12% of adolescents are overweight, with an almost equal distribution among males and females. Black, non-Hispanic females and Mexican

American males had the highest percentage of overweight individuals. With regard to obesity in certain ethnic groups, acculturation was deemed a factor to also consider (Popkin and Udry, 1998). For the Hispanic and Asian American populations, children born outside of US (first generation Americans) were less likely to be obese than children born of US immigrants (second generation Americans).

The average BMI for the Type 2 diabetes pediatric population in published reports ranges from 35 – 39 kg/m^2, while the normal range is 15 – 27 kg/m^2 (Pinhas-Hamiel et al., 1999). One third of the children with Type 2 diabetes have a BMI greater than 40 kg/m^2, indicating morbid obesity and 17% have BMI greater than 45kg/m^2. Waist to hip ratio of adolescents with Type 2 diabetes indicates that obesity in these patients is central (the "apple" shape) (Pinhas-Hamiel et al., 1999).

A key physiological implication of obesity and link to Type 2 diabetes is the adverse effects on glucose metabolism. For example, 55 % of variance in insulin sensitivity among healthy white children (i.e. non-diabetic) is accounted for by total adiposity (Bogardus et al., 1985). The amount of visceral fat in obese adolescents was directly correlated with hyperinsulinemia and inversely related with insulin sensitivity (Tamura et al., 2000). Therefore, it is not surprising that the Type 2 diabetes-obesity association is so strong.

Associations between low birth weight and an increased risk for Type 2 diabetes in adults have been described in various populations. In Pima children, low birth weight subjects

(<2.5 kg) have a higher prevalence of diabetes than individuals with normal birth weight (2.5-4.5 kg), but there is also a higher prevalence of diabetes in children with very high birth weights ($\geq$ 4.5 kg) (Dabelea et al., 1998).

Other Risk Factors:

Family History: Type 2 diabetes in children and adolescents is strongly associated with family history (Hale and Danney, 1998; Hale, 2000). Children and adolescents with Type 2 diabetes generally come from families in which the parents are also obese and tend to have insulin resistance or overt Type 2 diabetes themselves (Pinhas-Hamiel and Zeitler, 2001). Approximately 74-100% of affected children have a first or second-degree relative with Type 2 diabetes (Hale and Danney, 1998; Hale, 2000; Pinhas-Hamiel et al., 1996). Healthy siblings of patients with Type 2 diabetes have been shown to have elevated levels of proinsulin and C-peptide (Pinhas-Hamiel and Zeitler, 2001), both of which are associated with high risk of developing Type 2 diabetes. In addition, the authors reported first-degree family members to have "undiagnosed diabetes" on subsequent evaluation. Other studies demonstrated that children and adolescents, with mothers who had diabetes during pregnancy, are at a greater risk for a higher prevalence of Type 2 diabetes, suggesting that an abnormal intrauterine environment may be an independent risk factor for obesity and the early expression of diabetes in the offspring (Pettitt et al., 1988; Lindsay et al., 2000; Phillips, 1996).

Puberty: Puberty may also be playing a role as an increasing risk factor for Type 2 diabetes in children. Pinhas-Hamiel et al., (1996) demonstrated that mean age for their subjects was 13.8 years and that all their subjects were in mid-puberty. During puberty, there is increased resistance to the action of insulin, resulting in hyperinsulinemia. It has been shown that between Tanner stages II and IV there is 30% lower insulin-mediated glucose disposal compared with prepubertal children in Tanner stage I and compared with young adults (Arslanian, 2000). Sinaiko et al. (2004), indicated that increased insulin resistance is associated with a significantly higher systolic blood pressure after more than five years of follow- up. Since puberty is characterized by relative insulin resistance, it may be an aggravating factor in the appearance of overt Type 2 diabetes in obese adolescents.

Ethnicity: Results from the Bogalusa Heart Study demonstrated that after adjusting for age, weight, ponderal index, and pubertal stage, African American children aged 7 to 11 years, had higher insulin responses suggestive of insulin resistance than their White counterparts (Rosenbloom et al., 1999; Urbina et al., 1999). A study by Danadian et al. (1999), indicated that even among healthy, prepubertal African American children, a family history of diabetes is associated with an approximately 20% reduction in insulin sensitivity. High levels of insulin/hyperinsulinemia and decreased insulin sensitivity observed among 8 to 12 year old African American and Hispanic has been associated with both increased insulin secretion and decreased clearance of insulin (Arslanian et al., 2002; Goran et al., 2002). Studies from San Diego and Cincinnati demonstrated that two thirds of their children and adolescents with Type 2 diabetes were African American or

Mexican American respectively (Pinhas-Hamiel et al., 1996; Glaser and Jones, 1998). Thus, Type 2 diabetes tends to be more prevalent in some ethnicities.

Gender: Studies in Pima Indians, the First Nations of Canada, and Japanese school children, showed that female adolescents appear to have increased risk of Type 2 diabetes compared to male adolescents (Fagot-Campagna et al., 2000; Fagot-Campagna et al., 1999; Pinhas-Hamiel et al., 1996). Overall female-male ratio is of 1.7:1 regardless of age (Pinhas-Hamiel and Zeitler, 2001).

Hypertension: Hypertension occurs in 20 % to 30% of patients with Type 2 diabetes, but is rare in patients with Type 1 diabetes. The presence of both acanthosis nigricans and hypertension strongly suggests hyperinsulinemia (Pinhas-Hamiel & Zeitler, 2001). Obese children and adolescents with hypertension should be asked about family history of diabetes as well as examined for hyperglycemia (Pinhas-Hamiel & Zeitler, 2001). Hypertension in Type 2 diabetes youth is a major risk factor for nephropathy and cardiovascular disease (Alberti et al., 2004).

Metabolic Syndrome: National Cholesterol Education Program (NCEP) recently issued major new clinical practice guidelines on the prevention and management of high cholesterol. These guidelines, also known as Adult Treatment Panel III (ATP III) provided a definition of Metabolic Syndrome (MS) in adults and elicited the importance of MS as a risk factor for Type 2 diabetes and cardiovascular diseases. According to recent estimates, the age-adjusted prevalence of the metabolic syndrome was found to be

23.7% among US adults participating in NHANES III (Ford et al., 2002). Studies suggest that a substantial percentage of overweight youth may be afflicted with metabolic syndrome as many have 1 or more of the following: elevated triglycerides, low HDL-C, and high blood pressure (Cook et al., 2003; Falkner et al., 2002; Freedman et al., 1999). The definition for metabolic syndrome in adults and adolescents as defined by the NCEP ATP III clinical cut off points and Cook et al. (2003) respectively, are presented in Table 4. Metabolic syndrome is defined as having at least three of the following listed in the table.

Table 4: Metabolic syndrome definition

Criterion	Adults	Adolescents
High Triglyceride level (mg/dl)	≥ 150	≥ 110
Low HDL-C (mg/dl)		
Males	< 40	≤ 40
Females	< 50	≤ 40
Abdominal obesity (waist circumference in cm)		
Males	> 102	≥ 90^{th} percentile
Females	> 88	≥ 90^{th} percentile
High fasting glucose level (mg/dl)	≥ 110	≥ 110
High blood pressure (mm Hg)	≥ 130/85	≥ 90^{th} percentile

Source: Cook et al., 2003

Findings from the NHANES III (1988-1994) data indicated that overall prevalence of metabolic syndrome among youth aged 12-19 years was 4.2% (Cook et al., 2003). In adolescents with BMI $\geq$ 95th percentile, 28.7 % were classified as having the syndrome compared to 6.8% of at-risk adolescents (BMI $\geq$ 85th percentile) and 0.1% of those with BMI below the 85th percentile ($p<0.001$) (Cook et al., 2003). Another similar study among overweight Hispanic youth demonstrated that 30% of the subjects were classified as having metabolic syndrome (Cruz, et al., 2004). From these studies, it appears that in general a high proportion of overweight youth may be at increased risk for Type 2 diabetes and cardiovascular diseases.

2.4) Treatment of Type 2 diabetes in children and adolescents

Although there is no set cure for diabetes, the ideal goal for treatment is normalization of blood glucose values and Glycosylated Hemoglobin (GHB) (ADA, 1999). The ultimate goal of treatment is to decrease the risk of the acute and chronic complications associated with diabetes. There is strong evidence from the U.K Prospective Diabetes study (UKPDS) that the normalization of blood glucose substantially reduces the frequency of microvascular complications of Type 2 diabetes in adults (UKPDS Group, 1998). The early age of onset of Type 2 diabetes in children may particularly increase the risk of microvascular complications such as, which are known to be directly related to duration of diabetes and hyperglycemia (ADA, 2000). Hence, the goals for clinical management of Type 2 diabetes mellitus in children and adolescents should include therapies directed at treating the underlying pathologies of diabetes, effects of chronic hyperglycemia, and the prevention of long-term complications. Prevention and treatment of associated co-morbidities such as hypertension, hyperlipidemia, and obesity are important, but the ultimate goal is to maintain blood glucose levels and the risk of end-organ damage from diabetes, which is directly related to the duration of diabetes and level of hyperglycemia. Similar to Type 2 diabetes mellitus in adults, the first lines of therapy in children with Type 2 diabetes are diet, exercise and weight loss or maintenance, because these therapies are directed at the underlying pathology: insulin resistance, which is a primary associative feature of Type 2 diabetes.

Initial treatment of diabetes depends on the clinical presentation of the child or adolescent at the time of diagnosis. Clinical conditions can range from diabetic ketoacidosis or hyperglycemic hyperosmolar non-ketotic states that require aggressive initial therapy (insulin) and metabolic stabilization to asymptomatic hyperglycemia, that can be managed initially with diet and exercise (American Diabetes Association, 2000).

Diet and exercise are the foundation for the management of insulin resistance in Type 2 diabetes. Nutrition plans should be culturally appropriate, sensitive to family resources, provided to all caregivers, and encourage healthy eating habits for the entire family and suggest behavior modification strategies to promote physical activity and decrease high-caloric, high-fat food choices. Improving physical inactivity is another aspect. Structured exercise activities such as sports and athletic hobbies are recommended to provide physical activity that may not be part of the child's lifestyle. Reducing television watching and computer use are also effective in decreasing physical inactivity in children. Successful treatment with exercise and diet among youth is defined as cessation of excessive weight gain with normal linear growth, near normal fasting blood glucose levels (<126 mg/dl), near normal GHB (~7%), and the avoidance of hypoglycemia (American Diabetes Association, 2000). Currently there is no data to evaluate the efficacy of diet and exercise therapy in treating Type 2 diabetes in children.

In non-ketotic patients, the American Diabetes Association recommends that metformin (biguanide), an oral hypoglycemic drug, should be the drug of choice in children if drugs become necessary, because it lowers glucose levels without the risk of hypoglycemia, maintains or decreases body weight, lowers LDL-cholesterol and triglyceride levels (ADA, 2000; Silverstein and Rosenbloom, 2000). However, in patients who present with severe hyperglycemia or ketosis, insulin therapy in addition to metformin is recommended because of the potential for a transient insulin deficiency resulting from glucose toxicity. Once control is achieved, the insulin dose can be reduced gradually (Pinhas-Hamiel and Zeitler, 2001). There is currently no data pertaining to newer, so called insulin-sensitizing drugs, such as thiazolidinediones. Studies need to be done to examine the safety and efficacy of oral diabetes medications in the pediatric population. Pharmacological agents used for the treatment of Type 2 diabetes are summarized in Appendix A.

3) Assessment of control in diabetes

3.1) Definition of control

Diabetes control is defined as achieving and/or maintaining an ideal body weight, euglycemia and normal glycosylated hemoglobin or GHB, as well as normal fasting plasma cholesterol and triglycerides (American Diabetes Association, 2000). These outcomes are desired since obesity may predispose an individual to poorer diabetes control, such as aberrations in plasma glucose would result in abnormal lipid metabolism, and elevated plasma cholesterol and triglycerides could increase the possibility of atherosclerosis (American Diabetes Association, 2000).

3.2) Glycemic control

Glycosylated hemoglobin (GHB) is the glycosylated form of hemoglobin A, which constitutes 90-95 % of adult hemoglobin and that of infants older than six months (Torre et al., 1981). GHB is currently considered the best indicator of a patient's average glycemic control over the prior 120 days period (Blanc et al., 1981; Gabbay, 1982; Lenzi et al., 1987; Torre et al., 1981). The American Diabetes Association defines normal glycemic control as HbA_1c 4-6%, goal HbA_1c is <7%, and additional action is required if HbA_1c >8% (ADA, 2004). This value should reflect little to no change in blood glucose and hence maintenance of as near as normal as possible in a well controlled individual. Researchers have shown significant correlations between this measure and that of mean values for other indices of glycemic control such as fasting blood sugar (Gabbay et al., 1977; Rao et al., 1986)

GHB is generated by a non-enzymatic post synthetic modification of the beta chain in hemoglobin A, involving the formation of a stable keto-amine linkage at the terminal amino group. It is formed in direct relation to the prevailing glycemia to which the erythrocyte is exposed throughout its 120 days lifecycle (Galloway et al., 1988; Service et al., 1987). This measure therefore reflects the average serum glucose concentration due to the slow accumulation which occurs during the lifecycle of the erythrocyte. Hence, the percentage of hemoglobin that is non-enzymatically glycosylated is increased with chronic hyperglycemia. High repeatability and stability of GHB are attributed to the irreversibility of the Amadori re-arrangement formed with the keto-amine linkage (Galloway et al., 1988).

To date GHB has provided the most objective measure of control, which is independent of patient compliance with self-monitoring of blood glucose, fluctuations in glucose, and physical activity or food intake at a particular time (Gabbay et al., 1977). Advantages of using serum glycosylated hemoglobin levels include: no need for the patient to fast prior to the test; the test is not affected by recent physical and/or emotional fluctuations; and the fact that the test may be performed on anyone at any time without prior instructions (Skelton, 1986). In patients with either Type 1 or Type 2 diabetes, researchers have found that when an index based on traditional methods of glucose control was used in comparison to GHB, control in 30-40 % of patients was deemed incorrect when compared with the GHB (Lenzi et al., 1987). They concluded that if one out of three patients were incorrectly assessed on traditional methods, then the clinical usefulness of the GHB assay was justified.

In spite of the utility of GHB as a measure of glycemic control, there are some potential limitations. It must be noted that GHB does not indicate ways to improve control nor does it reflect the fact that a normal level might be at the price of hypoglycemia (Lenzi et al., 1987). Also, depending on the assay method used for determination of the GHB, other abnormal hemoglobin that occur in certain conditions may interfere with the result.

3.3) Lipid management

Individuals with Type 2 diabetes have an increased prevalence of lipid abnormalities that contributes to higher rates of cardiovascular diseases. Lipid management is aimed at: lowering LDL cholesterol; raising HDL cholesterol; and lowering triglycerides. Maintaining lipids within normal limits has been shown to reduce macrovascular disease and mortality in adult patients with type 2 diabetes, particularly those who have had prior cardiovascular events (American Diabetes Association, 2004). Normal lipid levels for youth are: LDL $\leq$ 110 mg/dl; HDL > 40 mg/dl; Triglyceride < 150 mg/dl; and cholesterol <170 mg/dl (National Cholesterol Education Program, 2004).

4) Determinants of diabetes control

Determinants of control in Type 2 diabetes may be (1) sociodemographic (age, sex, education, family income and culture); (2) biomedical (duration of diabetes, number of co-morbidities); and (3) behavioral (diet, weight, exercise, compliance, and lifestyle).

4.1) Socio-demographic factors

Alleyene et al. (1979) studied social factors in 54 patients with severe Type 2 diabetes defined as clinical evidence of neurological or vascular complications, and 49 patients with mild Type 2 diabetes without evidence of these complications in Jamaica, West Indies. Control was measured by glycosuria of less than two pluses suggesting little to no overflow of glucose in the urine due to hyperglycemia. Patients with severe diabetes, had fewer social amenities, were less likely to be employed, were less educated, and had less initial understanding and knowledge of the disease, and were more likely to use informal medication than those with mild diabetes. These patients were overall more likely to report difficulties in maintaining the dietary regimen because of unavailability of foods and financial problems.

Robinson et al. (1998), investigated the relationship between measures of social deprivation and mortality in adults with diabetes. He found that odds ratios for diabetes were higher for those of lower social class compared to higher social class (Type 1: OR= 1.34, CI= 0.61-2.96; Type 2: OR= 2.0, CI= 1.41-2.85); and were higher for those who left school before 16 years of age compared to those who left school at or after 16 years of age (Type 1: OR= 3.98, CI= 1.96-8.06; Type 2: OR= 2.86, CI= 1.93-4.25). Subjects who were unemployed had higher mortality rates than those employed at the time of the study (Type 1: OR= 3.10, CI= 1.67-5.97; Type 2: OR= 2.88, CI= 2.12-3.91), and those living in council housing had a greater mortality than those who were living in other types of housing (Type 1: OR= 2.57, CI= 1.35-4.91; Type 2: OR= 2.76, CI= 2.05-3.73).

McMurray et al. (1998), demonstrated that female adolescents with a low socioeconomic status were more likely to be overweight, while Mei et al. (1998), reported an increased prevalence of overweight among low-income preschool children. Since diabetes is a chronic illness, the escalating costs of health care no doubt make it difficult for many to cope with the rising costs (Jewler, 1988). Subsequently, many patients do not have access to private specialized diabetes care where as the American Diabetes Associations recommendations for standards of diabetes care are most likely to be part of routine practice. Hence, socioeconomic status may have implications for persons with diabetes.

4.2) Biomedical factors

Diabetes duration may have important implications for control. Duration of the disease is often taken into consideration in analysis of studies related to control in diabetes because Type 2 especially if not recognized or poorly controlled is assumed to have cumulative negative effects over time (Alleyne et al., 1979; O' Connor et al., 1987). Usually measured by the date of first diagnosis, duration is more likely duration of treatment as noted by a medical professional. It is not a precise measure of duration of disease from a physiological standpoint since medical care access and utilization and symptomatology may variably define the stage of the disease when diagnosed. Thus, it is difficult to know how to interpret findings based on this variable. However, it does provide the best method and some indication of time.

4.3) Self care behaviors

Appropriate behaviors as outlined under treatment strategies are imperative for diabetes management and hence control. These behaviors, as specified in the American Diabetes Association's guide to diagnosis and treatment of Type 2 for physicians are medication compliance as prescribed, home diabetes status monitoring to facilitate treatment strategies, appropriate regular physical activity as tolerated by the patient and advised by the health care provider, and dietary modification to enhance and maintain normal serum glucose and lipid levels (American Diabetes Association, 2004). This ability to achieve control of blood sugar in persons with diabetes depends to a large extent on the degree to which these self care behaviors are adhered to.

Although adolescents start exerting more control over their health behaviors, as they enter adulthood, results from studies have indicated that most adolescents do not relate unhealthy behaviors with negative health outcomes (Radius et al., 1980). Studies in Mexican-American youth in California (Jones, 1998), Native American youth in Canada (Dean, 1998) and the U.S. (Watkins and Whitcomb, 1998) attribute non-adherence to many factors such as denial about their diabetes because they are asymptomatic, and peer pressure to consume high-caloric foods and beverages high in sugar content. Numerous cultural and socioeconomic barriers interfere with implementation of dietary changes in youth with diabetes (Rosenbloom et al., 1999). Youth may lack familiarity with recommended food items, which may be costly, difficult for families to obtain, or may require special preparation (Dean, 1998; Jones, 1998).

In the last decade there has been a concerted national effort to reduce the negative impact of diabetes through improvements in self-care behaviors that lead to improved diabetes management. The bases for this effort are supported by the findings of the U.K. Prospective Diabetes Study (Turner et al., 1998) and the Diabetes Control and Complications Trial (DCCT, 1993). These findings emphasize the importance of self-care behaviors being incorporated as a part of an integrated program to maintain good blood glucose control over time. Type 2 diabetes patients require adoption and maintenance of multiple self-care behaviors to achieve and sustain good glycemic control (DCCT, 1993; Turner et al., 1998). These behaviors mainly include self-monitoring of blood glucose via finger prick tests, exercising regularly, and adhering to a recommended eating regime.

A study by Rost et al. (1990), evaluated the relationship of self-care behaviors to metabolic control in Type 2 diabetes patients. Self care behaviors assessed were the frequency of exercise, blood glucose monitoring and meal skipping. Results from this study demonstrated that the frequency of self-blood glucose monitoring was significantly associated with a decrease in glycated hemoglobin.

The Diabetes Prevention study demonstrated that lifestyle intervention (reduction of at least 7% of initial body weight through a healthy diet and physical activity of moderate intensity for 150 minutes/week) reduced the incidence of Type 2 diabetes by 58% as compared to the placebo group (Diabetes Prevention Program Research Group, 2002). On the other hand, research also demonstrates that adhering to a healthy diet and increasing physical activity are the most difficult components of a self-care regime (Sullivan and Joseph, 1998). People with diabetes were reported to be more resistant to dietary change when compared to people with other chronic diseases (Groop and Toumi, 1997).

Studies have shown that these self-care behaviors are influenced by psychosocial, behavioral, and environmental elements (Oltersdorf et al., 1999; Nestle et al., 1998).

Many studies, therefore have investigated behavioral and psychosocial issues influencing food selection and eating patterns (Oltersdorf et al., 1999; Nestle et al., 1998). A study by Travis (1997), among adults with Type 2 diabetes focused on psychosocial variables affecting dietary adherence and identified the variables that influenced diabetes self-care. Other quantitative studies specific to minority populations with adult Type 2 diabetes have suggested that factors such as culture, ethnicity, socioeconomic status, and psychosocial factors play a significant role in explaining certain self-care behaviors and outcomes (Fitzgerald et al., 1997; Chipkin and De Groot, 1998; Bell et al., 1995; Gilliland et al., 1998). A study by Wdowik et al. (2001) among college students with Type 1 diabetes indicated that, the most predictive attitude constructs of good diabetes management were *Intention* and *Importance of Health,* whereas barriers to good diabetes management were *Emotional Response* and *Situational Factors* (Wdowik et al., 2001).

Qualitative research has provided some additional information on the many psychosocial factors influencing the self-care behaviors of adults with Type 2 diabetes (Anderson et al., 1996; El-Kebbi et al., 1996; Maillet et al., 1996). Although these studies identified a number of important socio-cultural and psychosocial influences on self-management behaviors, and particularly dietary behaviors, it is also necessary to have information on the relative importance of these factors and how they are manifested in day-to-day living. Moreover, there is limited information on how unique personal dimensions, behavioral requirements, and environmental characteristics of those with Type 2 diabetes affect lifestyle factors especially of the youth.

Phase 2 of this study proposes to accomplish this task by: employing the ecological theory as a guide for identifying the structure, characteristics and function of systems that facilitate control of diabetes, based on what a group of Type 2 diabetes children and adolescents identify as having been their supports after diagnosis of diabetes. The goals for individuals with diabetes are to achieve and maintain a desirable body weight and optimal glycemic control to reduce the morbidity and mortality associated with diabetes (DCCT, 1993 and Turner et al., 1997). To achieve these goals for individuals with diabetes, nutrition educators need to appreciate and take into consideration the issues faced by those with diabetes as they strive to change and improve their eating patterns and lifestyles (Boyle et al., 1998).

Hence, the main purpose of this study was to examine the beliefs and experiences of youth with Type 2 diabetes regarding monitoring blood glucose, exercising regularly, dietary recommendations, food selection and eating patterns, and the aspects of daily living that influence their diabetes self-management practices. The end goal is to use this information to construct a picture of a supportive ecology for children and adolescents (with Type 2 diabetes) in managing their disease.

4.3.1) Medications

Chronic diseases such as diabetes mellitus, in conjunction with others such as hypertension, coronary heart disease and arthritis, require complex medication management regimens. The patient may inadvertently take or not take medications contrary to that prescribed. Prescribing practices of physicians as well as the memory and motivation of the patient may account for the ineffective accomplishment of this self-care behavior (Heisler et al., 2002; Hulka et al., 1976).

4.3.2) Home diabetes status monitoring

Self blood glucose monitoring, in the form of finger prick blood testing and/or urine testing by persons with diabetes plays an important role in maintaining blood glucose levels and is considered, the cornerstone of optimal self-care behavior in diabetes (Rubin et al., 1989). However, the literature is controversial in this respect and most of the studies are in relation to Type 1 diabetes in youth. Holmes and Griffiths (2002) reported a reduction in GHB in those who monitored glucose levels compared to those who did not measure. They also performed a meta-analysis on three studies (n=278) comparing GHB in subjects who performed blood glucose monitoring with those who performed urine monitoring. The reduction in GHB when monitoring blood glucose rather than urine glucose was -0.03% (95% Cl -0.52 - +0.47). This result was not statistically significant. The efficacy of blood and urine glucose monitoring testing alone, for people with Type 2 diabetes, in improving glycemic control as measured by GHB levels is still not conclusive. However, there is no doubt that knowledge of glycemic status especially if it is self determined could be a powerful motivating factor for action.

Rost et al., (1990) evaluated the relationship of self-care behaviors to metabolic control in Type 2 diabetes patients. Self care behaviors assessed were the frequency of exercise, blood glucose monitoring and meal skipping. Results from this study demonstrated that the frequency of self-blood glucose monitoring was significantly associated with a decrease in GHB.

4.3.3) Exercise

Exercise along with diet and medication has been considered one of the three cornerstones of diabetes therapy. A meta-analysis of 12 aerobic training studies and 2 resistance training studies among adults with Type 2 diabetes (mean age = 55 years) demonstrated a significant reduction in GHB in the exercise groups compared to the control groups (7.65% v/s 8.31%) (Boule et al., 2001). Mourier et al. (1997), demonstrated that physical training resulted in an improvement in insulin sensitivity with concomitant loss of visceral adipose tissue in Type 2 diabetes patients. Patients, who exercised, increased their VO_2 peak by 41% and their insulin sensitivity by 46%. Physical training significantly decreased abdominal fat evaluated by magnetic resonance imaging (umbilicus), with a greater loss of visceral adipose tissue (VAT) (48%) in comparison with the loss of subcutaneous adipose tissue (18%), but did not significantly affect body weight. In children, increased abdominal fat is associated with abnormal blood pressure, elevated serum levels of total cholesterol, LDL-C, triglyceride, and insulin, as well as lower levels of HDL (Freedman, et al.,1999). Research indicates an inverse relationship between visceral fat and insulin sensitivity, hence, exercising can be beneficial for people with diabetes.

Pan et al., (1997) demonstrated the effect of exercise and diet in delaying onset of Type 2 diabetes in subjects with impaired glucose tolerance. Results showed that the cumulative incidence of diabetes after 6 years was 67.7% (95% CI, 59.8-75.2) in the control group compared with 43.8% (95% CI, 35.5-52.3) in the diet group, 41.1% (95% CI, 33.4-49.4) in the exercise group, and 46.0% (95% CI, 37.3-54.7) in the diet-plus-exercise group ($P < 0.05$).

Results from the Diabetes prevention trial demonstrated that lifestyle intervention (reduction of at least 7% of initial body weight through a healthy diet and physical activity of moderate intensity for 150 minutes/week) reduced the incidence of Type 2 diabetes by 58% compared to the placebo group (Diabetes Prevention Program Research Group, 2002).

4.3.4) Diet

Nutritional factors concerned in blood glucose control are the total daily kilocalorie intake (Zimmerman and Service, 1988; Franz, 2004); type of sugar (glucose, fructose, sucrose, lactose) (Franz et al., 2004); type and amount of fiber (Vinkin and Jenkins, 1988; Bantle, 1988); and the percentage distribution of carbohydrates (Bantle, 1988; Kabedi, 1996), fat (Bantle 1988; Reaven, 1986), and protein (Bantle, 1988) of total kilocalorie intake. Before 1994, the nutrition principles and recommendations of the American Diabetes Association attempted to define an ideal nutrition prescription for all the people with diabetes (ADA, 1971; 1979 and 1987). After 1994, the nutrition recommendations shifted to one that emphasizes effect of nutrition therapy on metabolic control (ADA, 1994; Franz et al., 1994; Franz et al., 2002). The goal of nutrition intervention is to assist and facilitate individual lifestyle and behavior changes that will lead to improved metabolic control, and this continued in 2002 but for the first time the 2002 recommendations specifically addressed lifestyle approaches to diabetes prevention.

Studies have shown that replacing carbohydrate with monounsaturated fat reduces postprandial glycemia and triglyceridemia (Franz et al., 2004). However, there is a concern that increased fat intake may promote weight gain. Therefore, the contributions of carbohydrate and monounsaturated fat to energy intake should be individualized based on nutrition assessment, metabolic profiles, and treatment goals (Franz, 2004). Studies have demonstrated that in individuals with Type 2 diabetes, postprandial glucose levels and insulin responses to a variety of starches and sucrose are similar if the amount of carbohydrate is constant (Franz et al., 2002; Malerbi et al., 1996; Bantle et al., 1993). Glycemic index, the measure of glycemic response to carbohydrate-containing foods, has been used to physiologically classify dietary carbohydrates. Research indicated that habitual consumption of low glycemic index foods may lower the risk of Type 2 diabetes mellitus (Salmeron et al., 1997;) and improve metabolic control once the disease has developed (Miller, 2000). A Study by Brand et al. (1991), reported lower GHB in Type 2 patients consuming low glycemic index foods as compared to those consuming high glycemic index foods. Studies have also shown beneficial effects of fiber on glycemia (Chandalia et al., 2000; Jenkins et al., 1976). For example a diet supplemented with large amounts of water-soluble, gel-forming fiber, such as guar gum, (in other words high fiber diets) has been shown to reduce postprandial glycemia and plasma lipids (Chandalia et al., 2000; Jenkins et al., 1976).

The primary goal regarding dietary fat in patients with diabetes is to decrease intake of saturated fat and cholesterol (ADA 2001; Schwab et al., 2000; Hegsted et al., 1993). The recommendations are the same as for the general population: fat intake <30 % of energy intake, to reduce saturated fat intake to <10% of energy intake, and dietary cholesterol intake <300 mg/day. In subjects with diabetes, restrained eating behaviors with dietary fat restriction have shown to have beneficial effects on glycemia, plasmas lipids, and/or weight (Heilbronn et al., 1999; Storm et al., 1997; Walker et al., 1995).

There is no research on the nutrient requirements for children and adolescents with diabetes, and therefore the recommendations are based on requirements for all healthy children and adolescents (Institute of Medicine, Food and Nutrition Board 2001, 2000, and 1997; Food and Nutrition Board, 1989). Successful treatment for Type 2 diabetes in children and adolescents with nutrition therapy and exercise is comprised of cessation of excessive weight gain with normal linear growth and achievement of normal blood glucose and GHB levels (ADA, 2000). Behavior modification strategies to decrease high-energy high-fat food intake while encouraging healthy eating habits and regular physical activity for the entire family should be considered (Franz et al., 2004). These nutrition recommendations should also address co-morbidities, such as hypertension and dyslipidemia. Behavior modification to decrease high-calorie, high fat foods while encouraging healthy eating habits and regular exercise for the entire family should be considered (Ferguson et al., 1999). To enhance dietary adherence, patient inclusion in planning and regular follow-up would be an important consideration.

4.3.5) Weight control

Risk of Type 2 diabetes attributable to obesity is as much as 75 % (Manson and Spelsberg, 1994). Excess body fat is perhaps the most notable modifiable risk factor for the development of Type 2 diabetes (Edelstein et al., 1997). Weight loss is believed to improve glycemic control by decreasing exogenous insulin requirements and increasing insulin sensitivity, thereby decreasing morbidity and mortality overall (Wing 1995; Hansen, 1988; Wing et al., 1987b). Results from the Malmo Feasibility (intervened with reduced fat diets) study demonstrated that both weight reduction and increased fitness were associated with reduced incidence of diabetes in a lifestyle intervention group when compared to a control group (Eriksson and Linkgrade, 1991).

The benefit of weight loss in adult Type 2 diabetes patients has certainly been demonstrated even when the weight loss is modest (Wing et al., 1986; Wing et al., 1987a). Several recent studies have demonstrated the potential for moderate, sustained weight loss to substantially reduce the risk for Type 2 diabetes (Moore et al., 2000; Heymsfield et al., 2000; Sjostrom et al., 1999; Pan et al., 1997; Viswanathan et al., 1997; Eriksson et al., 1991). There is a paucity of literature showing the benefits of weight loss for children and adolescents with Type 2 diabetes, but since the majority of the children or adolescents with Type 2 diabetes are obese/overweight, weight loss should be one of the key treatment strategies for this population.

Motivated patients can usually lose weight successfully during the initial dietary and increased physical activity period, but it is important that he/she maintains a healthy weight by losing more weight if necessary. Weight control is therefore a complex issue that involves the integration of a number of different approaches. Approaches should however take into consideration each patient's individual needs, which may change, depending on the circumstances.

4.3.6) Education

Education should provide an important communication tool for the health care provider to increase patient knowledge and skills in the management of disease. With regard to diabetes, education has been shown to have a positive effect on diabetes control (Hasler et al., 2000; Raz et al., 1988; Mazzuca et al., 1986). Continuous education plays a critical role in the management of adolescents with diabetes (Pinhas-Hamiel and Zietler, 2001). All family members should be included in the education program, since they are often also overweight and themselves at high risk for developing Type 2 diabetes (Pinhas-Hamiel and Zietler, 2001). Involving the entire family enables the adolescent to comply more reliably with recommendations (Pinhas-Hamiel and Zietler, 2001). Studies measuring changes in diabetes knowledge demonstrate improvement with education (group sessions, individual sessions, interactive computer teaching, home-visits, teaching based on needs), including those with follow-up of 6–12 months after the last intervention contact (Norris et al., 2001; Campbell et al., 1996; Heller et al., 1988; Hawthorne and Tomlinson., 1997). Regular reinforcement or repetition of the intervention has been demonstrated to improve knowledge levels at variable lengths of follow-up: Bloomgarden et al. (1987) conducted nine visits in 18 months, Korhonen et al. (1983) conducted one visit every 3 months for 12 months, Campbell et al. (1996) who demonstrated positive results by regular reinforcement with visits and telephone calls over 12 months, and Rettig et al. (1986) did 1 visit very month for 12 months.

Review of literature established the increasing incidence of Type 2 diabetes in US, and demonstrated that complying with self-care behaviors such as diet, exercise, and medication play a vital role in diabetes management. Hence, Phase 1 of the this study focuses on determining the proportion of youth with Type 2 diabetes in Michigan and Phase 2 of this study includes an interview-based study, designed to identify social and behavioral variables that may be associated with diabetes control. The theoretical foundation for Phase 2 is presented below.

5) Theoretical foundation for conducting in-depth interviews related to self-care behaviors

Concepts related to diabetes control play a central role in the shaping of nutrition education programs for families whose children have Type 2 diabetes. Although diabetes control is often stated as a program goal, the concept lacks specificity. Past research on nutrition education and weight control often suffered from a failure to base programs on theoretical models (Johnson and Johnson, 1985). There is a need for research that includes exploration of the individual's objectives and priorities for diabetes self-management education and cares as they may differ from those of the health care team and published standards of care (American Association of Diabetes Educators, 2002). However, the person with diabetes has the right and responsibility to make these choices. Building programs around self-selected goals helps to maintain participant's interest in the education programs and provides the necessary knowledge and skills for personal goal attainment (American Association of Diabetes Educators, 2002). More in-depth information is needed about an individual's attitudes; beliefs; experiences; psychosocial status; cultural issues, personal, metabolic, and other goals.

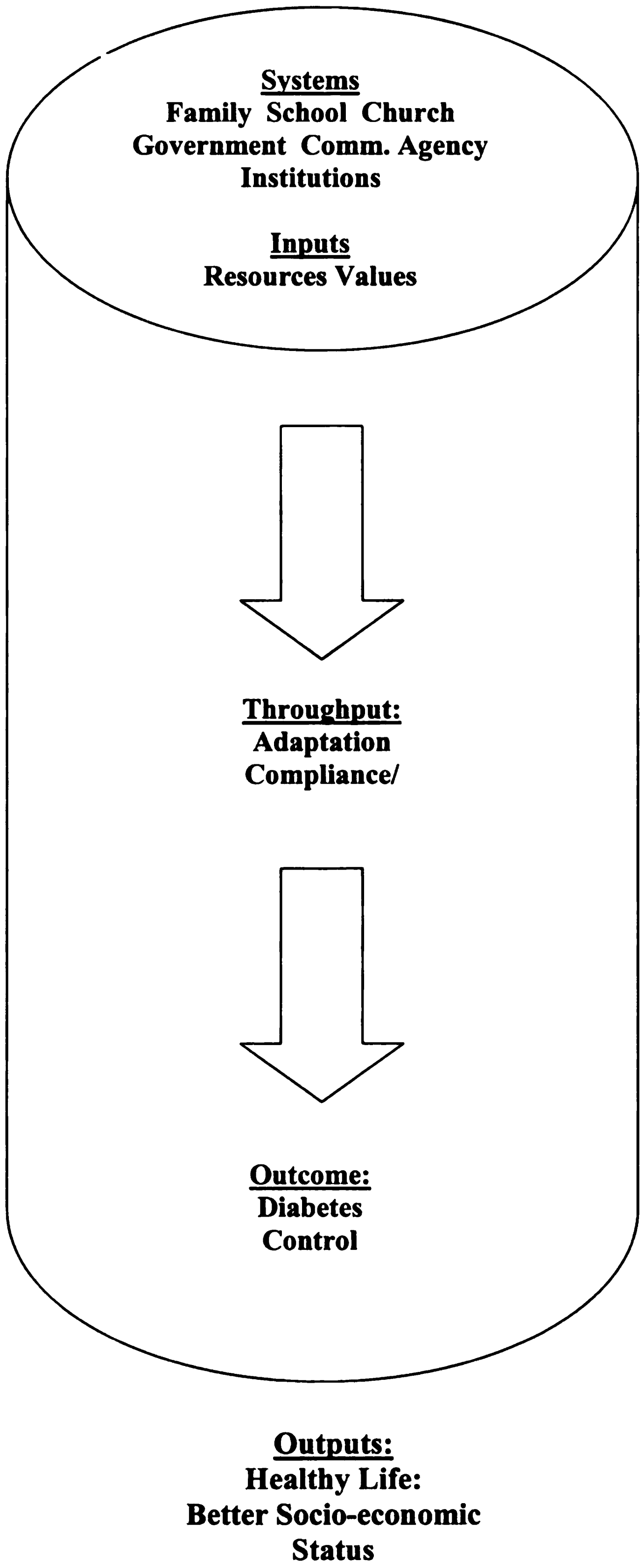
This study is grounded in the **human ecology theory** and employs an ecological framework that includes Bubolz and Sontag's (1993) human ecology theory and McLeroy's Social-Ecological Model for nutrition evaluation (1988). The intent is to elicit the unique experiences and voices of children and adolescents with Type 2 diabetes regarding expected self-care monitoring practices (monitoring blood glucose, exercising regularly, following dietary recommendations, selecting healthy foods and eating patterns), as well as social and institutional support and other potentially influential aspects of daily living.

Human Ecology Theory

Human ecological theory focuses on human beings as both biological organisms and social beings in interaction with their environment (Bubolz and Sontag, 1993). This theory presents the individual as part of the family, which is an energy transforming system that is interdependent with its natural, human built and socio-cultural milieu. In addition the access, use and management of resources for human adaptation and development are emphasized.

The ecological perspective as espoused by Bronfenbrenner (1989) provides a framework from which multiple contextual factors affecting the management of diabetes can be viewed. Bronfenbrenner and Ceci (1994) suggest that individual behavior and development is a culmination of many direct and indirect influences that either facilitate or impede individual potential. Bronfenbrenner's framework presents contextual influences within a 5-dimensional framework consisting of the Macro, Exo, Meso, Micro, and Chronosystems. In a bio-ecological model, a distinction is made between the concepts of the environment and process, with the proximal process in a central position that is defined in terms of its functional relationship to both the environment and to the characteristics of the developing person. Environmental contexts influence proximal processes and developmental outcomes not only in terms of the resources that they uncover, but also in the degree to which they provide stability and consistency over time that proximal processes require for their effective functioning (Bronfenbrenner, 1999). Bubolz and Sontag's theory is employed as a framework to illustrate the structure and process of supportive ecologies for children and adolescents with Type 2 diabetes (Figure 2). This theory looks at how the natural, human constructed and socio-cultural structures in an individual's environment contribute (inputs) and facilitate human adaptation (throughput) that results in healthy outcomes (outputs). This process illustrates the functioning of an individual's ecology.

Figure 2: Bubolz and Sontag's Model: Process by which Support Leads to Diabetes Control.

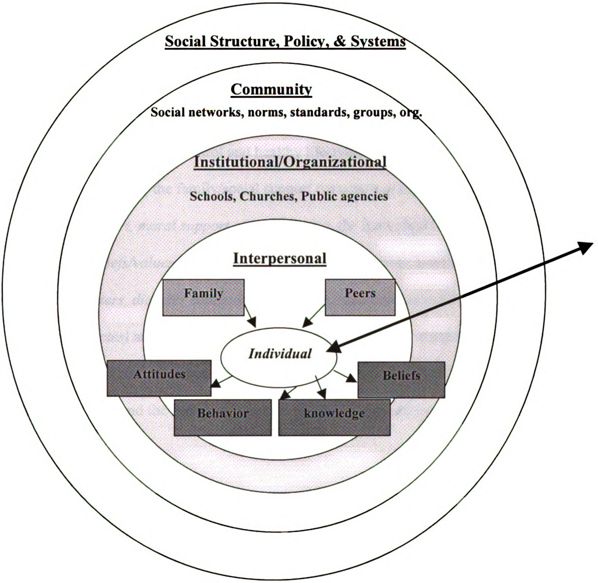


Social-Ecological Model

This model is based on the Bronfenberner model and provides a model that conceptualizes the social world in five spheres, or levels, of influence (Figure 3). These levels of influences are: social structure, policy, and systems; community; institutional/organizational; interpersonal; and individual.

The social structure, policy, systems sphere includes local, state, and federal policies that regulate or support organizational or individual behavior, including protection of or attention to children and special populations. The community level includes social networks, norms, and standards that exist formally or informally among individuals, groups, partnerships, and organizations. Community-level theoretical models believe that collaboration is a process of participation through which people, groups, and organizations work together to achieve desired results. The institutional/organizational sphere includes factors that influence organizational behavior in the private, public, and nonprofit sectors. These include schools, churches, public agencies, and businesses. The interpersonal level of influence includes primary groups, such as peers, family, and friends that provide social identity; support; role delineation and interaction for the individual. Individuals exist in a dynamic social environment in which the attitudes and actions of others influence their behaviors. Lastly the most specific level of influence is the individual itself. This level focuses on behavior choices, cognitive factors and psychological factors such as knowledge, attitudes, beliefs, and personality traits. This model is employed in this study to illustrate the ecology of families with children/adolescents with Type 2 diabetes and the supportive systems within it. Thus, the specific components of interest for children and adolescents with diagnosed Type 2 diabetes are the ecologies characteristic of the different systems at the different levels.

Figure 3: Model of supportive systems in etiologies of children and adolescents with Type 2 diabetes.



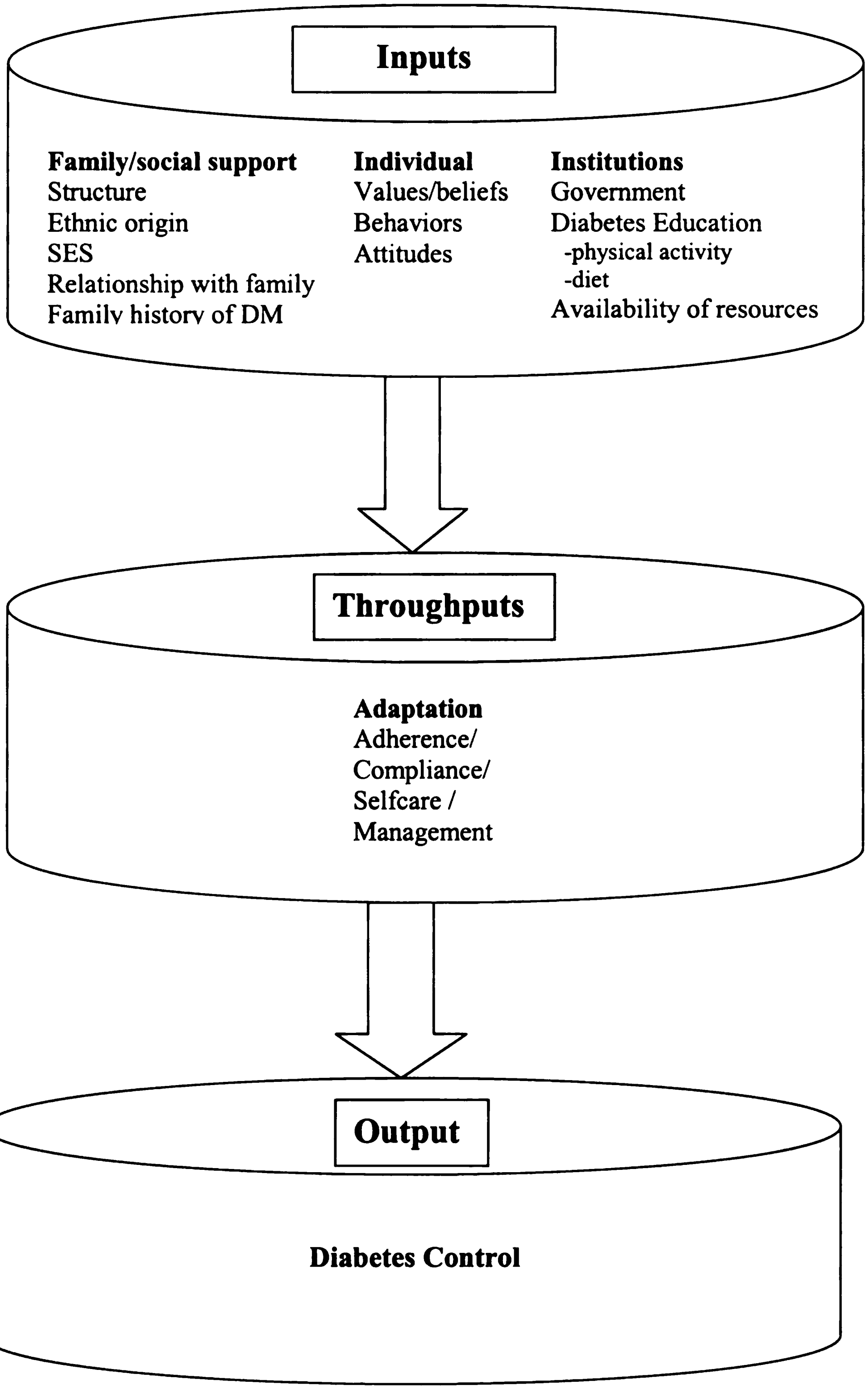
Conceptual Model:

By employing a combination of Bubolz and Sontag's (1993) human ecology theory and McLeroy's Social-Ecological Model for nutrition evaluation (1988), the things the children/adolescents diagnosed with Type 2 diabetes perceive as having assisted them in controlling diabetes and adapting to changes in lifestyle after the diagnosis will be characterized as the inputs into the ecology (Figure 4). In this conceptual model, the inputs will be characterized as representing one of the following systems: family/social support, individual themselves, and diabetes care institutions. How these inputs contribute to the throughput (controlling diabetes after diagnosis) and thus facilitate the outcome (good glycemic control and healthy lifestyle) are of specific interest. This model proposes that, the family/social support *(structure of the family, ethnicity, socio-economic support, moral support of parents etc.)*, the individual themselves *(their own behaviors, beliefs/values, attitudes, availability of resources)*, and the institutions *(diabetes centers, diabetes educators, physicians, insurance agencies, or other social support agencies)* are all inputs that influence an individual's adapting or adhering to the self care behaviors, and hence help in achieving better diabetes control. Based on the conceptual map and the literature, research questions were derived.

Research Questions:

1) How do family factors facilitate or inhibit the management of diabetes?
2) How do individual's values and behaviors influence the management of diabetes?
3) How do institutions influence the aspects of diabetes management?

Figure 4: Conceptual Framework adapted from Bubolz & Sontag, and McLeroy's theory



CHAPTER 3

Methods

Objectives and hypotheses

The objectives of this study were:

1) To estimate the proportion of diagnosed Type 2 diabetes among children and adolescents (6-19 years) who have either Type 1 or Type 2 diabetes at endocrinology specialty clinics in Michigan.
2) To determine glycemic control and associated factors (including biomedical, socio-demographic and family factors) in this population compared to Type 1 cases.
3) To determine the ecological factors that influence glycemic control in the population of children and adolescents with Type 2 diabetes.

Hypotheses for this study were:

1) The proportion of diagnosed Type 2 diabetes in children and adolescents aged 6-19 years from endocrine specialty clinics in the state of Michigan will be comparable to the national estimated rates of 8-45% for children and adolescents diagnosed with either Type 1 or Type 2 diabetes.
2) Glycemic control will be comparable in Type 1 versus Type 2 diabetes patients in this age group.
3) Data will show that patterns of self-care adherence related behavior (dietary practices, physical activity and home diabetes status monitoring) will differ

between good glycemic control (GHB <7%) and for these who have a GHB ≥7% for those diagnosed with Type 2 diabetes.

Design

This was a two phase, cross sectional study, which was descriptive and exploratory in nature. Data was collected for pediatric children with diabetes from medical chart reviews and patient interviews. This two-phase study was conducted in pediatric and adult endocrinology specialty clinics in Michigan. In Phase 1 of the study, data regarding total number of youth aged 6-19 years with diabetes (Type 2 or Type 1) was obtained from clinic data systems to estimate the percentages of diagnosed Type 2 diabetes. Additionally, glycemic control and associated factors (type of diabetes, age, gender, ethnicity, puberty, weight, and height) were abstracted from the charts to predict the effect of these independent variables on glycemic control in children with Type 1 or Type 2 diabetes. Phase 2 encompassed an in-depth interview study of a sub-sample from Phase 1 of Type 2 diabetes cases, to identify social and behavioral variables associated with glycemic control.

Sites

Pediatric and endocrinology clinics in the state of Michigan were selected for this study because of the fact that they are more likely than primary care clinics to have a diagnosed population of diabetes patients (Weatherspoon et al., 2001). Diabetes Centers with a significant number of children and adolescents (physician diagnosed cases ≥5) were considered eligible. Twelve clinics were contacted, but four were excluded due to insufficient or no cases of children or adolescents diagnosed with Type 2 diabetes. For this study, therefore eight endocrinology specialty clinics, each with over five identified cases of Type 2 diabetes consented to data collection. The eight eligible clinics are distributed over the state of Michigan: west central Michigan (Lansing-Sparrow Hospital, Grand Rapids- Saint Mary's Mercy Medical Center and DeVos Children's Hospital); southeast Michigan (Detroit- Henry Ford Children's Hospital and University of Michigan Medical Center); east central Michigan (Saginaw- Covenant Hospital and Hurley Medical Center in Flint) and south central Michigan (Jackson-Foote Hospital). DeVos Children's hospital and Children's Hospital of Michigan conducts satellite clinics in half of Michigan (West, Central, & East) and hence provides information for half of the state's pediatric population diagnosed with diabetes (age = 6-19 years). The excluded diabetes centers were from the Upper Peninsula, two clinics in Kalamazoo and one clinic in Midland.

Target Population

Study subjects for Phases 1 and 2 were children aged 6-19 years of age, medically diagnosed with either Type 1 or Type 2 diabetes, and treated at endocrinology clinics. Previous studies have shown 10-19 years as the probable age range for Type 2 diabetes cases in children and adolescents, but based on personal communications with physicians, Type 2 diabetes cases have been reported in as young as 6 years old. Hence, in order not to exclude these cases, the selected age range for this study was determined as 6-19 years of age.

The population base for Phases 1 and 2 was selected from all children and adolescents with a medical diagnosis of diabetes (Types 1 or 2) in the age group of 6-19 years, who were "Active" cases and whose records are accessible and available from the eight sites. "Active" was defined as having attended the clinic for at least six months prior to the starting date for data collection at that clinic. The patient population in these clinics was drawn from the entire state of Michigan. Six months was chosen as the criterion of active patient eligibility because the Type 2 patients are expected for clinic visits at three months intervals at least. The exclusion criteria were children 6-19 years old who have: 1) Physician noted maturity-onset diabetes of the young (MODY); 2) Type 2 diabetes caused by steroid use; 3) Type 2 diabetes secondary to cystic fibrosis; and 4) Children diagnosed with pre-diabetes (fasting blood glucose levels ≥110 mg/dl and < 126 mg/dl). These cases were excluded to obtain "true cases" of Type 2 diabetes as defined by the American Diabetes Association (ADA, 2000). For Phase 2, a sub sample from Phase 1 was selected.

Since Phase 1 consisted only of medical record reviews and no personal identification was used on the data abstraction form or for analyses, approval was required only from Michigan State University Committee on Research Involving Human Subjects (UCRIHS), the clinic directors and the Review Boards of the individual clinics. Human subjects study approval was granted on February 13th, 2002 by expedited review from UCRIHS. Phase 2 involved in-depth patient interviews. Therefore, additional approvals were necessary from UCRHIS and individual informed consent was obtained from the patients and their parents or guardians.

PHASE 1

Procedure for objectives 1 and 2

In Phase 1 of this study, data on the total number of youth aged 6-19 years with diabetes (Types 1 or 2) was obtained from clinic data systems. These data were used to estimate the proportion of diagnosed Type 2 diabetes in this population.

$$Estimated\ \ proportion\ \ of\ \ diagnosed\ \ cases\ = \frac{Diagnosed\ \ Type\ 2\ DM}{Diagnosed\ \ Type\ 1 + Type\ 2\ DM}$$

Additionally, a study comparing medically diagnosed Type 1 with Type 2 diabetes subjects in the age group of 6-19 years controlled for age and gender was also conducted. The medical records of these youth were compared for diabetes diagnosis, risk factors, and associated factors (demographic; biomedical-such as duration of diabetes, co-morbidities; control and treatment variables). The purpose of the medical record review was to estimate the prevalence of glycemic control in these populations and identify associative risk and control factors considered in intervention. A data collection form was used to abstract the information described above from the medical records (Appendix B). Content validity of data collection form was established by asking 6 diabetes professionals (2 pediatric endocrinologists, 1 nurse, 2 RD PhD's, 1 Dietitian) to review the data collection protocol sheet. Responses from 4 reviewers were obtained and the changes requested included: re- organization of questions, re-phrasing of questions to make them simpler, and deletion of questions which seemed irrelevant. Five trained people including the primary researcher conducted data abstraction at all centers to maintain consistency and confidentiality of records. The training for these researchers was conducted by the primary researcher.

Variable definitions

The variables of interest in Phase 1 of the study were: diabetes diagnosis; glycosylated hemoglobin; demographic data such as age, gender, race/ethnicity, family history, pubertal status; anthropometric data such as weight, height, and weight at birth; and lipid profiles as available. For the purposes of clearly understanding the parameters of interest, all the variables are defined in the following section.

Dependent variable:

Diagnosis of diabetes- Number of those diagnosed by the physician with either Type 1 or Type 2 was collected as noted on the patient chart or clinic records. This was used to calculate the proportion of those diagnosed with Type 2 diabetes among this population.

Diabetes control- Although lipid profiles can also be used to objectively assess diabetes control, glycemic control was selected because of the greater consistency of occurrence in the medical records. GHB is a continuous variable, but for bivariate analysis, it was recoded into a dichotomous variable ($\leq$7%, >7%). The cutoff point for glycemic control was selected from the American Diabetes Association guidelines which, defines the goal for ideal glycemic control as being less than or equal to 7% hemoglobin A1c (American Diabetes Association, 2000).

Independent variables

Age- Data was collected and entered in terms of date of birth (mm/day/yr). If we had a day missing for some subjects, but month of birth was available, then the first day of the month was considered as the day of birth.

Race/Ethnicity- Race/ethnicity was a self-reported categorical variable. Depending upon the sample size in each category, categories were collapsed.

Gender- The data was coded as 0 for male and 1 for female, a dichotomous variable.

Family History- Data regarding frequency of diabetes in first or second-degree relatives was collected. This was entered into the database as a dichotomous variable (yes=1 and no=0).

Gestational diabetes of the mother- These data were abstracted from the charts when available, and entered into the database as a dichotomous variable (yes=1 and no=0).

Height/weight- Height was recorded in meters and weight in kilograms, both were continuous variables. The BMI variable was created by using the formula BMI= wt (kg)/ht (m^2). The BMI was then recoded into percentiles, where ≥ 85^{th} to 95^{th} percentile is defined as at risk of overweight and ≥95^{th} percentile as overweight (CDC, 2000). Thus this variable was categorical.

Duration of diabetes- The duration of diabetes was determined from the medical record data as the number of years from the date of diagnosis, e.g., 2 years or if 6 months, then converted to 0.5 years, as an ordinal variable.

Diabetes management- Information regarding oral medication, insulin intake, dietary prescriptions, and exercise recommendation was recorded from medical charts as categorical variables.

Hospitalization- Data regarding number of hospitalizations (continuous variable) in the past year and reason for hospitalizations (categorical variable) was recorded from chart reviews.

Co-morbidities- Co-morbidities were recorded as reported in the charts. These data were entered into the dataset as yes (yes=1) and no (no=0) for each co-morbidity as a categorical variable.

Weight at birth- If available, birth weight data was collected in kilograms and entered as continuous variable. For analysis purposes birth weight was recoded into categories such as low birth weight (<2.5 kg), normal birth weight (2.5-4.5 kg) and high birth weight (≥ 4.5 kg) categories.

Puberty- Information regarding age at onset of puberty (continuous variable), stage of puberty at diagnosis of diabetes (ordinal variable), and current sexual maturation stage (ordinal variable) was collected as available in the charts.

Acanthosis Nigricans- Because of its association with higher rates of Type 2 diabetes mellitus in youth, Acanthosis Nigricans was viewed as a useful physical screening tool for the identification of high-risk youth subjects with Type 2 diabetes mellitus. Data for this information was recorded from medical charts and coded as a dichotomous variable: presence of Acanthosis Nigricans (yes=1) or absence (no=0).

Lipid Profile and other biochemical variables- Data regarding total cholesterol (mg/dl), Triglyceride (mg/dl), HDL cholesterol (mg/dl), LDL cholesterol (mg/dl), C-peptide, Insulin, Islet Cell Antibodies, and Blood Pressure was obtained from the charts. These were entered as continuous variables.

Data processing and analyses

Data from the medical record abstracting was coded for entry and analyzed with the SPSS version 11.0 (2002). To detect incorrect, obvious raw data entry problems, frequencies were run for all variables. Thus, contradictions and missing data could be identified and corrected where applicable.

Descriptive statistics as well as contingency table analysis of the proportion with GHB value $\geq 7\%$ by race, gender group, and selected medical history variables were used to determine bivariate relationships. Comparison of biochemical and clinical variables between children with Type 1 and Type 2 diabetes were also conducted. Multivariate analysis (logistic regression) was conducted to determine whether the findings from the overall and stratified bivariate analysis persisted, when potential confounders were adjusted for. Odds ratio were done to estimate magnitude of the association of a characteristic with an outcome.

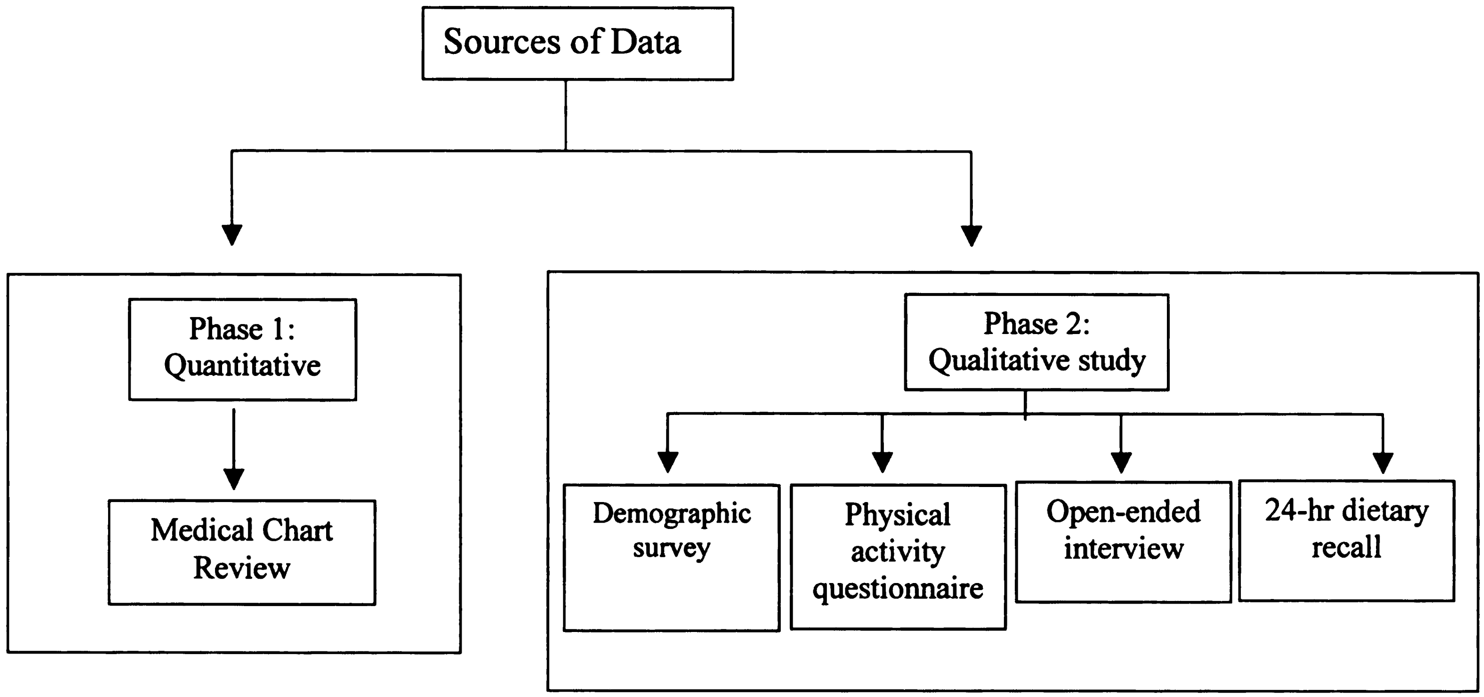
PHASE 2

Procedure for objective 3

Phase 2 was a triangulated qualitative study that included in-depth interviews and survey questionnaires to assess medication intake, home blood glucose monitoring, and dietary and physical activity patterns as well as barriers and facilitators. Triangulation refers to combining methods or sources of data to enhance understanding of the setting and the people being studied (Taylor and Bogden, 1998). Triangulation of data also serves to support the scientific status of research and increase its utility to readers (Reinharz, 1992) (Figure 1).

Figure 1: Figure showing different sources of data.

(Triangulation- different sources of data)



Hence, the research strategy used for this study which included an in-depth interview with diagnosed cases of Type 2 diabetes adolescents in conjunction with soliciting data regarding self-care practices via a questionnaire was the most effective way to best accomplish the goals for this Phase of the study (Fetterman, 1989; LeCompte & Preissile, 1993; Yin, 1989). More specifically information pertaining to parental attitudes, individual experiences, social networks and support systems was sought.

The self-care practices assessed in this study were: home-blood glucose monitoring, medication intake, physical activity and dietary patterns. The American Association of Diabetes Educators (2002), considers these diabetes self-care behaviors as important for determining the effectiveness of diabetes self-management education at individual and population levels, and each behavior is important to the overall management of diabetes.

Rationale for qualitative approach

Given the exploratory nature of the research questions, a qualitative approach was the best fit for this study. Qualitative research develops concepts, insights and understandings from patterns in the data rather than collecting data to assess pre-conceived models or theories (Taylor & Bogdan, 1998). Since the experiences of children and adolescents with Type 2 diabetes in relationship to how they deal with diabetes diagnosis and management has not been explored in previous research, qualitative methods provide an appropriate framework to allow data generation from emerging themes and patterns that are exhibited.

Qualitative data provides descriptive data in people's own written and spoken words and observable behavior. A key objective is to ascertain "the meanings that people attach to things in their lives" and is designed to ensure a close fit between the data and what people actually say and do (Taylor & Bogden, 1995).

For this study, representing or "knowing" a patient's living experience of diabetes is essential because diabetes is a self-managed disease (Anderson, 2001). It is the patient's self-management decisions that have the greatest effect on their health and well-being, and these decisions are influenced by the environment, society, family or any thing that directly or indirectly influences the individual. The most faithful representation of the patient's experience is reporting the patient's own story in his/her own words (Anderson, 2001). Qualitative research attempts to introduce rigor, objectivity, and analysis to story telling, while preserving as much of phenomenological richness of the patient's experience as possible. As long as diabetes remains a self-managed disease, representing a patient's personal experience will remain a key aspect in helping health professionals understand how to better assist patients with diabetes. Therefore the intent was for patients' stories to provide health professionals with necessary data to develop effective educational, behavior change and coping strategies.

Validity

Qualitative methods are designed to ensure a close fit between the data collected/reported and what people actually say and do. By interviewing people in their daily lives, interviewing them about what they think of a certain topic, and looking at the documents they produce, the qualitative researcher obtains firsthand knowledge of social life unfiltered through operational definitions or rating scales (Taylor & Bogdan, 1998). Qualitative methods provide more accurate information about subject's experiences as they have the potential to offer a forum for their experiences without succumbing to power imbalances and imposed categories (Epstein Jayaratne & Stewart, 1991).

Another feature of qualitative data is their richness and holism. Data have strength for revealing complexity and "thick descriptions" that are vivid, nested in real context and demonstrate truth in a way that it impacts the reader (Miles & Huberman, 1994).
The use of triangulation enhanced the validity of the study (Miles & Huberman, 1994). Triangulation permitted the capturing of a more complete, holistic and contextual picture of subjects, in their individual contexts, by gathering both qualitative and quantitative data (Epstein Jayaratne & Stewart, 1991). The use of mixed methods is a way to offset disadvantages of one method with the strengths of another (Jick, 1979). A combination of methods should result in more powerful research findings, which effectively tests theory and is convincing as well (Epstein Jayaratne & Stewart, 1991).

This project utilized the triangulation of qualitative and quantitative data to maximize research results. Integration of scholarly literature added further validity to this study.

Subject recruitment and eligibility

Subjects: The targeted study population was adolescents aged 14-18 years diagnosed with Type 2 diabetes (i.e. criterion-based sampling). This age group was selected based on the mean age of the sample from Phase 1 (mean age=16). Moreover, at this age adolescents are making more independent food choices, independently conducting blood tests, administering insulin injections, and are not monitored by parents to the same extent as at a younger age. All the participants were residents of Michigan. Subjects meeting the ADA target goal for glycemic control (HbA_1c <7%) as well as those who did not (HbA_1c ≥7%) were selected to determine whether differences in self-care behaviors (dietary, physical activity, home blood glucose monitoring, medicine intake) exist between the two groups. An effort was made to have equal number of subjects in both the groups.

Sample size: In qualitative studies, determination of sample size is usually done at the end of the research, as there is an inverse relationship between the number of informants and the depth to which you interview each subject (Taylor and Bogden, 1998). For this study, we anticipated based on similar qualitative studies published in the literature, that a sample of 20 subjects would be sufficient to obtain good quality data. However, the final number of 16 subjects was ultimately determined by data saturation.

Recruitment: Participants were recruited through fliers in physicians' offices at endocrinology clinics which participated in Phase 1. Participants received a $20 gift certificate and a pedometer as tokens of appreciation for agreeing to participate. The time and place of interviews was arranged according to the convenience of the participant. UCRIHS approval for Phase 2 was obtained from Michigan State University before data collection was commenced. In addition to UCRIHS approval from Michigan State

University, IRB from endocrinology clinics was also obtained, and all the participants and parents/guardians were requested to sign a consent form (Appendix C).

Data collection:

(1) Semi-structured interviews: Qualitative interviews were used to elicit in-depth opinions and views regarding various issues such as family support, individual's own behavior, and influence of institutions (School, diabetes center, church) from the participant's perspective. Interviews lasted approximately for 1 to 1 ½ hours in duration, and were tape-recorded in their entirety and transcribed verbatim.

The interview questions were clustered around five general themes and were open and intentionally non-directive to trigger broad, comprehensive responses. The core clusters included (a) experiences with diabetes prior to diagnosis (b) individual perspectives on diabetes self-management recommendations (c) current lifestyle practices (d) social and institutional conditions that influence their diabetes care (e) social support (family, friends). (Appendix D).

(2) Before commencing the main interview questions, there were some "warm up" survey questions which helped obtain data such as : ethnicity; age; education level; living status; duration of disease; family history of diabetes; number of doctor visits per year; and type of medications (Appendix D).

(3) Exercise/physical activity: The purpose of the physical activity questionnaire was to assess the type, frequency and duration of leisure time activity. A good physical activity regime for adults and adolescents is defined as participating in physical activity at least three times a week, but preferably all days of the week, for 30 or more minutes (USDA, 2002; Diabetes Prevention Program Research Group, 2002).

In this study a qualitative assessment for physical activity was sought, which was practical in terms of administration ease, time and cost for the investigator and the participants. Adaptation of the physical activity questions which were used by the National Longitudinal Study of Adolescent Health and Youth risk behavior survey (CDC, 2003), were regarded as appropriate for the study (Appendix E). It was important to establish whether subjects exercised at all, and then categorize the activities which would most likely be selected, and assess the frequency and duration. Consistent with other self-care variables, subjects were asked to discuss the barriers they encountered in achieving any exercise as recommended.

(4) 24-hour dietary recalls

The purpose of this section was to obtain information regarding subjects' usual eating habits or patterns, which could be used in targeting goals for nutrition education. Dietary intake and compliance can be assessed quantitatively or qualitatively via several methods. In this study to obtain dietary information, two 24-hour recalls (one weekend and one week day preferably) were used (Appendix F). Food recalls were conducted using the USDA multiple pass method (Moshfegh et al., 1999) by a trained interviewer. Since, only one person was interviewing, inter-person variability was avoided and consistency with the approach to interviewing was facilitated. Specific aspects to be examined in this study were the frequency and type of meals and dietary habits and patterns with regard to carbohydrate intake, fat intake, fiber intake, soda and snack consumption. Other aspects examined were: percentage kilocalorie coming from carbohydrates, carbohydrate intake, and percentage kilocalories from fat, total consumption of soft drinks and sport drinks consumed.

Data analysis:

A. In-depth interviews: The data was organized and analyzed in the following steps:

1) After each interview, the audiotapes were transcribed verbatim by the researcher who was present at the interviews. All transcripts were re-read while listening to the tape to check for accuracy and fix errors, and to help the researchers become more familiar with the data. Two researchers (a graduate student and a senior dietetics major student trained in qualitative studies) reviewed and discussed the transcripts for accuracy.
2) The transcripts were individually coded by two researchers, checked, and discussed by both the researchers until consensus was reached upon the correct code. Units were very rarely coded twice; this was done only when consensus could not be reached regarding which code to use. The coders met regularly throughout the coding process to compare codes. The constant comparative method developed by Glaser and Strauss (1967) and later modified by Lincoln and Guba (1985), where every data unit is compared with every other data unit, was used for analyzing the data. The team developed a preliminary list of code

words based on recurring themes and some pre-derived categories driven by the theoretical model based on the major research questions (Table 1).

3) Data from transcripts was loaded into NUD*IST N6 software (Non-numerical Unstructured Data by techniques of Indexing Searching and Theorizing, QSR, 2003) for tabulation and identification of responses by code word.

Based on the developed preliminary codes, a coding matrix was constructed. The researcher recorded all relevant statements from each subject's transcript on the coding matrix.

B. Physical activity:

Descriptive statistics was conducted to determine: Average amount of time spent exercising; types of exercises subjects were involved in; how many times per week they exercised; and how many met the recommendation of physical activity of 30mins/day & ≥3x/week (USDA 2002).

C. 24-hr dietary recall data:

Dietary analysis was conducted by using Nutritionist V (First DataBank, 1999). Descriptive statistics was conducted for percent kilocalories coming from carbohydrates, carbohydrate consumption, percent kilocalories from fat, and amount and number of times soda and sport drinks are consumed per day. Descriptive statistics was also conducted to determine how many subjects consumed breakfast, lunch, dinner and snacks, as well as how many meals were skipped per day.

Table 1: Themes and sub-themes derived based on data analysis.

Theory-driven	Theory operationalized	Findings		
Research Questions	**Interview Questions**	**Themes**	**Sub-themes**	**Thematic sections**
1. How do family/social factors facilitate or inhibit the management of diabetes?	1. Who do you consider to be your family? 2. Does anyone else in your family have diabetes? 3. When you first found out you had diabetes, who in your family was helpful? 4. To whom do you turn for help or comfort when you need help?	Family support/ influence of family	1. Family structure 2. Support system 3. Prior exposure to diabetes/ members with DM 4. Reaction to diagnosis - subject's reaction/feeling - family reaction/feeling	Social Support
2. How do subjects values and behaviors influence management of diabetes?	1. How has having diabetes changed your life? 2. What do you do now differently? 3. How has diabetes changed how you act with your friends 4. Is it important for you to manage your diabetes? Why? 5. What keeps you from taking care of yourself? 6. What helps you take care of yourself?	Effect of diabetes on daily life	1. Management behaviors - Diet - Exercise - Barriers to following diet & exercise recommendations - Facilitators to following diet & exercise recommendations 2. Self values/ beliefs - Managing DM important? (Why or Why not)	Individuals perspective
3. How do institutions influence the aspects of diabetes management?	1. Where did you learn how to take care of yourself? 2. What's been the most helpful resource for diabetes management? 3. What do you think the role of diabetes centers/your doctor should be in helping you with diabetes?	Influence of institutions/doctors on diabetes management	1. Source 2. Most helpful resource 3. Suggestions for improvement	Role of institutions

Working definitions of terms:

1. **Family:** Families in an inclusive sense are defined as composed not only of persons related by blood, marriage, or adoption, but also sets of interdependent but independent persons who share some common goals, resources, and a commitment to each other over time (Bubolz and Sontag, 1993).
2. **Need:** Requirements of families and individuals that must be met at some level if they are to survive and engage in adaptive behavior.
3. **Values:** Human conceptions of what is good, right, and worthwhile.
4. **Goals:** "Ends-in-view", something one is willing to work to achieve (Gross et al., 1980). Together with values, goals are a major motivating force in families.
5. **Attitudes :** A complex mental state involving beliefs, feelings, and values that make one act in certain ways.
6. **Resources:** Ways by which families meet needs and adapt to changing environments and stressors. Examples of personal resources include skills, health, knowledge, and intelligence. Examples of interpersonal resources are commitment, cohesion, and social integration. Some nonhuman resources include housing, clothing, money, and the like.
7. **Perspectives:** The process by which environmental information is registered by the senses, organized and made available for use (Melson, 1980). People respond selectively to environmental stimuli that are then symbolically interpreted through personal and cultural meanings.
8. **Social support:** Family, close friends, relatives who provide emotional support and help with management of diabetes.

9. **Institutions:** Diabetes education centers, government organizations, and other non-governmental organizations.

10. **Community Support:** Community agencies participating in the treatment of the family and/or one or more of its' members. They are professionals and agencies that provide services to the family.

11. **Individual:** In this study the individual is the participant diagnosed with Type 2 diabetes in the age group of 14-18 years.

12. **Adaptation:** Adaptation is the process of adjusting to changes. Individuals, regardless of their particular structure, transform information and engage in adaptation.

13. **Diabetes Control:** Subjects meeting the ADA target goal for glycemic control (HbA_1c <7%)

CHAPTER 4

Proportion of children and adolescents with Type 2 diabetes in Michigan

Abstract

Background: Type 2 diabetes mellitus (T2DM) in children and adolescents is a "newly recognized" pediatric disease, nationally and in the state of Michigan. Childhood overweight/obesity has been shown to be a strong predictor of this disease. The fact that the prevalence of overweight/obesity in youth is a serious concern in Michigan and there is no data on T2DM in this vulnerable age group, provided a strong justification for this study. If not identified or poorly controlled, there is a potential for devastating complications at an early age.

Objectives: 1) To estimate the proportion of diagnosed T2DM among children and adolescents (6-19 years) who have either Type 1 or T2DM at endocrinology specialty clinics in Michigan; 2) To determine the associated factors among youth with Type 2 diabetes; and 3) To assess glycemic control in youth with T2DM.

Study Design: Retrospective chart reviews of youth 6-19 yr diagnosed with diabetes were conducted at endocrinology clinics in Michigan. In-depth data was collected for those diagnosed with T2DM.

Results: Of a total of 2,018 subjects (6-19 yr) diagnosed with diabetes, 220 (11%) had T2DM. Among those 10-19 yr, the proportion of children with T2DM was significantly higher (14%). The estimated prevalence of T2DM in the lower peninsula of Michigan

was 11.03/100,000. The mean (±SD) age and body mass index (BMI) at presentation were 13 ± 2.8 years and 35 ± 12.5kg/m^2, respectively. The BMI for 85% of the youth was ≥ 95th percentile (overweight) and 83% were at ≥ Tanner stage III. Ethnicity distribution was as follows: African Americans (51%), Hispanic (15%), Caucasians (12%), and others (22%). The male to female ratio was 1.3:1, and females were diagnosed 1 year earlier than males. The majority of the youth had Acanthosis nigricans (73%), a positive family history of diabetes (95%), and 65% of the subjects were living in single-family households. There was a high prevalence of metabolic risk factors in youth with T2DM: high blood glucose HbA1c ≥ 7 (64%), elevated serum triglycerides ≥ 150 mg/dl (33%), HDL-C <40 (49%), and blood pressure ≥ 90th percentile (85%).

Conclusion: T2DM prevalence among children and adolescents in Michigan is high, mimicking the national rise in Type 2 diabetes and concomitant with the increase in childhood and adolescent obesity. While, ethnicity and obesity/overweight were significantly associated with T2DM in youth as would be expected, of greater concern were the metabolic aberrations. Once identified, controlling T2DM in children and adolescents is imperative to decrease the likelihood of devastating complications at a young age.

Introduction

Diabetes is clearly recognized as one of the most common and costly diseases in the United States today, affecting more than 15 million Americans with as many as half undiagnosed (Centers for Disease Control and Prevention (CDC), 2002). Of the two major classes of the disease, Type 1 and Type 2, the latter is the more predominant form of the disease (90%). The onset of Type 2 diabetes typically occurs primarily in older adults, whereas Type 1 diabetes typically occurs in children and young adults. However, T2DM in children and adolescents concomitant with the rising rates of obesity/overweight as referred to in youth, has recently emerged as a "newly recognized" pediatric epidemic in the US towards which enhanced state and national efforts need to be directed. Among adults, numerous studies document a significant correlation between the prevalence of T2DM and relative weight for height (Mokdad et al., 2000 & 2001; Ford et al., 1997; Headley et al., 2004). Ford et al., (1997) demonstrated that for every 1 kg increase in measured weight the risk of diabetes increases by 4.5% in a national sample of adults. In children the relationship of weight and height is assessed as greater than 85th percentile (at risk of overweight) and greater than 95th percentile (overweight). Childhood and adolescent overweight levels have been documented as steadily increasing between the 1960s and 1990s (Gortmaker, 1987; Campaigne, 1994; Webber, 1994). Current data from NHANES III (1998-1994) of a nationally representative sample of children, aged 6-11 years and adolescents, aged 12-17 years and the National Longitudinal Study of Adolescent Health (Add Health) (NCHS 1994, Flegal et al., 2001) indicate that approximately 14% of children and 12% of adolescents are overweight, with an almost equal distribution among males and females. Obesity-related studies in

Michigan have shown that in children aged 4 to 17 years, among boys, 38% were above the 85th percentile and 16% above the 95th percentile. Of the girls, 33% were above the 85th percentile and 13% were above the 95th percentile (Gautheir et al., 2000).

Studies have reported increasing rates of T2DM in American Indian, African American, and Hispanic children from North America (Dean et al., 1988; Dean et al., 1992; Harris et al., 1996; Pinhas-Hamiel et al., 1996; Pihoker et al., 1998; Fagot-Campagna et al., 2001; Neufeld, 1998). Reported rates of prevalence and estimates vary based on ethnicity, but CDC estimates that T2DM represents approximately 8-45% of all children and adolescents diagnosed with diabetes in large US pediatric centers (CDC, 2002). While the existing evidence would strongly support the conclusion that the incidence of T2DM in children and adolescents has increased significantly during the past several decades, the exact prevalence of the disease, both nationally and regionally, has yet to be determined. The limited data on the prevalence and incidence of T2DM and associated factors in children and adolescents, makes it difficult to identify and characterize the target population and plan interventions to better control diabetes in this age group. Associative factors such as being overweight, presence of acanthosis nigricans, and positive family history of diabetes might help identify & characterize specific type of diabetes in youth (Pinhas-Hamiel et al., 1996; Pihoker et al., 1998; Fagot-Campagna et al., 2001). In addition, the precise risk and control-related factors as related to T2DM in children and adolescents are not fully understood. Such information is critical if efforts to facilitate the prevention or amelioration of the many debilitating complications of unidentified or uncontrolled diabetes in the pediatric population are to be adequately addressed by the health professional community.

Recently Michigan has been ranked number three in the country for obesity, and one city Detroit, was classified as the "fattest city", warrants the importance of this study. There has been a national concern about increase in childhood overweight/at risk for overweight and these data are mirrored in the state of Michigan (Youth Risk Behavior Survey, 2003). Hence, the primary objectives of this study are: 1) To estimate the proportion of diagnosed Type 2 diabetes among children and adolescents (6-19 years) who have either Type 1 or Type 2 diabetes at endocrinology specialty clinics in Michigan; 2) To determine the associated factors among youth with Type 2 diabetes; and 3) To assess glycemic control in youth with Type 2 diabetes.

Research methods

A retrospective chart review of youth previously diagnosed as having T2DM was undertaken at the endocrinology clinics in Michigan. Data regarding the total number of youth 6-19 yr with diabetes (Type 2 or Type 1) was obtained from clinic data systems for each endocrinology clinic to estimate the percentages of diagnosed T2DM. Approval from Michigan State University Committee on Research Involving Human Subjects (UCRIHS), the clinic directors and the Review Boards of the individual clinics was obtained before data collection could be commenced.

Sites: Pediatric and endocrinology clinics in the state of Michigan were selected for this study, as they are more likely than primary care/ general family practice clinics to have a diagnosed population of diabetes patients based on researchers previous experience at primary care/ general family practice clinics (Weatherspoon et al., 2001). Diabetes centers with a significant number of children and adolescents (diagnosed cases $\geq$5) were considered eligible. Twelve clinics were contacted, but four were excluded due to insufficient or no cases of diagnosed T2DM children and adolescents. For this study, eight endocrinology specialty clinics meeting the eligibility criteria consented to data collection. The eight eligible clinics were distributed over the state of Michigan: west central Michigan (Lansing-Sparrow Hospital, Grand Rapids- Saint Mary's Mercy Medical Center, and DeVos Children's Hospital); southeast Michigan (Detroit- Henry Ford Children's Hospital and University of Michigan Medical Center); east central Michigan (Saginaw- Covenant Hospital and Flint Michigan) and south central Michigan (Jackson-Foote Hospital). DeVos Children's hospital and Children's Hospital of Michigan conduct satellite clinics in half of Michigan (West, Central, & East) and hence provides information for half of the state's pediatric population diagnosed with diabetes (ages 6-19 years). The excluded diabetes centers were the Upper Peninsula (Northern Michigan), two clinics in Kalamazoo (South East) and one clinic in Midland (East Central).

Target Population: Subjects for this study were children 6-19 yr of age, medically diagnosed with either Type 1 or T2DM, treated at endocrinology clinics. Previous studies have shown 10-19 years as the probable age range for T2DM cases in children and adolescents. However, based on personal communication with physicians, T2DM cases were reported to occur in children as young as 6 years old. Hence, in order to not exclude these cases, the selected age range for this study was determined as 6-19 years of age. The population base for this study included all children and adolescents with a medical diagnosis of diabetes (Types 1 or 2) in the age group of 6-19 years, who were "Active" cases and whose records were accessible and available from the eight sites. "Active" was defined as having attended the clinic for at least six months prior to the starting date for the study. The patient population in these clinics is drawn from the entire state of Michigan. Six months was chosen as the criterion of active patient eligibility because the Type 2 patients are expected for clinic visits at least at three-month intervals. The exclusion criteria were children 6-19 yr who had: 1) physician noted maturity-onset diabetes of the young (MODY); 2) Type 2 diabetes associated with steroid use; 3) Type 2 diabetes secondary to cystic fibrosis; and 4) children with pre-diabetes [whose blood glucose levels are higher than normal, but not yet high enough to be diagnosed as diabetes; Impaired fasting glucose $\geq$ 100 mg/dl but $<$ 126 mg/dl]. These cases were excluded to obtain "true cases" of T2DM as defined by the American Diabetes Association (ADA, 2000). ADA defines T2DM in youth as: Classic symptoms of diabetes (polyuria, polydipsia, and unexplained weight loss) and casual glucose $\geq$200 mg/dl (11.1 mmol/l) *OR* Fasting plasma glucose $\geq$126 mg/dl (7.0 mmol/l) *OR* 2-hour plasma glucose $\geq$ 200 mg/dl (11.1 mmol/l) during an Oral Glucose Tolerance Test (OGTT).

Data on the total number of youth aged 6-19 years with diabetes (Types 1 or 2) was obtained from the clinic data systems. These data were used to estimate the proportion of diagnosed T2DM in this population as follows:

$$\text{Estimated proportion of diagnosed cases} = \frac{\text{Diagnosed Type 2 DM}}{\text{Diagnosed Type 1} + \text{Type 2 DM}}$$

The purpose of the medical record review was to confirm the data system diagnosis and to estimate the prevalence of glycemic control in this study population/sample and to identify associative risk and control factors as clinical criteria and lab values (insulin & C-peptide) are the best determinants to help correctly identify T2DM and describe the medical condition of this vulnerable group. Therefore, medical records of youth with T2DM were reviewed for diabetes diagnosis, risk factors, and associated factors such as demographic data, anthropometrics data, clinical symptoms, and lab values. The presence of the following metabolic risk factors (metabolic syndrome cut points) was noted: elevated serum glucose ($HbA_1c \geq 7$), hypertension (blood pressure $\geq 90^{th}$ percentile for height), elevated serum triglycerides ($\geq$ 110 mg/dL), and low HDL-C ($\leq$ 40 mg/dL) (Cook et al., 2003). A data collection form was used to abstract the information described above from the medical records. Content validity of data collection form was established by asking 6 diabetes professionals (2 pediatric endocrinologists, 1 nurse, 2 Registered Dietitians with doctoral degrees and 1 practicing Registered Dietitian working with patients with diabetes) to review the data collection protocol sheet. Responses from reviewers were obtained and the changes that were requested included: organization of questions, re-phrasing questions to simplify, and deletion of perceived irrelevant questions. Four trained people conducted data abstraction at all centers to maintain consistency and confidentiality of records.

Statistical Analysis: Data was analyzed using SPSS version 11.0 (2002). Descriptive statistics (means ± standard deviation and frequency of distribution) were calculated to describe the sample. Prevalence was estimated using census data for the year 2002 for Michigan and proportions obtained from the chart reviews. Bivariate analysis (chi-square analysis) was conducted to determine the differences across gender and ethnicity by selected medical history variables to determine relevant association. Comparison of biochemical and clinical variables across gender and ethnicity was also conducted.

Results

Of a total of 2,018 patients 6-19 yr with diagnosed Diabetes Mellitus (DM), 220 (11%) had T2DM. When data was analyzed for youth in the age range of 10-19 years, the proportion of diagnosed cases of T2DM was significantly higher (14%). The distribution of the sample by clinic is presented in Table 1. The proportion of children with T2DM ranged from 6.5 to 21%. The majority of the subjects (98%) were in the age group of 10-19 years. The estimated prevalence rate of T2DM in the lower peninsula of Michigan was calculated to be 11.03/100,000.

Characteristics of the subjects with Type 2 Diabetes

The majority of cases were diagnosed during a routine physical examination for school or sports. Signs of polyuria, polydypsia, and polyphagia were the most frequently mentioned symptoms noted. Table 2 presents the descriptive characteristics of the sample.

Race, gender, and Age. Fifty one percent of the subjects were African Americans, followed by Caucasians and Hispanics. The gender distribution indicated that the majority of the youth with T2DM were females (56%). The overall female to male ratio was 1.3:1.

The mean age for diagnosis of T2DM was 13.00 ± 2.8 years for the total sample. Female patients were identified approximately one year earlier than the male patients except for the Caucasian females. Caucasian females were diagnosed much later than Caucasian males ($p=0.06$). Hispanic males were diagnosed at a much later age than other males ($p<0.05$) and females of other races. Puberty data were available for only 65 subjects.

Of these 65 subjects, 83% were in mid puberty (Tanner stage III or greater) at the time of diagnosis.

Body mass index: The mean BMI in patients with T2DM was 35.0 ± 12.5 kg/m^2 (Table 2). Seventy eight percent of the T2DM subjects were ≥ 95^{th} %tile for BMI, 11% were ≥ 85^{th} %tile, and 11% were between the 5^{th} and 85^{th} percentiles (Figure 2). The majority of cases ≥ 95^{th} %tile, were females (55%) and African Americans (50%) compared to males and other races respectively ($p<0.05$).

Family History, Acanthosis Nigricans, & Living Status: Ninety-five percent of T2DM subjects had a positive family history of diabetes. Acanthosis Nigricans was present in 73% of the subjects at the time of diagnosis. Data regarding living status of the subjects with T2DM indicated that 65% of the subjects with T2DM were living with single parents (Table 3).

Clinical parameters: Mean ± SD of clinical parameters are reported in Table 4. Mean glycosylated hemoglobin (HbA_1C) recorded at the first visit for the total sample of Type 2 DM subjects was 9.3 ± 3.1. Both C-peptide and insulin values for these subjects were higher than normal values. More in-depth data analysis revealed that more subjects who had their HbA_{1C} ≥ 7% also had high total cholesterol ($p<0.05$)and high LDL-C ($p<0.05$). Subjects with BMI ≥ 95^{th} percentile had TG ≥ 150 mg/dl ($p=0.09$) and HDL-C ≤ 40 mg/dl ($p<0.001$).

Discussion

This study demonstrates that the proportion of diagnosed T2DM among children and adolescents in Michigan is very comparable to the results published by previous studies ranging from 8-45% (Pinhas-Hamiel, 1996; Pihoker et al., 1998; Neufeld et al., 1998; Glaser, 1998; Macalusco et al., 2002). Our study demonstrated that diagnosed T2DM accounted for 11.1% of all children and adolescents diagnosed with diabetes in the age group of 6-19 years, and 14% of all children and adolescents diagnosed with diabetes in the age group of 10-19 years at the adult and pediatric clinics in the state of Michigan. Adolescents in the age group of 10-19 years have a higher proportion of youth with diagnosed T2DM, similar to that of some of the previously published studies (Pinhas-Hamiel et al., 1996; Glaser, 1998; Neufeld et al., 1998). However it is important to note that this disease is also a problem in youth who are as young as 6 years. This makes it important for adequate screening to be done when youth have risk factors, even if not symptomatic at the time of clinic visit. Studies have shown inadequate screening of youth for diabetes or diabetes risk factors (O'Brien et al., 2004; Weatherspoon et al., 2001).

This study is a multi-clinic study and included adult and pediatric endocrinology clinics throughout the lower peninsula of Michigan. Hence, the population of these clinics is representative of the population of the lower peninsula of Michigan. Therefore a good estimate of the proportion of children and adolescents in Michigan, who may have T2DM is provided. The data indicates that the estimated prevalence of T2DM among adolescents aged 6-19 years in the lower peninsula of Michigan is 11.3/100, 000.

Michigan Department of Community Health estimates that based on Blue Cross Blue Shield (BCBS) information, 0.32% children under the age of 18 years with all types of diabetes. However, we do need to take into consideration the fact that the data from Blue Cross Blue Shield might not be representative of all the youth in Michigan as there are many subjects who might not be covered by BCBS insurance, and there might also be a higher proportion of undiagnosed cases of T2DM in Michigan similar to the prevalence of undiagnosed trends noticed in adults.

Results from previous studies reported that T2DM accounts for 2 to 3% of all patients with diabetes mellitus aged 0 to 19 in the United States (Dabelea et al., 1998), but the prevalence is higher among children in populations with a relatively high prevalence of T2DM in adults as one would expect (Glasser, 1997). In our study, there was a higher prevalence among African Americans. Based on both the adult literature and clinic based studies in youth with African American patients, T2DM is clearly a noteworthy problem in this ethnic group. However, it should be noted that the proportion of Caucasian cases was also high suggesting that risk factors other than ethnicity may be even stronger predictors of the disease.

Results from a study conducted in Cincinnati showed that the proportion of children (10-19 yr) with T2DM increased from 4% in 1982-1991 to 16% in 1994 (Pinhas-Hamiel, 1996). In Tokyo, the incidence rates of T2DM in school children between 1975 and 1990 increased 1.5 fold, along with a similar increase in the prevalence of obesity

(Kitagawa et al., 1994). However, in our study we were not able to compare the increase over a period of time as this was a cross sectional study.

In our clinic the mean age at diagnosis for T2DM was 13.0 ± 2.8 years, which is very similar to data from Pinhas-Hamiel et. al. (1996). Females on average were diagnosed at least 6 months earlier than males; this was especially evident for African American females who were diagnosed 1 year earlier than females from other ethnicities and males on average. Among the males, Hispanic males were diagnosed at a much later age compared to males from other ethnicities (14.57 years). The earlier onset of diabetes in females may be attributed to onset of puberty. In females puberty starts on an average of 1 year earlier compared to males and more female subjects (54%) were pubertal when diagnosed with T2DM. Relative insulin resistance that is characteristic of puberty may be playing a role in this early appearance of T2DM in these adolescents. It has been shown that between tanner stages II and IV there is 30% lower insulin-mediated glucose disposal compared with prepubertal children in Tanner stage I and compared with young adults (Arslanian, 2000). Since puberty is characterized by relative insulin resistance, it may be an aggravating factor in the appearance of overt T2DM in obese adolescents. This study also demonstrated higher levels of insulin and C-peptide in this sample, thus emphasizing that the β-cell's are still functioning and that insulin resistance may be an important factor to take into consideration in this sample.

In adults, obesity has been strongly associated with T2DM. In our study population, a similar association was noticed. For the past few years Michigan has been ranked among the top 3 states with the highest obesity rates. Moreover, results from other studies describing T2DM in youth have also demonstrated a strong association with obesity (Pinhas-Hamiel, 1996; Glaser, 1997; Neufeld et al., 1998). A key physiological implication of obesity and probable link to T2DM is the adverse effects on glucose metabolism. For example, 55 % of the variance in insulin sensitivity among healthy white children (i.e. without diabetic) is accounted for by total adiposity (Bogardus et al., 1985). The amount of visceral fat in obese adolescents was directly correlated with hyperinsulinemia and inversely related with insulin sensitivity (Tamura et al., 2000). Therefore, it is not surprising that the T2DM-obesity association is so strong.

Data regarding family history, demonstrated that 84% had family members with diabetes. These results of family history are in line with those published in the reported literature (Pinhas-Hamiel, 1996; Glaser, 1997; Neufeld et al., 1998). Therefore, the importance of family history as a notable risk factor cannot be over emphasized. Practitioners unfortunately do not always note family history of diseases such as diabetes in children/youth (Weatherspoon, 2004). Since the onset of T2DM can be asymptomatic for prolonged periods of time, and the age of onset also varies, the prevalence of T2DM among family members can be much higher than reported (Glaser & Jones, 1998). On the other hand, studies with children with Type 1 diabetes have demonstrated that only 8 to 16% have a family history of Type 1 diabetes and about 1-25% have a family history of T2DM (Levy-Marchal et al., 1992; Pociot et al., 1993; Quataro et al., 1990).

An additional factor, not previously reported, was family composition. The majority of the youth with T2DM were living in single parent families. Also, in the state of Michigan, all children are covered by children's special health insurance and hence lack of medical support/access to medical services might not be a significant contributor. Therefore, these findings demonstrated that besides genes, and/or medical/physiological factors, social factors also play a huge role in the development/control of T2DM.

Even during the short period of follow up (mean disease duration 3.0 ± 2.3), with these patients some serious metabolic aberrations like hyperglycemia ($HbA_1c > 7\%$), hypertension, increased triglycerides, low HDL-C were already present in the majority of these youth. If aberrations persist, these youth will likely incur severe complications at an early age (Neufeld, 1998). Poor compliance with recommended treatment is a well known problem among youth with Type 1 diabetes (Weissberg-Benchell et al., 1995), and this problem is likely to be more pronounced among youth with T2DM as non-compliance will not be likely to produce immediate symptoms (Neufeld et al., 1998). Dean et al. (1992) stated that if poor compliance persists into adulthood, these children with T2DM will be at a higher risk of developing macrovascular and microvascular complications of diabetes with an impaired quality of life at a relatively young age compared to adults who are diagnosed with the disease (Dean et al., 1992).

In conclusion, our study demonstrates that T2DM in youth in the state of Michigan is occurring at rates similar to the published literature from other states in the US. This is the first multi-clinic study with a representative sample of diagnosed cases with diabetes in the lower peninsula of Michigan. Since no statewide data or estimates exist, this study provides some useful baseline information about diagnosed T2DM in youth aged 6-19 yr for Michigan. It is expected that similar to adults, there might be a large proportion of undiagnosed cases of T2DM in youth across the nation given the obesity epidemic. In this sample the strong associative factors were: obesity/overweight, pubertal stage, and a positive family history of diabetes. This study supports and strengthens the results published by previous studies that there is a strong association between the development of T2DM and obesity. In addition, the fact that social factors such as the challenge of single parenting might be playing a pivotal role in disease manifestation and management, was an interesting finding previously not reported. Hence, a second phase of this study was designed to study the influence of social factors in management of T2DM in this vulnerable age group. As demonstrated among adults, T2DM and it's complications accounts for the majority of the health costs. The early onset of this disease will therefore have long-term public health consequences, both emotionally and economically. Results from this study and previous studies on T2DM among children and adolescents offer health care providers with sufficient justification to ensure that subjects at high risk because of obesity and/or positive family history of diabetes or other risk factors are adequately screened. A recent publication from Chicago (Drobac et al., 2004), demonstrated that at a busy urban clinic the diabetes screening protocol proposed by the American Diabetes Association (ADA, 2000) for youth was inconsistently being used. Only presence of acanthosis nigricans and higher rate of documentation of nutritional counseling were a driving factor for screening (Drobac et al., 2004). Hence, implementing proper use of screening protocols and screening youth at high-risk of developing T2DM at a younger age is essential in order to delay/prevent the development of diabetes and diabetes related complication. Once diagnosed, careful monitoring and diligent patient compliance with treatment protocols are essential for disease management and a potentially longer healthier life.

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Table 1: Proportion of diagnosed Type 2 diabetes mellitus cases among youth diagnosed with and treated for diabetes (6-19 yrs.).

Sites	**6-19 yr** **%(T2DM/T2DM +T1DM)**	**10-19 yr** **%(T2DM/T2DM +T1DM)**
Clinic 1	8 % (55/700)	10.5%(54/530)
Clinic 2	21% (27/130)	28% (27/97)
Clinic 3	6.5%(7/107)	8.5%(7/82)
Clinic 4	8% (1/13)	8% (1/13)
Clinic 5	20% (82/411)	24% (82/340)
Clinic 6	14.7% (11/75)	17.5% (10/57)
Clinic 7	5.4% (23/435)	6.5% (23/334)
Clinic 8	10% (14/140)	11.8% (11/93)
Total	11% (220/2018)	14% (214/1556)

Table 2: Characteristics of patients with Type 2 diabetes mellitus.

Gender	Race	No. (%)	Age at diagnosis (yrs)	BMI (kg/m2) Mean ± SD	BMI percentile ≥ 85th %tile % (n/N)
All	Afri American	111 (57)	12.7 ± 3.0	35.5 ± 14.9	47% (101/111)
	White	33 (17)	12.6 ± 2.3	33.0 ± 7.1	14% (31/33)
	Hispanic	25 (14)	14.0 ± 2.7	36.4 ± 11.0	11% (24/24)
	Others	45 (12)	12.89 ± 2.8	34 ± 8.8	19% (42/45)
	All	214	13.0 ± 2.8	35.0 ± 12.5	90% (191/213)
Female	Afri. American	70	12.3 ± 3.1	36.0 ± 17.0	54.2 % (65/69)
	White	16	13.3 ± 1.8	35.0 ± 6.6	12.5% (15/16)
	Hispanic	11	13.5 ± 2.1	34.7 ± 14.7	8.3% (10/10)
	Others	25	13.3 ± 2.8	34.3 ± 8.7	19.2% (23/25)
	All	122	12.7 ± 2.8	35.4 ± 14.2	94.2% (113/120)
Male	Afri. American	42	13.26 ± 2.8 ^{b}	34.7 ± 10.6	38.7% (36/42)
	White	17	12.14 ± 2.3 ^{b}	30.6 ± 7.8	17.3 % (16/17)
	Hispanic	14	14.57 ± 3.1 ^{a}	37.8 ± 8.1	14.0% (14/14)
	Other	20	11.00 ± 3.0	30.2 ± 7.0	20.4% (19/20)
	All	93	13.04 ± 2.8	34.2 ± 9.5	91.5% (85/93)

*$p<0.05$; within a column with different superscripts are significantly different at $p<0.05$

Table 3: Presence of Type 2 diabetes associated risk factors among diagnosed cases of Type 2 diabetes youth by ethnicity and gender.

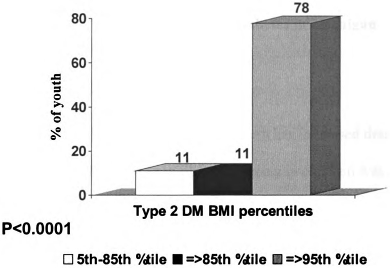
Gender	Race	Positive Family History of DM (%)	Presence of Acanthosis Nigricans (%)	Living Status(single parent) (%)
All	Afri. Amer.	56 [a]	55	57 [a]
	White	14 [b]	13	16 [b]
	Hispanic	10 [b]	14	8 [b]
	Others	20 [b]	18	19 [b]
Female	Afri. Amer.	58	60	60 [a]
	White	14	12	17 [b]
	Hispanic	8	13	7 [b]
	Others	20	15	16 [b]
Male	Afri. Amer.	53	48	54 [a]
	White	15	14	14 [b]
	Hispanic	13	16	9 [b]
	Other	19	23	23 [b]

*p<0.01; within a column with different superscripts are significantly different at p<0.05

Table 4: Presence of clinical parameters among youth with Type 2 diabetes.

		Type 2 DM cases
Hemoglobin A1c: (n=200)	mean ±S.D.	8.76 ± 2.9
	< 7	36%
	≥ 7	64%
C-peptide (ng/L): (n=66)	mean ±S.D.	4.1 ± 3.0
Insulin (μIu/L): (n=44)	mean ±S.D.	38 ± 28
Blood Pressure (mmHg):	Systolic: mean ± S.D.	127 ± 15
	< 90th percentile	15%
	≥ 90th percentile	85%
Triglyceride (mg/dl): (n=69)	mean ± S.D.	167± 195
	< 150	67%
	≥ 150	33%
Total Cholesterol (mg/dl): (n=130)	mean ± S.D.	179 ± 44
	< 170	47
	≥ 170	53
HDL-C (mg/dl): (n=68)	mean ± S.D.	43 ± 12
	< 40 (low)	49%
	≥ 40	51%
LDL-C (mg/dl): (n=64)	mean ± S.D.	106 ± 43
	< 110	61%
	≥ 110	39%

Figure 1: BMI percentile distribution of youth with Type 2 diabetes



CHAPTER 5

Comparison of glycemic control and associated factors in youth (6-19 yr) with Type 2 or Type 1 diabetes in Michigan

Abstract

Background: Type 2 diabetes (T2DM) in youth has increased dramatically over the past few years. Historically diabetes mellitus occurring in children was primarily Type 1 diabetes (T1DM) however, recently more cases of T2DM have been diagnosed. This increase in youth with T2DM has been associated with the increasing rates of obesity in this age group. The challenges of management issues in youth with T1DM, which have been extensively studied are important references to better understand the potential severity of this new and growing disease.

Objective: To compare the characteristics of youth (6-19 yr) with T2DM and T1DM cases matched for age and sex.

Methods: Retrospective in-depth chart reviews of youth diagnosed with Type 2 or Type 1 diabetes were conducted to assess glycemic control and associated factors. Youth with T2DM were compared to youth with T1DM matched for age and gender to determine if glycemic control and associative factors of diabetes (example: lab values, anthropometrics, socio-demographic, and self-care management behaviors) differed by the type of diabetes in this age group.

Results: Of a total of 2018 youth, 6-19 yr diagnosed with diabetes at endocrinology clinics in Michigan, 220 (11%) had T2DM, whereas 14% of 10-19 year old youth had

T2DM. The mean age for T2DM onset was significantly higher than T1DM cases (13 yr vs 8.7 yr) and the majority was at Tanner stage 3 or higher (83% vs 27%). Ethnic distribution of the sample indicated that more African Americans (52% vs 22%) and Hispanics (12% vs 1%) compared to Caucasians were diagnosed with T2DM. Based on body mass index (BMI) percentiles, 78% of youth with T2DM were >95th %tile (overweight), but for youth with T1DM, 81% were between the 5th-85th %tile (normal). Youth with T2DM had: lower HDL-C (48%), elevated serum triglyceride (33%), hypertension (85%), and elevated HbA1c (62%). Self-care behavior data indicated that the majority of the youth with T2DM were not following their diet (80% vs 42%) or exercise (64% vs 38%) recommendations compared to youth with T1DM

Conclusions: The results of this multi-clinic study show that poor glycemic control was common among youth with either T1DM or T2DM. However, other metabolic risk factors (low HDL-C, high TG, hypertension) were higher in youth with T2DM. Poorer compliance of self-care behaviors for diabetes management was also more prevalent in youth with T2DM. It is important therefore that health practitioners address these risk factors and target self-care behaviors via both screening and intervention strategies because of the potential long-term ramifications.

Introduction

There has been a dramatic rise in the incidence of Type 2 diabetes (T2DM) in youth over the past few years. In 10-19 year old African American and White children referred to a major pediatric center in Cincinnati, Ohio, the incidence of diagnosed T2DM increased 10-fold, from 0.7/100,000 in 1982 to 7.2/100,000 in 1994 (Pinhas-Hamiel et al., 1996). Data from the Indian Health Service (1988 to 1996), also documented a 54% increase in prevalence of reported diabetes in 15-19 year old adolescents (Fagot-Campagna et al., 2002). Case studies in California, South Carolina and a few other states have shown increasing percentages of incident pediatric cases of diagnosed diabetes, with fewer than 4% reported before 1990s and up to 45% in recent studies (Pinhas-Hamiel et al., 1996; Willi et al., 1997; Fagot-Campagna et al., 2002). Traditionally, T2DM was known as an adult disease, and was strongly associated with obesity, positive family history and sedentary lifestyle (Rewers & Hamman, 1995; Simmons et al., 1995). However, the predominant form of diabetes in youth was Type 1 diabetes (T1DM). While T1DM is still the predominant form of the disease in youth, the recent rise in T2DM cases has lead to the Surgeon General proclaiming it to be an epidemic in 1998.

T2DM among adults has been extensively studied. Among adults, numerous studies document a significant positive correlation between the prevalence of T2DM and relative weight for height (Mokdad et al., 2000 & 2001). Researchers have demonstrated an association between obesity, insulin resistance, and a progressive transition from glucose intolerance to being diagnosed with diabetes (Kenny et al., 1995; Scott et al., 1997; Rewers & Hamman, 1995; Segal et al., 1996). The typical age of onset for T2DM is over 45 years. However, within the last decade, the age of onset of T2DM has decreased. T2DM has been reported in children and adolescents worldwide, with a greater proportion of children of color affected. More recently, several clinical reports have published data of increasing incidences of T2DM among African American children in Cincinnati and Arkansas (Pinhas-Hamiel et al., 1996; Pihoker et al., 1998); first nation (American Indian) children in Manitoba (Dean et al., 1988; Dean H, 1992); American Indian in Ontario (Harris et al., 1996); Hispanic children in California (Fagot-Campagna et al., 2001); and Japanese children in Tokyo (Kitagawa et al., 1994 & 1998). The incidence rates reported in these studies ranges from 8 to 45%. In Tokyo, for example the annual incidence of T2DM among junior high school children, increased from 7.3 per 100,000 in 1976-1980 to 12.1/100,000 in 1981-1985, and to 13.9/100,000 in 1991-1995 (Kitagawa et al., 1998 & 1994).

The ideal goal for treatment is normalization of blood glucose values and glycosylated hemoglobin (GHB) (American Diabetes Association, 2000). The ultimate goal of treatment is to decrease the risk of the acute and chronic complications associated with diabetes. There is strong evidence from the U.K Prospective Diabetes study (UKPDS) that the normalization of blood glucose substantially reduces the frequency of microvascular complications (such as retinopathy) of T2DM in adults (UKPDS Group, 1998). Similarly, the Diabetes Complications and Control Trial (DCCT) showed that in the case of T1DM, normalization of blood glucose reduced the risk of retinopathy, nephropathy, and neuropathy substantially (DCCT, 1993). The early age of onset of T2DM in children may particularly increase the risk of microalbuminuria and nephropathy, which are known to be directly related associated with duration of diabetes and hyperglycemia (ADA, 2000). Prevalence of metabolic syndrome (MS) (having at least 3 of the following: abnormal glucose, low HDL-C, elevated serum triglyceride, abnormal waist circumference, and high blood pressure) among youth aged 12-19 years was 4.2% (Cook et al., 2003). The authors suggest that a substantial percentage of overweight youth may be inflicted with the MS. Hence, the goals for clinical management of T2DM in children and adolescents should include therapies directed at treating the underlying pathologies of diabetes, effects of chronic hyperglycemia, other metabolic risk factors and the prevention of long-term complications. Prevention and treatment of associated co-morbidities such as hypertension, hyperlipidemia, and obesity are important, but the ultimate goal is to maintain blood glucose levels and reduce the risk of end-organ damage from diabetes, which is directly related to the duration of diabetes and level of hyperglycemia. Similar to T2DM mellitus in adults, the first lines of therapy in children with T2DM are diet, exercise and weight loss or maintenance, because these therapies are directed at the underlying pathology, insulin resistance, which is a primary associative feature of T2DM.

The main objective of this study was to assess distinguishing characteristics of youth (age, gender, ethnicity, puberty, weight, height,) with Type 2 versus T1DM in Michigan to determine if differentiation is clear at this vulnerable age. We were specifically also interested in determining if diabetes/glycemic control and associated factors (self-care management and monitoring behaviors, and other metabolic behaviors) differed by type of diabetes in this age group.

Research methods

A retrospective chart review of youth (6-19 yr) previously diagnosed with Type 2 or T1DM was undertaken at pediatric and adult endocrinology clinics in Michigan to determine if independent variables were associated with glycemic control in children based on type of diabetes. Youth diagnosed with T2DM were matched for age and gender with children with T1DM for comparison purposes. If there were more than one T1DM subject with an age similar to a T2DM subject, random matching was conducted. Approval from Michigan State University Committee on Research Involving Human Subjects (UCRIHS), the clinic directors and the Review Boards of the individual clinics was obtained before data collection was commenced.

Sites: Data was collected at eight pediatric and endocrinology clinics in the state of Michigan. The eight eligible clinics were distributed over the state of Michigan: west central Michigan (Lansing-Sparrow Hospital, Grand Rapids- Saint Mary's Mercy Medical Center and DeVos Children's Hospital); southeast Michigan (Detroit- Children's Hospital of Michigan and Ann Arbor- University of Michigan Medical Center); east central Michigan (Saginaw- Covenant Hospital and Flint- Hurley Medical Center) and south central Michigan (Jackson-Foote Hospital).

Target Population: Subjects were youth aged 6 to 19 yr, medically diagnosed with either Type 1 or T2DM. Previous studies have shown 10-19 years as the probable age range for T2DM cases in children and adolescents, but based on personal communication with local physicians, T2DM cases have been reported in children as young as 6 years old. Hence, in order not to exclude these cases, the selected age range for this study was determined as 6-19 years of age. The population base for this study included all children and adolescents with a medical diagnosis of diabetes (Type 1 or 2) who had attended the clinic for at least six months prior to the commencement date for the study. Exclusion criteria were children 6-19 years old who have: 1) Physician noted maturity-onset diabetes of the young (MODY); 2) Type 2 diabetes associated with steroid use; 3) Type 2 diabetes associated with cystic fibrosis; and 4) Children with pre-diabetes (whose blood glucose levels are higher than normal, but not yet high enough to be diagnosed as diabetes). These cases were excluded to obtain "true cases" of T2DM as defined by the American Diabetes Association (ADA, 2000). ADA defines T2DM in youth as: Classic symptoms of diabetes (polyuria, polydipsia, & unexplained weight loss) and casual glucose ≥200 mg/dl (11.1 mmol/l) *OR* Fasting plasma glucose ≥126 mg/dl (7.0 mmol/l) *OR* 2-hour plasma glucose ≥ 200 mg/dl (11.1 mmol/l) during an Oral Glucose Tolerance Test (OGTT).

Estimating the proportion of diagnosed T2DM among youth 6-19 yr with diabetes (T1DM or T2DM) in the state of Michigan was conducted by Handu et al., 2004 (Chapter 4). After confirming the proportion of T2DM cases to be higher than usually expected, similar to other nationally reported rates, it was important to compare and contrast T2DM and T1DM in this vulnerable age group. The purpose of the medical record review was to firstly estimate the prevalence of glycemic control in these populations because of the importance of good glycemic control on later quality of life. Secondly, it was important to identify associative risk and control factors to determine if the challenges faced by T2DM were different, and to inform health care professionals who diagnose or counsel

T2DM youth on associated family and health care behaviors which might be different between these two groups of youth.

The medical records of youth with T2DM and matched cases with T1DM were reviewed for diabetes diagnosis, glycemic control and associated factors, and self-care behaviors (home blood glucose monitoring, following recommendations of exercise and diet). The presence of the following metabolic risk factors (metabolic syndrome cut points) was also compared: elevated serum glucose, blood pressure ≥ 90^{th} percentile for height, elevated serum triglycerides ≥ 110 mg/dL, and low serum High Density Lipoprotein- Cholesterol (HDL-C) ≤ 40 mg/dL (Cook et al., 2003). Metabolic syndrome is defined as having at least three of the before mentioned metabolic risk factors and has been reported to be potentially associated with serious ramifications such as cardiovascular disease if present. Typically in adults, cardiovascular disease is a leading cause of death among individuals with T2DM (Cook et al., 2003). Diabetes mellitus is often accompanied with metabolic aberrations; therefore it was critical to determine if these aberrations were present in youth with T2DM. To abstract the information described above a data collection form was used (Appendix B). Content validity of the data collection form was established by asking 6 diabetes professionals (2 pediatric endocrinologists, 1 nurse, 2 registered dietitian's with doctorate degree and 1 dietitian who has experience working with diabetes youth) to review the data collection protocol sheet. Responses from reviewers were obtained and the changes requested included: organization of questions, re-phrasing questions to simplify, and deletion of perceived irrelevant questions. Four trained people conducted data abstraction at all centers to maintain consistency and confidentiality of records.

Body mass index (BMI) and BMI percentiles for each subject was calculated by using Epi-Info software (Dean et al., 2002). Epi- Info also provided BMI and height percentiles specific for age and sex. Height percentiles were used for calculating blood pressure percentiles. Blood pressure percentiles were calculated based on tables developed by the National Heart and Lung Blood Institute (NHLBI, 2004). These tables are standardized for age and sex. Tanner stage data was noted as reported in the medical charts. Tanner stage at diagnosis of diabetes and current tanner stage were also noted as the literature indicates that during puberty, insulin sensitivity is reduced and hence, it was critical to know at what stage of puberty are youth diagnosed with diabetes.

Statistical Analysis: Data were analyzed using SPSS version 11.0 (Norusis, 2002). Means ± standard deviation and frequency distribution were calculated to describe the sample. Bivariate analysis (chi-square analysis) was conducted to determine if differences existed by gender and ethnicity for selected medical history, and biochemical and clinical variables. Logistic regression models were generated to determine the odds ratios (OR) for risk of T2DM compared to T1DM, risk of having low HDL-C, and risk of having high triglyceride among 6-19 year old youth when controlling for gender, ethnicity, type of diabetes, and BMI percentiles. A p-value of <0.05 was considered statistically significant.

Results

Of a total of 2018 children (6-19 yr) with diagnosed diabetes (Type 1 or Type 2) at eight endocrinology clinics in the state of Michigan, 220 (11%) had T2DM. Among subjects 10 to 19 years of age, T2DM accounted for 14% of the diagnosed cases of diabetes (Type 1 or Type 2). The gender and age distribution between the two types of diabetes was similar because of the age and gender matching. Table 1 depicts the demographic and age of onset comparisons. T2DM was diagnosed at a significantly higher age compared to T1DM in youth ($p<0.001$). Compared to T1DM cases, significantly more African Americans and Hispanics were diagnosed with T2DM ($p<0.001$). In addition, 65% of T2DM subjects were living in single parent households compared to only 40% of subjects with T1DM ($p<0.001$). Data regarding income estimates demonstrated that 41% of T2DM subjects were supported by government assistance insurance. For T1DM cases this was true for only 37% of T1DM subjects.

Data regarding BMI indicated that youth with T2DM had significantly higher mean BMI compared to youth diagnosed with T1DM (34.9 ± 12.4 vs 21.6 ± 5.6, $p<0.001$). Classification of subjects by BMI percentile showed that the majority of youth with diagnosed T2DM were $\geq 95^{th}$ percentile, whereas the majority of youth diagnosed with T1DM had a BMI %tile between the 5^{th} and 85^{th} percentiles (Figure 1).

Data analysis of the other variables indicated that more of subjects with T2DM had a positive family history of diabetes compared to T1DM subjects (85% vs 61%). Acanthosis nigricans was present in 73% of those with T2DM compared to 6% in those with T1DM ($p<0.001$). When pubertal status was examined, the majority of the youth with T2DM were in Tanner stage 3 or higher at the time of diagnosis (83% vs 28%, $p<0.001$) (Table 2).

Biochemical parameters measured most frequently in both groups included HbA_1c and lipid profile (Table 3). HbA_1c was higher among youth with T2DM compared to T1DM, but these results were not statistically significant. For both groups however, the mean HbA1c was higher (>7%) than the target set by ADA for optimum control. Mean triglyceride (TG) values were significantly higher among T2DM subjects compared to those with T1DM. Mean HDL-C was significantly lower among the subjects with T2DM. When data were analyzed according to normal cut off points for each of these parameters, T2DM subjects were more likely to have serum TG ≥ 150mg/dl ($p<0.01$), HDL-C ≤ 40 mg/dl ($p<0.01$), and TC ≥ 110 mg/dl than those with T1DM. Data were also analyzed by using the metabolic syndrome cut off points (serum TG ≥ 110mg /dl; blood pressure %tile ≥ 90^{th} %tile; and HDL-C ≤ 40 mg/dl). Compared to subjects with T1DM, T2DM subjects had higher serum TG, lower serum HDL-C, and higher blood pressure ($p<0.05$). Based on the criteria for metabolic syndrome classification (Cook et al., 2003), 57% of T2DM subjects compared to only 28% of T1DM subjects qualified as having metabolic syndrome ($p<0.001$). Eighty six percent of T2DM youth had at least 2 metabolic syndrome risk factors and 59% had at least 3 metabolic syndrome risk factors. Information regarding subject compliance with dietary and exercise recommendations, and self-monitoring of blood glucose at home as recommended showed that a significant percentage of T2DM subjects were not following their dietary and exercise recommendations compared to subjects with T1DM (Table 4). Twenty two percent of subjects with T2DM compared to only 6% of subjects with T1DM were not checking their blood sugars at least 2 times per day ($p<0.001$).

The significant variables in the bivariate associations were tested in a logistic regression model to assess the effect of the independent variables on risk of T2DM, risk of high HDL-C, and risk of high TG, while controlling for each of the independent variables in the model. Model 1 (Table 5) predicted the likelihood of Type of diabetes (Type 2 vs Type 1) relative to gender, race, and body mass index. Odds ratios (OR's) and 95% confidence intervals (CI) for each of these variables are shown in Table 5. The odds of being diagnosed with T2DM relative to T1DM was 75.0 times greater for those with a BMI $\geq 95^{th}$ percentile, compared to those with a BMI $<85^{th}$ percentile. Subjects with a BMI $\geq 85^{th}$ percentile were 3.4 times more likely to develop T2DM compared to T1DM ($p<0.001$). Hispanic and African American youth were 31.9 and 6.9 times respectively more likely than Caucasian youth to be diagnosed with T2DM when gender and BMI were controlled for or held constant ($p<0.001$).

Model 2 predicted the odds of serum TG $\geq$ 150 mg/dl when controlling for gender, age, BMI percentile, and Type of diabetes (Type 1 or Type 2). The odds of serum TG $\geq$ 150 mg/dl was 2.8 times greater for those with a BMI $\geq 95^{th}$ %tile compared to those with a BMI $<85^{th}$ %tile. Subjects with T2DM had significantly higher odds of having serum TG $\geq$ 150 mg/d when compared to T1DM subjects (OR= 4.0, CI: 11.1-17.0, $p<0.05$) (Table 5).

Model 3 determined the odds of HDL-C ≤ 40 mg/dl while controlling for gender, age, BMI percentile, and type of diabetes (Type 1 or Type 2). The odds of HDL-C ≤ 40 mg/dl was 4.1 times greater for subjects with BMI ≥ 95^{th} percentile compared to those with BMI <85^{th} percentile, and 7.8 times greater for subjects with T2DM compared to those with T1DM. (Table 5)

Discussion

This study was unique in showing that the majority of youth with T2DM were living with single parent families compared to youth with T1DM. Further analysis showed that this was especially true for African Americans. In fact in this ethnic group, regardless of whether they had Type 1 or T2DM, the majority were from single family parents. In addition, insurance data indicated that more of youth with T2DM were using government assisted insurance support compared to youth with T1DM. Therefore social factors are key factors for consideration in this population.

Key distinguishing features of T2DM among children and adolescents as presented by this and other studies are obesity, acanthosis nigricans, and positive family history of diabetes (Pinhas-Hamiel et al., 1996; Pihoker et al., 1998; Dean 1998). Abnormal lipid profile and presence of metabolic syndrome were more prevalent among youth with T2DM compared to youth with T1DM cases, indicating a clustering of cardiovascular risk in this sample of T2DM youth. Similar to data reported by Pinhas-Hamiel et al. (1996), African Americans were over represented among the youth with T2DM in both of these studies. The number of Hispanic youths diagnosed with T2DM compared to Michigan's ethnic distribution indicates that Hispanics were at a higher odds of being diagnosed with T2DM compared to T1DM. These results mimic the adult scenario where populations of color are at an increased risk of developing T2DM.

The age of onset of diabetes was significantly higher among youth with T2DM compared to youth with T1DM. However, the age of T2DM onset in this sample is significantly lower than is usually predicted for the onset of this disease. Hence, this disease, which historically was common among adults is now becoming a pediatric problem, which needs to be addressed. Similar results have been demonstrated by Neufeld et al. (1998) and Pinhas-Hamiel et al. (1996). In addition, puberty data analysis indicated that more of T2DM subjects were at Tanner stage 3 or higher compared to T1DM youth. Therefore based on puberty information and age of onset, puberty might be a precipitating factor for T2DM in youth in conjunction with other risk factors such as overweight or obesity. Due to hormonal changes (growth hormone) during puberty, there is increased resistance to the action of insulin. The increased demand for insulin during puberty may exceed beta-cell capacity resulting in overt diabetes mellitus (Arslanian, 2000). Among normal children and adolescents, having normal β-cell function, insulin resistance during puberty is compensated by increased insulin production and secretion leading to high circulating insulin levels. However, in youth genetically predisposed to developing diabetes or having strong associative factors of diabetes, these physiological changes likely tip the balance from normal to impaired glucose tolerance (Liu et al., 2004).

The strong association of family history of diabetes with the occurrence of T2DM in the youth identified in our study was not surprising. A positive family history of T2DM in a first degree relative is a known risk factor for T2DM. Children with T2DM have a strong link to positive family history of diabetes (Hale, 2000; Hale & Danney, 2000). Pinhas-Hamiel et al. (1996), demonstrated that 65% of their subjects had a positive family history of first degree family member with T2DM and 85% had a first or second degree relative with T2DM. A study from First Nation children in Ontario indicated that 92.9%

of T2DM cases had a positive family history of diabetes (Harris et al., 1996). Studies have demonstrated that inheritance of T2DM is multigeneic and heterogeous. While some genes have been associated with T2DM in some studies, the findings vary in different populations (Rosenbloom et al., 1999). On the other hand, relationship between family lifestyle and diabetes has also been shown. Pinhas-Hamiel et al. (1996), examined the "Type 2 family", and found that family members were more likely to have central obesity and lifestyles characterized by high fat intake, minimal physical activity, and a high incidence of binge eating (Pinhas-Hamiel et al., 1999; Liu et al., 2004). Therefore, family environment rather than genetics per se might be a key factor to note as well.

Acanthosis nigricans was a key distinguishing factor in the T2DM cases compared to T1DM. It has been estimated that acanthosis nigricans can be found in 90% of children and adolescents with diagnosed T2DM (Dabelea et al., 1999; Callahan & Mansfield, 2000). Acanthosis nigricans is a marker of insulin resistance and is associated with many different conditions and symptoms that include insulin resistance and compensatory insulin secretion (Liu et al., 2004). African American youth have a 25-fold higher prevalence than other populations (Stuart et al., 1998). In our data 61% of African Americans had acanthosis nigricans compared to Caucasian Americans (23%). Hence, the presence of acanthosis nigricans is a good clinical indicator, as hyperinsulinemia correlates with the presence and severity of acanthosis nigricans, making it a useful indicator of risk for T2DM in youth.

The exceptionally strong association of T2DM in youth with overweight/obesity was similar to studies published by Scott et al. (1997), Pinhas-Hamiel et al. (1996), Dabelea et al. (1999), and Macaluso et al. (2002). Recent data from the National Health and Examination Survey (NHANES) 1999-00 suggests a continued rise in the prevalence of overweight in youth, with approximately 15% at risk of overweight and another 15 % overweight (Ogden et al., 2002). Overweight prevalence over the past 20 to 30 years has doubled for children 2-5 years old and almost tripled for those 6 to 19 years of age (Liu et al., 2004). A key physiological implication of overweight and link to T2DM is the adverse effects on glucose metabolism. For example, 55 % of variance in insulin sensitivity among healthy white children (i.e. who do not have diabetes) is accounted for by total adiposity (Bogardus et al., 1985). The amount of visceral fat in overweight adolescents was directly correlated with hyperinsulinemia and inversely related with insulin sensitivity (Tamura A et al., 2000). Therefore, it is not surprising that the T2DM-obesity association is so strong.

In the present study HbA_1c levels were higher but not statistically significant among T1DM youth compared to youth with T2DM. The reason for this is not clear but perhaps the longer duration of diabetes in the T1DM cases and/or the metabolically unstable nature of T1DM may be a primary factor. However, for both the groups HbA_1c were higher than the normal recommendations by ADA ($HbA_1c < 7$). This was an important biomarker of diabetes control for both T1DM and T2DM. Hence, developing programs targeted specifically for youth to control blood glucose levels is important. Except for the HbA_1c, all other biochemical parameters measured in this study were higher among

T2DM youth compared to youth with T1DM. Triglycerides were significantly ($p<0.05$) higher and HDL-C significantly ($p<0.0001$) lower among youth with T2DM compared to youth with T1DM. Total cholesterol and LDL-C also tended to be higher among youth with T2DM compared to youth with T1DM, but the levels were not statistically significant. These findings are unique and not previously reported. Therefore, controlling and testing only HbA_1c in this population is not sufficient. It is imperative that lipid profiles are also considered, because of the fact that cardiovascular disease is the leading cause of death in people with T2DM (American Diabetes Association, 2000; CDC, 2004). Cardiovascular disease markers are thus just as important for the prevention or amelioration of potential complications.

Although both T2DM and T1DM are serious conditions, youth with T2DM appear to present with more metabolic aberrations compared to T1DM youth. According to the American Diabetes Association (2000), dyslipidemia far outweighs all other risk factors for cardiovascular disease in adults with T2DM. Hence, the scenario is likely to be similar and even more for youth with T2DM.

More youth with T2DM had higher blood pressure percentiles compared to T1DM youth. According to Carla Scott (1997), high blood pressure in youth may be secondary to their overweight rather than a complication from diabetes. Our data indicated that among youth with T2DM who had blood pressure percentiles $>90^{th}$ percentile, 87% had BMI $\geq 95^{th}$ percentile. Many national health surveys have also demonstrated youth-onset hypertension as associated with overweight (Gotmaker et al., 1987). A combination of poorly controlled diabetes and hypertension could predispose individuals to chronic renal failure and ultimately dialysis. While this is already a significant problem in older individuals with T2DM, a much earlier onset of T2DM in youth might result in these complications occurring at a much younger age, and hence potentially lead to a low quality of life.

The data regarding adherence to self-care behaviors among T2DM youth were discouraging. Youth with T2DM had poorer reported adherence to recommended dietary advice, exercise, and monitoring blood glucose levels at home as regularly as recommended compared to T1DM youth. Anecdotal information from our clinic staff suggested that subjects frequently missing clinic appointments had poorer glycemic control compared to those regularly attending clinics. These findings are similar to those presented by Neufeld et al., 1998, for a sample of 11 Mexican-American subjects. Self-care behaviors as recommended by the Association of American Diabetes Educators (AADE), are an important aspect of controlling/maintaining normal blood glucose levels (AADE, 2002). Poor compliance with self-care behaviors may be a major contributor towards development of diabetes mellitus complications in this age group. One of the proposed reasons is that T2DM cases are at a higher risk than those with T1DM for failing to adhere to prescribed recommendations to control their disease and prevent long term complications (Pinhas-Hamiel & Zeitler, 1998). T2DM subjects may not perceive any immediate benefits from following their prescribed treatment regimen because the severity of the response might not be as clearly evident. In the case of T1DM youth, a missed insulin dose would, for example, result in pronounced effects, perhaps to the extent of being admitted to the hospital.

Our results clearly show that youth with T2DM were less likely to adhere to treatment regimens and dietary and exercise recommendations prescribed by the physician. Even during the short period of follow-up, data obtained from medical records demonstrated that the majority of these youth had abnormal lipid profiles and higher than normal blood pressure levels.

T2DM in youth is becoming a major concern because of the very young age of onset. Hence, if they are exposed to hyperglycemia for a longer duration compared to those who develop diabetes in adulthood/older age. This places them at greater risk of developing more severe complications earlier in life. This becomes a greater problem with the added factor of poor compliance with recommended care. Poor compliance has been a well-known problem in adolescents with T1DM (Weissberg-Benchell et al., 1995), and this problem is likely to be aggravated in youth with T2DM because of the insidious nature of T2DM. Hence, aggressive intervention is needed to help control/delay development of diabetes related complications in this very vulnerable population.

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Table 1. Descriptive characteristics of youth with Type 1 or Type 2 diabetes.

	Type 1 Diabetes	Type 2 Diabetes
Age at diagnosis****	8.7 ± 4.0	13 ± 2.8
Gender : Male	92 (44%)	92 (44%)
Female	123 (56%)	123 (56%)
Ethnicity****: African American	48 (22%)	114 (52%)
Caucasian	92 (43%)	33 (15%)
Hispanic	2 (1%)	25 (12%)
Others	73 (34%)	45 (21%)
Living Status****: Single parent Family	82 (40%)	128 (65%)

****p<0.0001

Mean age: Type 1: 16±2.4; Type 2: 16±2.5

Table 2. Risk factor comparisons of youth with Type 1 or Type 2 diabetes youth.

	Type 1 (%)	Type 2 (%)
Family history of DM ***: Yes	61	85
(N=193) No	13	4
Unknown	26	11
Acanthosis Nigricans****:Yes (N=167)	6	73
Puberty status at diagnosis****: (N=65)		
≥ Tanner 3	28	83
< Tanner 3	72	17

****p<0.0001, ***p<0.001

Table 3. Comparison of clinical parameters of Type 1 and Type 2 diabetes cases.

	Type 1 DM % (n/N)	Type 2 DM % (n/N)
Hemoglobin A1c (mean ± SD)	9.4 ± 2.1	8.76 ± 2.9
≥ 7	92% (201/219)	62% (132/212)
Triglyceride* (mg/dl) (mean ± SD)	90 ± 43	127 ± 97
≥ 150	9 % (7/77)	33 % (23/69)
Total Cholesterol (mg/dl) (mean ± SD)	172 ± 38	178 ± 43
≥ 170	48% (78/163)	53% (73/139)
HDL-C**** (mg/dl) (mean ± SD)	57 ± 15	43 ± 12
≤ 40 (low)	12% (10/83)	48% (33/68)
LDL- C (mg/dl) (mean ± SD)	100 ± 31	106 ± 41
≥ 110	29% (23/78)	38.5% (28/73)
Blood Pressure****(mmHg)		
Systolic/ Dystolic (mean ± SD)	115 ± 13 / 65 ± 10	127 ± 15 / 68.2 ± 11
≥ 90^{th} %tile	74% (136/183)	85% (152/178)
Metabolic Risk Factors		
HDL-C*** (mg/dl): ≤ 40 (low)	12% (10/83)	48% (33/68)
Blood Pressure****(mmHg): ≥ 90^{th}%tile	74% (136/183)	85% (152/178)
Triglyceride* (mg/dl): ≥ 110	34% (28/82)	49% (38/78)
Metabolic Syndrome****	28% (23/80)	57% (43/75)

**** $p<0.0001$, * $p<0.05$;

NCEP cutoff points, NCEP 2003. Metabolic syndrome cut off points. Cook et al., 2003

Table 4. Reported adherence to recommended self-care behaviors for youth with Type 1 or Type 2 diabetes.

		Type 1 DM % (N)	Type 2 DM % (N)
Follow Diet Rx****	Yes	58% (94)	20% (32)
	No	42% (69)	80% (124)
Follow Exercise Rx*** *	Yes	62% (91)	36% (52)
	No	38% (56)	64% (91)
Self Glucose Monitoring/day****	< 2x	6 % (11)	22% (31)
	≥ 2x	94% (173)	78% (109)

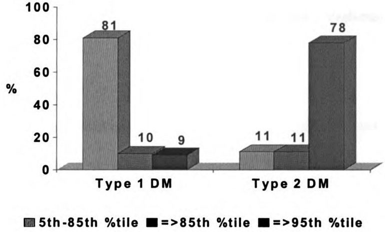
****p<0.0001

Table 5. Risk for being diagnosed with Type 2 diabetes compared to Type 1 diabetes, serum triglyceride ≥ 150 mg/dl, and serum HDL-C ≤ 40 mg/dl.

Models	Odds Ratio (CI)	Significance
Model 1: risk of being diagnosed with Type 2 diabetes		
Gender (females)	0.94 (0.5,1.7)	0.84
Race		0.0001
Caucasian (ref)		
AA	6.9 (3.1, 15.2)	0.0001
Hispanic	31.9 (5.5, 184)	0.0001
BMI		0.0001
<85th %tile (ref)		
85th - 95th %tile	75 (35, 160)	0.0001
≥ 95th %tile	3.4 (1.5, 7.9)	0.005
Model 2: risk of having TG ≥ 150 mg/dl		
Gender (females)		
Race	1.4 (0.5,3.5)	0.50
Caucasian (ref)		0.98
AA		
Hispanic	0.3 (0.7, 0.99)	0.04
BMI	1.5 (0.33, 7.0)	0.60
<85th %tile (ref)		0.38
85th - 95th %tile		
≥ 95th %tile		
Type of Diabetes	2.8 (0.6, 14)	0.20
Type 1 (ref)	2.3 (0.5, 11)	0.30
Type 2		
	4.0 (1.1-17.0)	0.05
Model 3: risk of having HDL-C ≤ 40 mg/d		
Gender (females)	0.94 (0.5,1.7)	0.84
Race		0.003
Caucasian (ref)		
AA	0.6 (0.04, 0.5)	0.002
Hispanic	6.2 (0.5, 84)	0.17
BMI		0.0001
<85th %tile (ref)		
85th - 95th %tile	4.1 (1.1, 16)	0.04
≥ 95th %tile	3.3 (0.8, 13)	0.08
Type of Diabetes		
Type 1 (ref)		
Type 2	8.0 (1.9, 34)	0.005

Logistic regression controlled for Gender, Race, & BMI, Type of diabetes

Figure 1. BMI percentile distribution of youth by Type 1 or Type 2 DM



p<0.0001

CHAPTER 6

Ecological factors influencing adherence to self-care behaviors among children and adolescents with Type 2 diabetes

Abstract

Objective: The objective of this study was to examine the beliefs and perspectives of adolescents with Type 2 diabetes regarding important self-care disease management behaviors.

Design: In-depth interviews explored subjects' experiences with diabetes prior to diagnosis, participants' views of diabetes self-management recommendations, current lifestyle practices, and how social and institutional conditions influence their diabetes care. In addition, physical activity and dietary intake data were collected with a questionnaire and 24-hr dietary recalls respectively.

Results: Adolescents reported that the most difficult behavior was to follow dietary recommendations. Perceived barriers to achieving dietary compliance included: eating out, fast food temptation, and eating with friends. Family support was identified as a facilitator for many subjects. In the case of single parent families, however, the mother's busy schedule and income generating capacity were substantial factors, which influenced self-care behaviors. Friends and institutions were deemed both helpful and detrimental in helping subjects to follow their diabetes management behavior.

Implications: Diabetes education programs should focus on eating habits, time management, relationship with family and friends, and making healthy choices when

eating out. A family based approach rather than an individual approach to diabetes management should be the focus of education programs. Further research is needed to refine the model developed, based on the findings of this study.

Introduction

Type 2 diabetes is a serious and growing health problem affecting all segments of the population (Bolanos et al., 1995). Traditionally, Type 2 diabetes was known as an adult disease and was strongly associated with obesity, positive family history and sedentary lifestyle (Rewers & Humman, 1995; Simmons et al., 1995). However, over the last decade, the age of onset of Type 2 diabetes has decreased and Type 2 diabetes has been reported in children and adolescents worldwide with a greater proportion of minority children being affected. Not only does diabetes have negative health consequences but also its impact on patients is also considerable (Mitchell, 1998).

In the last decade there has been a concerted national effort to reduce the negative impact of diabetes through improvements in self-care behaviors that lead to improved diabetes management. Type 2 diabetes patients require adoption and maintenance of multiple self-care behaviors to achieve and sustain good glycemic control (DCCT, 1993; Turner et al., 1998). Such behaviors mainly include self-monitoring of blood glucose via finger prick tests, exercising regularly, and adhering to a recommended eating regime. The bases for this effort are supported by the findings of the U.K. Prospective Diabetes Study (Turner et al., 1998) and the Diabetes Control and Complications Trial (DCCT, 1993). These findings emphasize the importance of self-care behaviors being incorporated as a part of an integrated program to maintain good blood glucose control over time.

Studies have shown that these self-care behaviors are influenced by psychosocial, behavioral, and environmental elements (Oltersdorf et al., 1999; Nestle et al., 1998).

Many studies, therefore have investigated behavioral and psychosocial issues influencing food selection and eating patterns (Oltersdorf et al., 1999; Nestle et al., 1998). A study by Travis (1997) of adults with Type 2 diabetes focused on psychosocial variables affecting dietary adherence and identified the variables that influenced diabetes self-care. Other quantitative studies specific to populations of color with adult Type 2 diabetes have suggested that factors such as culture, ethnicity, socioeconomic status, and psychosocial factors play a significant role in explaining self-care behavior patterns and outcomes (Fitzgerald et al., 1997; Cgipkin et al, 1998; Bell et al., 1995; Gilliland et al., 1998).

Adolescence can be challenging especially when combined with a chronic illness such as diabetes. Hence, it poses a unique problem for several reasons including: developmental priorities competing with the demands of health care, chronic illness interfering with social integration or psychosocial functioning, and the shift in responsibility of care from parents to the individual, sometimes resulting in confusion and anxiety (Court, 1991). In addition, children and adolescents spend a substantial part of their day at school and school personnel play an integral role in their daily diabetes management (Greenhalgh et al., 1997). Students often have to incorporate glucose monitoring, insulin/medication intake, and meal plans into their school routines (Siminerio and Koerbel, 2000). Numerous cultural and socioeconomic barriers interfere with implementation of dietary changes in youth with diabetes (Rosenbloom et al., 1999). Youth may lack familiarity with recommended food items, which also may be costly, difficult for families to obtain, or may require special preparation (Dean, 1998; Jones, 1998). Although adolescents do start exerting more control over their health behaviors as they enter adulthood, results from studies have indicated that most adolescents do not associate unhealthy behaviors with negative health outcomes (Radius et al., 1980). Studies in Mexican-American Type 2 diabetes youth in California (Jones, 1998), Native American youth with Type 2 diabetes in Canada (Dean, 1998), and Native American youth with Type 2 diabetes in the U.S. (Watkins et al., 1998) attribute non-adherence to many factors such as denial about their diabetes because they are asymptomatic, and peer pressure to consume high-caloric foods especially highly sugared beverages.

Studies in adolescents with Type 1 diabetes have demonstrated that Type 1 diabetes interferes with the achievement of developmental tasks more during adolescence than in any other period of the life cycle because of the conflicts between developmental needs and glucose goals (Cerreto & Travis, 1984). Smith et al., (1991) indicated that adolescents with Type 1 diabetes, who had better diabetes control reported more conflict about issues of becoming independent and more concerns about family relationships (Smith et al., 1991). Thomas et al., (1997), indicated that adolescents are less adherent to their diabetes regimen than younger children.

The Diabetes Prevention Study among adults demonstrated that lifestyle intervention (reduction of at least 7% of initial body weight through a healthy diet and physical activity of moderate intensity for 150 minutes/week) reduced the incidence of Type 2 diabetes by 58% as compared to the placebo group (Diabetes Prevention Program Research Group, 2002). However, research among adults also demonstrated that adhering to a healthy diet and increasing physical activity were the most difficult components of a self-care regime (Sullivan & Joseph, 1998). People with diabetes were reported to be more resistant to dietary change when compared to people with other chronic diseases (Groop and Tuomi, 1997).

Qualitative research has provided additional insights into the various psychosocial factors influencing self-care behaviors of adults with Type 2 diabetes (Anderson et al., 1996; El-Kebbi et al., 1996; Maillet et al., 1996). Although these studies identified a number of important socio-cultural and psychosocial influences on self-management behaviors, and particularly dietary behaviors, it is also necessary to have information on the relative importance of these factors and how these manifest in day-to-day living. Moreover, there is limited information on how unique personal dimensions, behavioral requirements, and environmental characteristics of those with Type 2 diabetes affect lifestyle factors, especially of youth.

This study proposes to contribute to what is known about lifestyle factors related to diabetes control by employing the ecological theory of Bubolz and Sontag (1993), and Mcleroy's social-ecological model for nutrition evaluation (1988), as a guide for identifying the structure, characteristics, and function of systems that facilitate control of diabetes specially in youth. The conceptual framework based on these two ecological theories proposes that the family/social support *(structure of the family, ethnicity, socio-economic support, moral support of parents etc.)*, the individual themselves *(their own behaviors, beliefs/values, attitudes, availability of resources)*, and the institutions *(diabetes centers, diabetes educators, physicians, insurance agencies, or other social* *support agencies)* are all inputs that influence an individual's adapting or adhering to self-care behaviors and to achieving glycemic control. Based on the conceptual map and the literature reviewed, the following research questions were derived.

1) How do family factors facilitate or inhibit the management of diabetes in youth?
2) How do individual's values and behaviors influence the management of diabetes?
3) How do institutions influence aspects of diabetes self-care practices?

Research methods

This study is a part of larger cross sectional study of diagnosed Type 2 diabetes in youth. This phase of the study was a triangulated qualitative study that included in-depth interviews, as well as assessment of the following self-care behaviors: medication intake, home blood glucose monitoring, and dietary and physical activity patterns via a questionnaire. The American Association of Diabetes Educators (2002) considers these diabetes self-care behaviors as measures to determine the effectiveness of diabetes self-management education at individual and population levels. Each behavior is important for the overall management of diabetes.

Triangulation refers to combining data collection methods or data sources to enhance the understanding of the setting and the target population (Taylor and Bogden, 1998). Triangulation of data also serves to support the scientific status of research and increase its utility to readers (Reinharz, 1992). The qualitative methodology selected corresponds to the nature of the data sought: parental attitudes, individual experiences, social networks and support systems (Fetterman, 1989; LeCompte & Preissile, 1993; Yin, 1989).

Subject recruitment and eligibility:

Subjects: The targeted study population was adolescents 14-18 yr diagnosed with Type 2 diabetes (i.e. criterion-based sampling). This age group was selected because at this age adolescents are making independent food choices, independently conducting blood tests, administering insulin injections, and are not as closely monitored by parents as a younger child. At this age, girls are past their growth spurt while many males are still having growth spurts. Subjects diagnosed with Type 2 diabetes less than six months were excluded from the study due to the less duration of experience with diabetes management. All the participants were residents of Michigan. The difference between subjects with good glycemic control ($HbA_1c < 7\%$) and those with poor glycemic control ($HbA_1c \geq 7\%$) was also determined. The 7% cut point is the target set by the American Diabetes Association (ADA) for good control (ADA, 2004).

Sample size: In qualitative studies, determination of sample size is usually done at the end of the research, as there is an inverse relationship between the number of informants and the depth to which an interview was conducted with each subject (Taylor and Bogden, 1998). Based on similar qualitative studies published in the literature, we anticipated that a sample of 20 subjects would be sufficient to obtain good quality data. After 16 interviews were completed it was noted that no new information was forthcoming in the interviews. Therefore, based on data saturation, 16 subjects were determined as an adequate sample size for analyses.

Recruitment: Participants were recruited through advertisements (or fliers) in physicians' offices and diabetes education centers. Subjects received a $20 token (gift certificates) and a pedometer to acknowledge participation, once the data was collected. The time and place of interviews were arranged according to the convenience of the participant. Before the commencement of data collection, approval from the Internal Research Review Board (IRB) for Human Subject research was obtained from Michigan State University and the endocrinology clinics. In addition, all the participants were requested to sign an assent form and parents/guardians were requested to sign a consent form. Consent from parents/guardians was necessary as subjects were under the age of 18 yr.

Procedures:

Semi-structured interviews: Qualitative interviews by two researchers were used to elicit in-depth opinions and views regarding various issues like family and individual's own behavior, and influence of institutions from the participant's perspective. Each interview was 1 to 1 ½ hours in duration. All interviews were audio taped in their entirety and transcribed verbatim.

The interview questions were clustered around five general themes and were open and intentionally non-directive to trigger broad, comprehensive responses. The core clusters included: a) experiences with diabetes prior to diagnosis; b) individual perspectives on diabetes self-management recommendations; c) current lifestyle practices; d) social and institutional conditions that influence their diabetes care; and e) social support (family, friends).

Before commencing these core interview questions, several descriptive questions were asked to obtain data such as: ethnicity; age; education level; living status; duration of disease; family history of diabetes; number of doctor visits per year; and type of medications.

Physical activity: The purpose of the physical activity component of the questionnaire was to assess the type, frequency, and duration of leisure time activity. A physical activity regime for adults and adolescents minimal to maintain health is defined as participating in physical activity at least three times a week, but preferably all days of the week, for 30 or more minutes based on 2002 dietary guidelines (United States Department of Agriculture, 2002).

In this study, a qualitative assessment for physical activity was sought, which would be practical in terms of administration ease, time and cost for both the investigator and the participants. Adaptation of the physical activity questions which were used by National Longitudinal Study of Adolescent Health and Youth risk behavior survey of the Centers for Diseases Control (CDC) (CDC 2003) were regarded as appropriate for the study. It was important to first establish whether subjects exercised at all, and then to categorize the activities which would most likely be selected, and finally assess frequency and duration. The analysis was conducted to assess hours spent in active sports such as: football, basketball, soccer; playing video games/ watching TV; and sleeping. Consistent with other self-care variables, subjects were also asked to discuss the barriers they encountered in achieving physical activity as recommended.

24-hour dietary recalls: The purpose of this section was to obtain information regarding subjects' usual eating habits or patterns, which could be used in targeting goals for nutrition education. Dietary intake and compliance can be assessed quantitatively or qualitatively via several methods. To obtain dietary information, two 24-hour recalls (one weekend and one week day preferably) were used. Food recalls were conducted using the USDA multiple pass method (Moshfegh et al., 1999) by a trained interviewer (1 interview in-person and 1 over the telephone). Since, only two people were conducting the interviews, inter-person variability was low and consistency with the approach to interviewing was facilitated. Specific dietary aspects of interest were the frequency and type of meals as well as dietary habits and patterns with regard to intake of carbohydrate, fat, fiber, soda, and snacks. Beverage consumption was defined as intake of soda, juice, and milk.

Data analysis:

The data were organized and analyzed in the following steps:

1) After each interview, the researchers present at the interviews transcribed the audiotapes verbatim. All transcripts were re-read while listening to the tape to check for accuracy and fix errors, and to help the researchers become more familiar with the data.
2) The transcripts were individually coded by two researchers, checked for accuracy, and discussed by both the researchers until consensus was reached upon the correct code. Units were very rarely coded twice. This was done only when consensus could not be reached regarding which code to use. The two researchers

developed a preliminary list of code words based on recurring themes and some pre-derived categories driven by the theoretical model based on the major research questions (Table 1).

3) Data from transcripts was loaded into NUD*IST N6 software (Non-numerical Unstructured Data by techniques of Indexing Searching and Theorizing, QSR, 2003) for tabulation and identification of responses by code word.
4) Based on the developed preliminary codes, a coding matrix was constructed. The researcher recorded all relevant statements from each subject's transcript into the coding matrix.

Physical Activity: Descriptive statistics was used to look at: average amount of time spent exercising; types of exercises subjects were involved in; frequency per week they exercised; and how many subjects met the recommendation for physical activity of 30mins/day and ≥3x/week (USDA 2002).

24-hr recall data: Dietary analysis was conducted by using Nutritionist V (First DataBank, 1999). Descriptive statistics was used to assess percent kilocalories coming from carbohydrates, carbohydrate consumption, percent kilocalories from fat, and amount and number of times soda and sport drinks were consumed per day. Descriptive statistics were also conducted to demonstrate how many subjects consumed breakfast, lunch, dinner, and snacks, as well as how many meals were skipped in a day.

Results

Participant characteristics: The demographic characteristics are provided in Table 1. The mean age for the subjects were 15.1 ± 2.4 years, and the majority were females (57%), African American, and came from single parent families (lived with their mothers).

Key themes from participant narratives: The main themes that evolved from this analysis were: the influence of family (social support); the influence of lifestyle changes and individual's perspectives about being diagnosed with diabetes, diet, and physical activity; the role of institutions; and the new emerging theme was the role of friends. Table 2 displays the themes and sub-themes that emerged. Table 3 presents a count of responses for some themes. A description of the participants' views of each of these themes is provided below.

Social support (influence of family): The majority of the subjects stated that they had a very supportive family, which mainly consisted of a mother, grandmother, and siblings. Whenever subjects had problems with their diabetes management or other things in life, they went to their mothers for support. Mothers represented the major part of subjects' support systems. One subject said, for example: *"I go to my mom if she's there, but if she's not there, I go to my grandmother."* Four out of sixteen subjects also mentioned that friends were an important support system.

When asked about their reaction or feelings after being diagnosed with diabetes, most responded with sadness, fear, surprise, devastation, a sense of separation from other youth, and denial. One youth stated, *"I was in denial, like, no, I don't. You guys are like idiots or something."* Another subject's reaction was, *"I was devastated. I thought everything was over."* Parents' reactions towards their child's diagnosis of diabetes were mixed. Some parents felt scared, some were surprised, but most expressed that they would support and help their children in any way. One of the parents expressed, *"You know, getting it now, so young, that's why I tell her, whatever it takes, you know for her to live, we should do."*. All subjects reported that somebody in their family had either Type 1 or Type 2 diabetes. However, not all reported that it was helpful for them to have family members with diabetes.

Influence of lifestyle changes/ individual's perspectives: When youth were asked about whether diagnosis of diabetes had changed their lifestyle, most (10 out of 16) stated that their lifestyle changed tremendously. One of the subjects stated, *"I got to take time...like take time aside to test my sugar and see what that is and if I need something to eat, go get something to eat or whatever."* Another responded, *"I can't eat what I used to eat, I don't go out a lot."*

Most reported that their diet had changed since being diagnosed. Subjects were consuming diet soda more often than regular soda. Food selection for all the subjects meant limiting carbohydrate intake and avoiding high fat foods and candy. Most felt that they had to cut back on chips, chocolates and sweets, pizza, fried foods, regular soda, and juice. One subject reported, *"I had to stop eating so many fried foods, chips, and candies."* Subjects were aware that they had to eat more fruits and vegetables. Some of the responses were, *"I eat healthier, not a lot of carbs, but baked foods, salads, fruits, and vegetables, but I love fatty foods"*; *"I guess the fact that I have to eat more vegetables helps me. I don't like it, but it helps."* Most youth reported that they did not like any vegetables except salads. Most youth reported a good understanding of diet in diabetes management, but felt that it was difficult to follow. As one of the subject said, *"I think diet is tougher to do, because you are consistently faced with different fast food commercials giving you um, discount on this big burger…."* Also, many reported that they were tempted to consume foods that were part of their lifestyle, prior to the diagnosis of diabetes. In summary, diet was very difficult to follow for all the subjects. These subjects had a good understanding of what to eat and what to avoid for diabetes management. However, they were not practicing what they knew. Also, most mentioned that eating packaged foods, canned foods, and fast foods were routine. These eating practices were mainly as a result of parent's busy schedules or lack of family mealtime.

Results from 24-hr recalls indicated that the 71% of subjects received >30% of their total calories from fat. Fifty-seven percent of the subjects had >10% of their fat calories from saturated fat. When parents were asked about the preparation method of certain food items, it was noted that they practiced deep-frying of chicken, leaving the skin and fat on chicken, and not eating enough vegetables.

Responses to exercise questions indicated that all subjects had started to exercise more regularly and frequently than prior to their diagnosis of diabetes. For example, one of the subjects reported, *"I walk and dance, and go to recreational center to do weights"*. Most of the subjects' felt that they could exercise, but not maintain a diet as easily.

Subjects also reported some barriers and facilitators of their diabetes management (Table 3). Subjects indicated that it was difficult to follow healthy dietary patterns when spending time with friends and eating out. Laziness and fear of being made fun of kept some participants from exercising. The facilitators for diabetes management in this group were mainly: supportive family; positive attitude; and fear of sickness as a result of uncontrolled diabetes.

Most subjects (9 out of 16) reported a high regard for their mothers. The reason for this admiration was mostly because of the way she handled her life and took care of the children. Most of the subjects looked up to their mothers and wanted to have her strength and positive attitudes when they grew up. Managing diabetes was very important to the subjects (11 out of 16), because they feared the complications that could occur as a result of uncontrolled Type 2 diabetes. In this respect, one of the subjects reported, *"I'd rather take care of myself than die."* Another responded, *"I am scared of the side effects of diabetes, that's why managing diabetes is important."* This reinforced the fact that education regarding the negative impact diabetes can have in the long run is known by this study population, yet the subjects were not able to adhere to the recommended self-care behaviors. Also, when asked about what they valued in life, the majority (8 out of 16) reported that they valued family, followed by friends, church, and education.

Role of institutions: Only 8 out of 16 subjects reported attending formal diabetes education programs offered by their hospitals. The other half of the subjects said that they had received diabetes information from their doctor, dietitian, and the nurse. These classes and sessions with doctors/dietitian helped them to understand what diabetes was, it's complications, foods to avoid, foods to consume and so on. Only 3 subjects mentioned that the school was really supportive for managing their diabetes. Subjects and their parents/guardians also offered some ideas about how the nutrition education programs provided by hospitals and diabetes classes could be improved. The most frequent request made by the subjects/parents/guardians was for more advice on planning healthy meals. Parents were also confused about the type of diabetes their children had and the use of oral medications/insulin. Most of the patients and family felt that, *"If I have Type 2 diabetes why am I on insulin"*, and *"Does being on insulin mean that my diabetes state is really bad."* Some of the subjects thought that avoiding food all together would help them deal with diabetes and were consuming 1 or 2 meals in a day. One of the subjects also felt that basic diabetes classes for all healthy adolescents should be conducted to make them aware of diabetes. This subject stated, *"giving talks or sessions in school would be helpful to normal kids not just diabetics"* and *"younger people need to be more aware of how important it is, and how easy it is to become a diabetic."* Talking with the subjects revealed that to help them successfully manage diabetes, constant reinforcement is needed for this age group.

Role of friends: When subjects were asked whether they talked about their diabetes with their friends, the majority said "no" (10 out of 16). The main reason for not discussing their diabetes with friends, was that they would be teased and discriminated against. One subject stated, *"Because they would make fun of me."* Some of the subjects revealed that they were teased at school for being overweight and did not want to aggravate the situation. Among subjects who informed friends about their diabetes, most specified that it was only after a few years when they were much older. One of the subjects summarizes this explanation as follows: *"Well I did not really start telling my friends, until I got like to middle school, junior high."* Most of the subjects indicated that none of their friends knew what diabetes was, and did not understand or care about it. Another interesting finding in this respect was that subjects felt that if they drank diet soda or did not eat some candy/fries, they stood out and that their friends would then tease them about being on a diet *("why you are having that, are you on a diet").*

Physical activity: Physical activity data indicated that subjects spent on an average 7.8 ± 5.5 hours per week in active sports while they spent 25 ± 12.8 hours per week in sedentary activities. When data for television watching/playing video games was analyzed, it was noted that subjects spent on an average 21.2 ± 11.4 hours per week on these activities. The most often reported barriers to exercising were bad weather (36%), laziness (36%), and feeling sick (36%).

24-hour recall results: Descriptive data for dietary data are present in Table 4. Total calorie consumption of subjects was in the normal range that is recommended for this age group. However, for 73% of subjects, more than 30 percent of calories came from fat. Calcium consumption was low compared to the DRI's for this age group (518 v/s 1300 mg). Dietary patterns indicated that only 40% of subjects had breakfast every day of the week, 40% of the subjects had 3 meals per day, 7 out of 16 subjects had only 1 fruit in a day, 4 out 16 had any vegetables in a day, and 9 out of 16 subjects had eaten out on their days of 24-hour recalls. Beverage consumption data (beverage includes juice, milk and soda) indicated that a median of 14 oz was consumed per day. Median diet soda consumption, regular soda consumption, and juice consumption were: 8 oz, 8 oz, and 12 oz per day respectively.

Data were also analyzed to compare youth with $HbA_1c < 7\%$ (n=9) and $HbA_1c \geq 7\%$ (n=7). Quantitative analysis of dietary recalls and physical activity data indicated no significant difference between the two groups. Total calories, fat, saturated fat, and % fat of total kilocalorie intake was greater among subjects with $HbA_1c \geq 7\%$ compared to subjects with $HbA_1c <7\%$, but these results were not statistically significant. A similar trend was noticed for hours spend in active sports. Subjects with $HbA_1c \geq 7\%$ spent fewer hours per week in any active sport compared to those with $HbA_1c < 7\%$ (6 hrs v/s 8.3 hrs, p=0.49). Qualitative data indicated, that adjusting to diet changes after diabetes diagnosis was better in subjects with $HbA_1c < 7\%$ compared to those with $HbA_1c \geq 7\%$. The majority of the subjects with $HbA_1c \geq 7\%$ indicated that they did not follow dietary recommendations. Qualitative information regarding exercise showed that a similar pattern existed between both the groups.

Discussion

The key findings showed that incorporating recommended changes in lifestyles after the diagnosis of diabetes were difficult to follow, and that family support as well as friends and were important facilitators of diabetes management. Following dietary recommendation was one of the most difficult behavior changes for adolescents. Many barriers, such as eating out, not able to give up fast foods, and eating with friends were indicated as influencing dietary choices. Family support was a facilitator for many subjects, but single parent status added a new perspective to the support system. Role of friends and institutions was both helpful and detrimental in helping subjects follow their management behavior for diabetes. Figure 1 presents the model based on these research findings and illustrates a preliminary view of how these components might relate to each other and influence adolescents adherence to diabetes management behaviors.

Individual's perspective: In this study, one main observation that stood out was "difficulty in following dietary recommendations". Observations from this study indicated that being diagnosed with diabetes did not always result in change of eating habits. Previous qualitative studies among adults with diabetes have indicated a positive relationship between eating history prior to diabetes and its influence on current dietary practices (Hampson et al., 1990; Schoenberrg et al., 1998; Hunt et al., 1998). Hence, past eating habits need to be integrated into nutritional counseling considerations for diabetes subjects. Most subjects in the present study demonstrated a good understanding of food selection and meal planning in relation to their diabetes. Previous studies among adults have indicated a positive relation between knowledge of food selection and meal planning and level of subjects' dietary adherence (Travis, 1997). Glasgow et al. (1989) demonstrated that knowledge about food selection and portion was a better indicator of dietary self-care behaviors than any demographic variable (Glasgow et al. 1989). In this study, the majority of the subjects felt that they had the knowledge, but they were not able to transfer this knowledge into maintaining a balanced diet. It is known that adolescents spend a large amount of time outside of the home, and they do not have much control over food purchasing and preparation. Hence, parents/guardians need to be included in nutrition education programs, and adolescents should be encouraged to participate in planning family meals. Family-based education classes should be conducted to encourage healthy eating and meal planning.

The barriers mentioned in this study could be targeted during interventions to change a desired behavior. For example, the noted potential barriers included social support, time management, and attitude/self-efficacy. More specifically, the purported lack of school-based support was particularly disturbing. Similar variables have been identified in other diabetes self-management studies among adults and adolescents with Type 1 diabetes (Ellison and Rayman, 1998; O'Connor et al., 1997; Hunt et al., 1998; Samuel-Hodge et al., 2000).

Family Support: The majority of the subjects reported that they had a very supportive family. However, the fact that so many subjects came from single parent families might have limited the mothers' ability and time to provide the kind of support she would have liked. La Greca and Bearman (2002) demonstrated that among adolescents with Type 1 diabetes, the family support variables that were most associated with adolescents' adherence involved daily management tasks like meals, glucose testing, and insulin administration, rather than exercise or emotions (La Greca & Bearman, 2002). On the other hand, a study by Anderson et al. (2001) indicated that a family's emotional support may help adolescents prevent or minimize feelings of depression, which were reportedly high among individuals with diabetes (Anderson et al., 2001). These previous findings when applied to the present study suggest that single parents with a busy schedule might not have enough time to support their adolescents with diet, exercise, and emotions.

Influence of friends: Support from friends and influence on self-care behaviors was identified as a major factor in this study. Subjects were not comfortable informing friends about their diabetes. However, as subjects became older (middle school or junior high), they shared their diabetes problem with friends. A small number of subjects also mentioned that their friends helped them keep away from eating junk food at school, though this attitude of friends bothered subjects at times. On the other hand, most subjects felt that when in the company of friends, they were more likely to consume fatty foods and drink regular soda. Previous studies have indicated that support from friends is mainly oriented toward companionship and emotional support (La Greca et al., 1995; Bearman & La Greca, 2002). This support from friends is typically more occasional than daily support (La Greca et al., 1995; Bearman & La Greca, 2002).

Role of institutions: Results regarding the role of institutions provided very mixed information about schools. Only 3 out of 16 subjects surprisingly indicated that schools acted as a positive support system for them. These were the schools that had a nurse on staff. At these schools, parents felt that the children were receiving healthy meals. Adolescents spend on an average one-third of the day at school. Hence, school staff plays an integral part in daily care (Clayton et al., 2002). Previous studies have suggested that teachers are not well trained to care for students with diabetes (Ratner et al., 2002; Gormanous et al., 2002; Siminerio et al., 2000), school nurses are not always available (Brener et al., 2001), and care of students at school is restricted (Brener et al., 2001). In the present study, parents felt that schools were offering high fat foods, drinks, and a la carte snacks that were not healthy for their children. Previous studies indicated that adolescent students with diabetes and their parents expressed concerns about unhealthy school meals. They expressed a desire for a greater variety of healthy choices in the cafeteria and vending machines (Hayes-Bohn et al., 2004). The American Diabetes Association (ADA) and the American Association of Diabetes Educators (AADE) have position statements regarding diabetes care at school and both state that professionals at schools should be trained, and that schools should partner with health care providers to develop or support individualized diabetes care plans (AADE Position Statement, 2000; ADA position statement 2002).

Implications for practice: Nutrition education emerged as a key foundation for effective diabetes management. Diabetes management was strongly affected by individual's behavior (diet and exercise). As mentioned earlier, changing eating habits/following a diet was indicated to be the most difficult part of self-care behaviors. Although the diagnosis of diabetes may change an individual's personal view of life, elements of daily living like family, friends, and food preferences remain the same. When planning an intervention, an important point to keep in mind is that adolescents with Type 2 diabetes are different from those with Type 1 diabetes. Type 2 diabetes subjects do not perceive any immediate benefits from following their prescribed treatment regimen because lack of adherence might not result in any serious metabolic symptoms. However, youth with Type 1 diabetes would see pronounced effects even to the extent of being admitted to the hospital if they missed their insulin. Hence, intervention strategies should be individualized, explain the course of disease, and focus on all the aspects that influence dietary behavior including the "silent effects" that might later be manifested in irreversible physiological complications that could have been averted.

Educators can facilitate adoption of healthy eating patterns among subjects by helping them assess their eating habits. Education programs should incorporate skill-building activities to help develop self-efficacy, time management, and problem solving techniques. Educators need to individualize education and help subjects develop routines based on their lifestyle. Results from this study indicated that most of the subjects were unsuccessful in transferring diabetes knowledge into practice. It is known that adolescents spend a large amount of time outside of the home, and they do not have much control over food purchasing and preparation. Hence, parents/guardians need to be included in nutrition education programs and adolescents should be encouraged to participate in planning family meals. Family-based education classes should be conducted to encourage healthy eating and meal planning. The barriers mentioned in this study can help plan interventions providing solutions on how to deal with these barriers. All adolescents should be encouraged to attend diabetes camps, or support groups that help adolescents share their problem about diabetes or share how they deal with diabetes (ADA 2004; CDC 2001).

Limitations of the study: Some of the limitations of this study are, firstly this was a small sample of adolescents with Type 2 diabetes. To generalize these findings, more ethnic representation is needed and a larger sample size from different demographics is required. In five cases, parents were present at the time of interviews and might have influenced subject responses. It was observed that when asked about role of institutions and how institutions could be more helpful in management of diabetes, parents were very eager to respond. Hence, in future studies it would be beneficial to interview both parents and youth separately to help obtain different perspectives. Additional research is needed to confirm the proposed behaviors, barriers, and facilitators mentioned in this study. Future research can help refine and validate the proposed model (Figure 1) for management of diabetes. Research in the area of stages of change might provide some idea about self-efficacy of Type 2 diabetes adolescents regarding their preparedness to change their eating and lifestyle factors, and why transferring knowledge into practice is a problem in this specific population.

Conclusion

In summary, this is one of the first studies that provided a glance into the lifestyles of adolescents with diagnosed Type 2 diabetes. It provides information regarding how adolescents feel about diabetes, the typical problems they face and even provides suggestions for health care providers (examples- information about diabetes, educating students at school about diabetes, more specific information on type of foods to consume). Thus, diabetes education programs specific for this youth population that seeks to help individuals reduce the barriers associated with achieving recommended self-care behaviors is pertinent.

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Table 1: Descriptive characteristics of the total sample (N=16).

Age in years (mean ± S.D.)	15.1 ± 2.4
Gender: Females (n=9)	56%
Males (n=7)	44%
Ethnicity: African American (n=12)	75%
Hispanic (n=2)	12.5%
Caucasian (n=2)	12.5%

Table 2: Themes and Sub themes derived based on data analysis.

Theory-driven	Theory operationalized	Findings		
Research Questions	**Interview Questions**	**Themes**	**Sub-themes**	**Thematic sections**
1. How do family/social factors facilitate or inhibit the management of diabetes?	1. Who do you consider to be your family? 2. Does anyone else in your family have diabetes? 3. When you first found out you had diabetes, who in your family was helpful? 4. To whom do you turn for help or comfort when you need help?	Family support/ influence of family	1. Family structure 2. Support system 3. Prior exposure to diabetes/ members with DM 4. Reaction to diagnosis - subject's reaction/feeling - family reaction/feeling	Social Support
2. How do subjects values and behaviors influence management of diabetes?	1. How has having diabetes changed your life? 2. What do you do now differently? 3. How has diabetes changed how you act with your friends 4. Is it important for you to manage your diabetes? Why? 5. What keeps you from taking care of yourself? 6. What helps you take care of yourself?	Effect of diabetes on daily life	1. Management behaviors - Diet - Exercise - Barriers to following diet & exercise recommendations - Facilitators to following diet & exercise recommendations 2. Self values/ beliefs - Managing DM important? (Why or Why not)	Individuals perspective
3. How do institutions influence the aspects of diabetes management?	1. Where did you learn how to take care of yourself? 2. What's been the most helpful resource for diabetes management? 3. What do you think the role of diabetes centers/your doctor should be in helping you with diabetes?	Influence of institutions/doctors on diabetes management	1. Source 2. Most helpful resource 3. Suggestions for improvement	Role of institutions

Table 3: Responses of subjects to the themes identified.

Theme	Definition		No. of responses	Positive response/ Negative responses
1. Family	a. Who do you consider your family	a. Family structure		
		• Mom	13	
		• Dad	6	
		• Sibling	9	
		• Grandparents	5	
		• Aunt/uncle/cousins	3	
		• Friends	6	
		• Other relatives	1	
	b. To whom do you go for support	b. Support system		
		• Mom	13	+
		• Dad	2	+
		• Sibling	5	+
		• Grandparents	7	+
		• Aunt/uncle/cousins	1	+
		• Friends	2	+/-
	c. How did patients react the first time they were diagnosed with diabetes	c. Reaction to Diabetes		
		• Patients reaction to diabetes		
		• Family's reaction to diabetes		
	Was the family supportive of patients diabetes diagnosis		16	+/-
			7	+/-
	d. Anybody in the family with diabetes	d. Family history of Diabetes		
		• Yes	16	+/ no response
		• No		

Table 3. Responses of subjects to the themes identified (Contd.)

2. Individual	a.	a. who do you admire		
		• Mom	10	+
		• Dad	2	+
		• Myself	1	+
		• Sister	1	+
		• Pastor	1	+
		• Uncle	1	+
3. Diabetes Education	Where did patients receive education regarding diabetes	Education source		
		• Hospital/Doctor/Dietitian/Nurse		
		• Teacher/school	15	+
		• Church	5	+
			1	+

Positive response= positive or desirable comment related to definition

Negative response= negative or undesirable comment related to definition

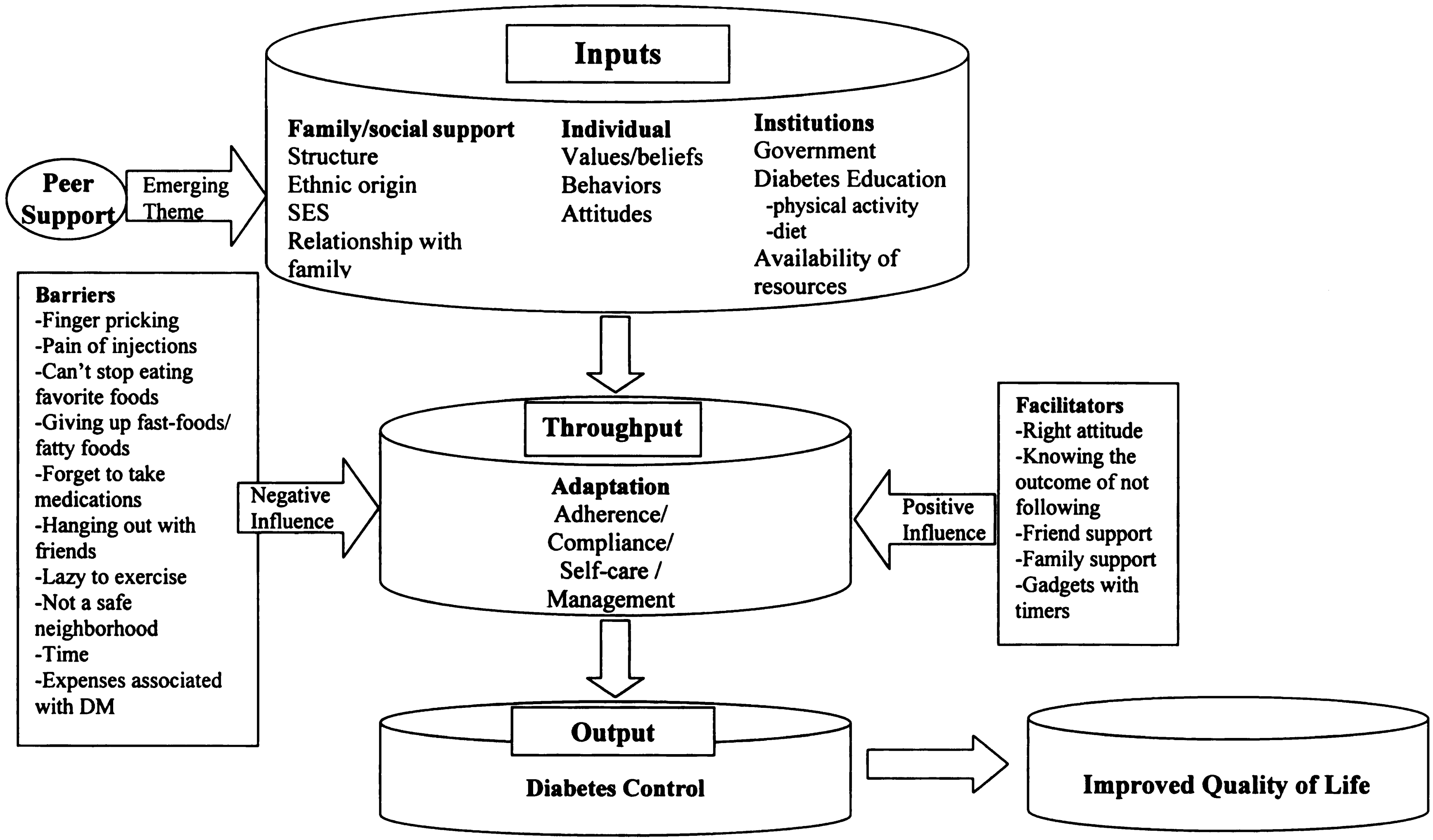
Table 4: Barriers and facilitators indicated by Type 2 diabetes youth.

Facilitators	Barriers
"My right attitude helps me. I take it more seriously" "Knowing that if you don't manage it right you can get real sick"	"....a lot of pricking does really hurt...my fingers and stuff so, that's the only I can really think of" "The only thing I would say is the pain of injections that would stop me from times um, taking injections or a shot because of the pain. It hurts. You know, after you do it over and over you know a period of time it hurts"
"Friends support me" "Family was supportive, they helped me in remembering to take my tablets and test blood sugar"	"Harder to stick to my diet" "Very expensive to buy all stuff. And me and his aunt bought it and the we tried to keep up with the strips but their expensive".
"I am more conscience of my health. And um, I also more conscience of other diseases that um, can effect how um, you would normally live. And I was not really aware of um how much diabetes can change you life and how much it can actually improve your awareness of yourself and others"	"Forget to take medications, or sometimes to not eat certain things"
"It helps me so much because it lets me know where I am at were I need to go and where I don't need to go and um, that's what helps me"	"Kids making fun is not helpful at all"
"My family helps me take care of my diabetes" "Mostly my family. My watch helps me. Um, it got a timer on here and I got it set to when I got to take my medicine"	"Because of my weight, I don't get to play" "Giving up eating fast foods and fatty foods is hard"
"My mom helps me take care of myself" "Friends are supportive, one friend that's a diabetic"	"Easier to eat fatty snacks when come back from school" "Can't stop eating the favorite foods"
	"When you go on school trips, it is hard to eat things different from others" "I don't go out to play because people make fun of me, because of my weight"

Table 5: Dietary intake (24- Hour Recall) descriptive for total sample (N=16).

		N=16
Kilocalories	mean ± S.D. Range	1893 ± 743 748, 3348
Protein (g)	mean ± S.D. Range	68.5 ± 32 22, 157
Carbohydrate (g)	mean ± S.D. Range	207 ± 97 117, 396
Fat (g)	mean ± S.D. Range	83 ± 49 22, 195
Saturated fat (g)	mean ± S.D. Range	25 ± 16 7, 54
Cholesterol (g)	mean ± S.D. Range	205 ± 154 22, 660
Total sugar (g)	mean ± S.D. Range	69 ± 41 26, 122
Calcium (mg)	mean ± S.D. Range	518 ± 257 128, 1032
Sodium (mg)	mean ± S.D. Range	2926 ± 1617 1137, 6997
% fat >30% of total kcal	mean ± S.D. >30%	38 ± 10 73% (11/16)
% sat. fat >7% >10%		87% (13/16) 60% (9/16)

Figure 1: Conceptual model with new emerging theme and barriers or facilitators identified in this study.



CHAPTER 7

Summary and conclusions

Diabetes is clearly recognized as one of the most common and costly diseases in the United States today, affecting more than 18 million Americans with as many as half undiagnosed (Centers for Disease Control and Prevention (CDC), 2002). Type 2 diabetes in children and adolescents concomitant with the rising rates of obesity has recently emerged as a "newly recognized" pediatric epidemic in the US, towards which enhanced national and state efforts need to be directed.

Among adults, numerous studies have documented a significant correlation between the prevalence of Type 2 diabetes and relative weight for height (Mokdad et al., 2000 & 2001). Data of a nationally representative sample from NHANES III (1998-1994) and National Longitudinal Study of Adolescent Health (Add Health) (NCHS 1994, Flegal et al., 2001) indicated that approximately 14% of children aged 6-11 years and 12% of adolescents aged 12-17 years are overweight, with an almost equal distribution among males and females. Obesity-related studies in Michigan have shown that among children aged 4 to 17 years, 38% of the boys were above the 85th percentile and 16% above the 95th percentile for weight. Of the girls, 33% were above the 85th percentile and 13% were above the 95th percentile (Gautheir et al., 2000).

Reported studies on prevalence/incidence of Type 2 diabetes among youth have demonstrated a significant recent increase in the number of youth diagnosed with Type 2 diabetes. These studies have concluded that this increase was strongly associated with obesity. The fact that Type 2 diabetes is strongly linked to obesity and Michigan was recently ranked number three in the country for adult obesity, and one city, Detroit, was classified as the "fattest city", warrants the importance of this study (Michigan Department of Community Health, 2004). Because this is a topical area of research, there is a paucity or very limited data, both nationally and for Michigan. True prevalence is difficult to determine since there is undoubtedly an undiagnosed population similar to that, which exists for adults. However, the proportion of those who have been recognized as having the disease and who are being treated at endocrinology clinics will provide useful information.

Therefore, the purpose of this study was to estimate the number of children and adolescents (6-19 yr), who have diagnosed Type 2 diabetes among those who have either Type 1 or Type 2 diabetes at endocrinology specialty clinics in Michigan. Endocrinology data was used because they were the most likely to have significant numbers of diagnosed cases. Additional useful information was obtained for professionals who diagnose or counsel children with Type 2 diabetes on glycemic control differences between Type 2 and Type 1 diabetes and associated biomedical, family and health behavior factors.

A two-phase study was conducted using an in-depth medical chart review and subject interviews. In Phase 1 of this study, data on the total number of youth aged 6-19 years with diabetes (Types 1 or 2) was obtained from clinic data systems. These data were used to estimate the proportion of diagnosed Type 2 diabetes in this population. Additionally, a comparison study for medically diagnosed Type 1 and Type 2 diabetes subjects in the age group of 6-19 years controlling for age and gender was also conducted. Phase 2 of this study, involved an in-depth qualitative interview and survey study with diagnosed cases of Type 2 diabetes adolescents. The main aim of this phase was to determine which factors were most likely to influence diabetes control in the population of children and adolescents with Type 2 diabetes.

The primary finding of this multi-clinic study demonstrated that the relatively high proportion of diagnosed Type 2 diabetes among children and adolescents in Michigan is comparable to the results published by previous single clinic studies (Pinhas-Hamiel, 1996; Pihoker et al., 1998; Neufeld et al., 1998; Glaser, 1998; Macalusco et al., 2002). This study demonstrated that diagnosed Type 2 diabetes accounted for 11.1% of all children and adolescents diagnosed with diabetes in the age group of 6-19 years, and 14% of all children and adolescents diagnosed with diabetes in the age group of 10-19 years at 8 pediatric and adult clinics in the state of Michigan. Adolescents were more likely to be diagnosed with Type 2 diabetes than those younger than 10 yrs, similar to that of some of the previously published studies (Pinhas, 1996; Glaser, 1995; Neufeld et al, 1998). The population of these clinics was representative of the population of the lower peninsula of Michigan. Hence, extrapolations based on the results of this study and census data, it was determined that in the lower peninsula of Michigan, the estimated prevalence of Type 2 diabetes was approximately 11.03/100,000. These results imply that healthcare providers must be aware of the possibility of Type 2 diabetes in youth and be alert to identify subjects at high risk because of the strongly associated factors such as obesity and family history of diabetes. The need for successful treatment of Type 2 diabetes in youth is critical give the possible onset of secondary complications from this disease at such early ages.

Comparison of Type 2 and Type 1 diabetes cases matched for age and gender, indicated that obesity, acanthosis nigricans, positive family history of diabetes and abnormal lipid profile are more significantly associated with Type 2 diabetes compared to Type 1 diabetes cases. Children and adolescents, more likely to be diagnosed with Type 2 diabetes relative to Type 1 diabetes, were significantly more overweight, African American, or Hispanic and the age of diabetes onset was much higher.

The mean age of diagnosis for Type 2 diabetes was 13.0 ± 2.8 years, which is very similar to data from Pinhas-Hamiel et. al. (1996). Females on average were diagnosed at least 6 months earlier than males. The earlier onset of diabetes in females may be attributed to the onset of puberty. The age of onset of diabetes was significantly higher among youth with Type 2 diabetes compared to youth with Type 1 diabetes (13 ± 2.8 v/s 8.7 ± 4). More youth with Type 2 diabetes were at Tanner stage 3 pubertal status or higher compared to youth with Type 1 diabetes. Typically in females, puberty begins on average, one year earlier compared to males. More female subjects (54%) were pubertal when diagnosed with Type 2 diabetes. Due to hormonal changes during puberty, there is increased resistance to the action of insulin. The increased demand for insulin during puberty may exceed beta-cell capacity resulting in overt diabetes mellitus (Arslanian et al., 2000). Among normal children and adolescents, in the presence of normal β-cell function, insulin resistance during puberty is compensated by increased insulin production and secretion leading to high circulating insulin levels. However, in youth who are genetically predisposed to developing diabetes or have the presence of strong associative factors for diabetes, these physiological changes can tip the balance from normal to impaired glucose tolerance (Liu et al., 2004).

The exceptionally strong association of Type 2 diabetes in youth with overweight/obesity are in line with similar studies published by Scott et al., 1997, Pinhas-Hamiel et al., 1996, Dabelea et al., 1999, and Macaluso et al., 2002. Classification of subjects by BMI percentile showed that the majority of youth with diagnosed with Type 2 diabetes were ≥ 95^{th} %tile, whereas the majority of youth diagnosed with Type 1 diabetes had BMI %tile between the 5^{th} and 85^{th} %tile.

Family history of diabetes was significantly higher in youth with Type 2 diabetes (84%) compared to in youth with Type 1 diabetes (61%). The fact that family history appeared to be a strong predictor, is not surprising given the strong association seen in previously reported studies (Pinhas-Hamiel, 1996; Glaser, 1998; Neufeld, 1998).

Acanthosis nigricans was present among 73% of Type 2 diabetes cases compared to only 6% of Type 1 diabetes cases. It is estimated that acanthosis nigricans can be found in 90% of children and adolescents with diagnosed Type 2 diabetes (Dabelea et al., 1999; Callahan et al., 2000). Acanthosis nigricans is a marker of insulin resistance and is associated with many different conditions and symptoms that include insulin resistance and compensatory insulin secretion (Liu et al., 2004).

Lipid profile data indicated that triglycerides were significantly higher and high density lipoprotein –cholesterol (HDL-C) was significantly lower among youth with Type 2 diabetes compared to youth with Type 1 diabetes. Total cholesterol and low density lipoprotein- cholesterol (LDL-C) were also higher among youth with Type 2 diabetes compared to youth with Type 1 diabetes, but these results were not statistically significant. These are some prominent findings, not previously reported. Of specific relevance was the fact that contrary to what is commonly believed, controlling and testing for HbA_1c only in this population is not enough. It is imperative that lipid profiles are also considered. Although both Type 2 and Type 1 diabetes are serious conditions, youth with Type 2 diabetes were more likely to have metabolic aberrations compared to youth with Type 1 diabetes. According to the American Diabetes Association (2000), dyslipidemia far outweighs all other risk factors for cardiovascular disease in adults with Type 2 diabetes. Hence, the same scenario might also be true for children with Type 2 diabetes. Since cardiovascular disease is the leading cause of death in people with diabetes, it is imperative that dyslipidemia's are carefully monitored. Risk of microvascular complications in this Type 2 diabetes population, due to the early age of onset, may be significantly higher because these complications are directly related to duration of diabetes and hyperglycemia. In addition, significantly more youth with Type 2 diabetes had higher blood pressure percentiles compared to youth with Type 1 diabetes.

Youth with Type 2 diabetes were significantly less likely to eat, exercise, or self-monitor blood glucose as recommended when compared to youth with Type 1 diabetes. Poor compliance with self-care behaviors may be a major contributor towards development of diabetes mellitus complications in this age group. One of the proposed reasons is that Type 2 diabetes cases are at a higher risk than the Type 1 diabetes population for not following prescribed recommendations to control their disease and prevent long term complication (Pinhas-Hamiel, 1998). It may be that Type 2 diabetes subjects do not perceive any immediate benefits from following their prescribed treatment regimen because lack of adherence is not frequently associated with any serious metabolic symptoms. However, in the case of individual with Type 1 diabetes, the effects of poor compliance are severe and almost immediate. An additional factor of concern is frequency of medical/clinic visits. Subjects who miss their clinic appointments frequently had poorer glycemic control compared to those attending clinics regularly.

Another striking finding of this study was the *living status of youth*. Sixty five percent of youth with Type 2 diabetes were living with single parent families, while this was the case for only 40% of youth with Type 1 diabetes. The in-depth interviews demonstrated that the majority of the subjects had a very supportive family. However, in the case of single parent families, the mother's busy schedule and income generating capacity were substantial factors, which influenced self-care behaviors. Support from friends and influence on self-care behaviors in this study was important. It was noted that subjects were not comfortable informing friends about their diabetes. However, as subjects became older (middle school or junior high), they were more likely to share their diabetes problems with friends. A small number of subjects also mentioned that friends helped them refrain from eating "junk food" at school. However by the same token, a large number felt that when in the company of friends, they were more likely to consume fatty foods and drink regular soft drinks such as coke.

Youth with Type 2 diabetes mentioned that, changing eating habits/following a diet was the most difficult part of self-care behaviors. Reducing or eliminating high fat foods and fast foods was especially difficult for these youth. The majority of the subjects felt that they had the knowledge about food selection and food preparation in relation to diabetes, but they were not able to transfer this knowledge into maintaining a balanced diet and eating a variety of foods. Adolescents spend a large amount of time outside the home, and they do not have much control over food purchase choices and preparation.

Strengths

The strengths of this study were: 1) this was the first reported multi-clinic study and included adult as well as pediatric endocrinology clinics throughout the lower peninsula of Michigan. Hence, the population of these clinics was representative of the population of the lower peninsula of Michigan. This provided a good estimate of the proportion of children and adolescents in lower Michigan who may have Type 2 diabetes among children with either Type 1 or Type 2 diabetes. 2) The procedures for this study involved both quantitative and qualitative methods to obtain data. Data from Phase 1, indicated that obesity, acanthosis nigricans, positive family history of diabetes and abnormal lipid profile are more significantly associated with Type 2 diabetes compared to Type 1 diabetes cases. Qualitative interviews in Phase 2 of the study helped provide an in-depth picture of barriers or facilitators to achieving recommended self-care behaviors necessary for good diabetes control. Social and institutional supports as well as subjects' own willingness were examined. Poor adherence to self-care behaviors have been noted among adults with Type 2 diabetes, but this is the first reported study to demonstrate a similar problem among youth with Type 2 diabetes. The fact that this study indicated that the majority of youth with Type 2 diabetes were living in single parent families, highlighted an often unrecognized factor that might be crucial in some cases to adequacy of care and monitoring. An additional strength of the study, not often mentioned, was the level of volunteerism. The nurses, dietitians, physicians, and office staff who volunteered to assist with this study did so without any financial compensation, and were extremely helpful in verifying the accuracy of data or identification of missing or difficult to find data.

Limitations

While this study had significant strengths, it also had limitations. During Phase 1 of the study, we would have liked to have included a clinic from the Upper Peninsula, so that we could get a more representative sample for the entire state of Michigan. However, the upper peninsula, did not have an established pediatric endocrinology clinic. A temporary physician visits every two months instead. At the time they were contacted, the response was that no youth with Type 2 diabetes were being attended to. Data collection over a longer period of time (8 to 10 years) in order to assess true incidence changes over the years would have been very helpful but was not feasible. However, this was a PhD dissertation, and thus limited by the amount of time.

Future Directions

This study will add to the limited data that is available from other states in the US, and ultimately towards estimating national statistics. A platform for conducting a more in-depth study with continuous data collection at the sites covered in this study was provided. Contacts and relationships have already been established and medical staff is willing to participate in an on-going data collection effort to better document the problem of Type 2 diabetes in Michigan. Michigan has no registry of Type 2 diabetes for youth. Hence this study is a stepping-stone for creating a registry. The data about self-care behaviors and findings about barriers and facilitators from the interview phase provide important information for designing an intervention program to help better control diabetes.

A prospective study with youth with Type 2 diabetes will help us understand the course of the disease in this group, and monitor the development of complications associated with diabetes. An intensive intervention study duplicating the Diabetes Prevention Program in adult, in order to circumvent the condition could be planned for youth at risk for Type 2 diabetes.

Also, a study using the stages of change can be employed in this population to study the self-efficacy of these youth in following dietary and exercise recommendations. Results from Phase 2 of this study indicated that the majority of the subjects felt that they had a very good understanding of food selection and meal planning in relation to their diabetes, but they were not able to transfer this knowledge into maintaining a balanced diet and eating a variety of foods. Stages of change might help us determine how many subjects are at precontemplation, contemplation, preparation, action, and maintenance stages. This information will help develop education program, skill-building activities to increase self-efficacy, and problem solving techniques as suitable for an individual person.

In summary, Type 2 diabetes among children and adolescents (6-19 years) in the state of Michigan is as high or higher than reported studies in other states. Most of these youth are overweight/obese, from single families, 10-19 yrs old, and demonstrate poor compliance with diabetes management self-care behaviors. This study highlighted the fact that besides medical/physiological factors, social factors also play a prominent role in diabetes management. Metabolic aberrations were more prevalent among Type 2 diabetes youth compared to Type 1 diabetes youth, suggesting that the likelihood of developing complications was high. The problem is compounded by the fact that the vast majority has multiple risk factors. Therefore, it is important that health practitioners address these risk factors via both screening and intervention strategies.

APPENDICES

APPENDIX A

Pharmaceutical Agents For The Treatment Of Type 2 diabetes (Evert, 2002)

Class	Mechanism of action	Name	FDA approval
Sulfonylureas	Promote insulin secretion	Acetohexamide, cholpropamine, glimepiride, glipizide, gylburide, tolazamide, tolbutamide	Safety and effectiveness in pediatric patients not been established
Biguanides	Decrease hepatic glucose output, enhance hepatic and muscle sensitivity to insulin, no direct on beta-cell	Metformin	Safety and effectiveness for treatment of Type 2 diabetes has been established in pediatric patients 10-16 years of age
Meglitininde, nataglinide	Short-term promotion of glucose-stimulated insulin secretion	Repaglinide, nataglinide	No studies performed in pediatric patients
Alpha-glucosidase inhibitor	Slows hydrolysis of complex carbohydrates, slows carbohydrate absorption	Acarbose, miglitol	Safety and effectiveness in pediatric patients has not been established
thiazolidenedione	Improve peripheral insulin sensitivity	Rosiglitazone, pioglitazone	Safety and effectiveness in pediatrics patients has not been established

APPENDIX B

DATA ABSTRACTION FORM

Children and Adolescents Diagnosed with Type 2 Diabetes in Pediatric and Adult Endocrinology Clinics in Michigan, Glycemic Control and Associated Factors.

Study Site: Date Abstracted:

Subject I.D.: Reviewer :

Supervising Physician:

Date of Birth: _ _ / _ _ / _ _ _ _

Zip Code of Residence:

Diagnosis of Diabetes: Yes ______
No ______
Uncertain (e.g. glucose tolerance) _______

"If diabetes was noted on chart, then"
Type as recorded on chart- Type 1 _________
Type 2, without insulin ________
Type 2, with insulin" _________
DM, difficult to classify_________
Gestational ________

Duration of Disease - ________no. of years
OR
Date of diagnosis- _________________

Diabetes Management:

1. Oral Medication:
   Yes ________ No_______
   Name of the drug/drugs: a-________________________ b-__________________
   c-_________________________ d- ___________________
   Dosage-__________

2. Insulin :
   Insulin injections: Yes _______ No ________
   Type: a. ______________________ b. _________________

c. ______________________ d. ______________________
Dosage: _______________

Insulin pump: Yes ________ No __________
Type: a. _________________________ b. ______________________________
c. _________________________ d. ______________________________
Dosage: _______________

3. Diet:
   Yes _______ No __________
   If Yes, diet prescription as noted ______________

4. Exercise:
   Yes _____________ No____________
   frequency of exercising________________Type of exercise________________

5. Self glucose monitoring:
   times per day :_________________

6. Stress management: Yes ________ No ___________

Race: African American ______
Caucasian American _____
Hispanic American/Latino American _______
Native American_________
Asian American __________
Other : specify __________

Gender: Male ____
Female _____

Medical Insurance:
None_________________
Medicare_______________ Medicaid ______________________
Private- HMO ________ PPC_________

Income (monthly): _________________ OR Income (yearly):__________________

Height: ______feet and inches

Weight: ______pounds

No. of clinic visits in the past year: ____________

No. of hospitalizations in the past year: __________

Reason for clinic visit:
Acute problem _______
Health Maintenance _______
Chronic Illness follow-up ______
Others ____
____

Comorbidities:

____
____
____
____
____
____
____

Family History of Diabetes Mellitus: Yes/No

Mother ________
Father ________
sibling(s) ________
Grandparent(s) ________
Uncle/aunts ________
Great grandparent(s) ________

Living Status:

With Mom only ________
with Dad only ________
With both parents ________
With grandparent/s ________
"Other, specify ________

Sibling information:

Number of siblings _________

Parent information:

Married _________
Separated _________
divorced _________
Never married _________
Widowed _________
Other, specify _________

Age of Parents:
MotherDOB:____________ OR current age: ____________ yrs.
Father DOB:____________ OR current age: ____________ yrs.

Parent employment:
Father: Yes _____ NO________
Mother: Yes______ NO________

Skin pigment changes in chart (neck, under arms, back of legs)
Yes _____
No _____

Puberty information:
1. Age at onset of puberty: ______age in years
2. Stage of puberty at diagnosis of DM:________
3. Current sexual maturation: ________________

Glycemic control indices on record:

Tests over past 2 years	Date	Value	Date	Value
GHB				

Lipid Profile done: Yes______ No______

Tests over past 2 years	Date	Value	Date	Value
Total cholesterol (mg/dl)				
Triglyceride (mg/dl)				
HDL cholesterol (mg/dl)				
LDL cholesterol(mg/dl)				
Total cholesterol : HDL ratio				

Others Biochemical tests:

Tests over past 2 years	**Date**	**Value**	**Date**	**Value**
C-peptide				
Insulin				
Islet cell Antibodies				
Microalbuminuria				
Blood Pressure				
Others:				

Appendix C

Informed Consent Form

Participant/Guardian Consent Form

Children and Adolescents Diagnosed with Type 2 diabetes in Pediatric and Endocrinology Clinics in Michigan, Glycemic Control and Associated Factors.

Investigators: Lorraine Weatherspoon PhD, RD
(517) 355-8474 ext. 136

Deepa Handu MS
(517) 355-8474 ext. 164

Purpose: We invite you to participate in a research project designed to study the unique experiences and voices of youth with Type 2 diabetes regarding monitoring blood glucose, exercising regularly, dietary recommendations, food selection and eating patterns, social support, institutional support and the aspects of daily living that influence their diabetes self-management practices.

Type 2 diabetes mellitus (90-95% of all cases of diagnosed diabetes) has clearly been identified as a serious epidemic in our society, which can be prevented or ameliorated by self-managed lifestyle changes, especially diet and physical activity. Although the American Diabetes Association and other similar organizations have established target behaviors for management of the disease, the traditional medical model has been unsuccessful in effectively facilitating target behaviors. There is need for research that includes exploration of the individual's objectives and priorities for diabetes self-management education and care as they may differ from those of the health care team and published standards of care. This project will ask you questions about how you deal with diabetes management. Our purpose for this study is to learn more about your experiences so that we can be more helpful to families who have youth with the Type 2 diabetes.

Procedure/What you will be asked to do if you participate:

Your voluntary participation in this study will involve one meeting with the researcher which should take approximately 1- 1 ½ hours. We will be talking/discussing about doctor and health professional recommendations that help with blood sugar control and how easy or difficult it is to follow this advice and why. The procedures followed are: 1) you will be asked to participate in an interview with a researcher; and 2) A 24- hour dietary recall will be conducted by the researcher.

The purpose of this project is to help develop successful intervention for youth with Type 2 diabetes. Your participation in this research project is completely voluntary. You will continue to receive diabetes center services and medical care as you usually do whether or not you choose to participate in this research. You can refuse to answer any questions that you do not wish to answer. The interview or discussion will be audio-taped. The tape will be used for transcription purposes only and will be destroyed following transcription. Your name or any identifier will not appear on the transcription and will not be associated with the study findings in any way. You can withdraw your participation at any time. At the end of the interview, you will receive a $25 gift card to Meijer's/Best Buy/ Cash in appreciation for your participation. If for any reason, you decide to discontinue with the interview (dropout before it ends) you will only receive a pedometer in appreciation for your participation.

RISKS AND BENEFITS: There are no risks or discomforts associated with this research. You may feel tired during or after the evaluation. Some psychological discomfort may be experienced from revealing personal information or thinking about things that are related to you diabetes experiences. Keep in mind that you may take a break at any time and you can refuse to answer any questions that make you uncomfortable. There are no implied benefits for the participants in this study. However, the results from this study may be beneficial to youth who have Type 2 diabetes mellitus and their families in the future. If desired, you may learn of the study results by asking the investigators that the results be available to you when the study is completed

Confidentiality:

During and after this research, your privacy will be protected to the maximum extent of the law. All information that refers to you, or can be identified with you will remain confidential to the maximum extent permitted by law. If you choose to sign this consent form, you are also giving consent to have the interview audio-taped, so that the researchers have complete and correct information from the interview. You may request at any time to have the taping stopped and you can refuse to be taped at all. All data, including audio-tapes, will be kept for three years and then destroyed.

Other than this form, all data will be identified only with a code number. A list linking your name to the code will be kept in a locked file for the duration of the study. Once all the data are collected and analyzed, the list linking the names to the code numbers will be destroyed.

Who to contact for answers: If there are any questions you have at any time about this research project or your participation in it, please contact one of the investigators:

Lorraine Weatherspoon, PhD, RD	OR	Deepa Handu, MS
334 A GM Trout FSHN Bldg.		301 GM Trout FSHN Bldg.
Michigan State University		Michigan State University
East Lansing, MI 48824		East Lansing, MI 48824

If you have questions or concerns regarding your rights as a study participant, or are dissatisfied at any time with any aspect of this study, you may contact (anonymously, if you wish) – Ashir Kumar, M.D., Chair of the University Committee on Research Involving Human Subjects (UCRIHS) by phone: (517) 355-2180, fax: (517) 432-4503, email: UCRIHS@MSU.EDU, or regular mail: 202 Olds Hall, Michigan State University, East Lansing, MI 48824.

Your participation in this project is voluntary: Your participation in this study is voluntary. If you wish, you may decline to participate, simply by telling the project investigator. If you decide to participate in this study, and later decide that you do not wish to continue, you may at any time withdraw your consent and stop participation. You decision not to participate, or to participate and later withdraw from the study will not in any way result in a penalty to you, or a loss of benefits to which you are otherwise entitled.

Your signature below indicates your voluntary agreement to participate in this study.

Print Name of the Subject: ____

______________________________________ ______________

Signature of Parent or Legal Guardian Date

______________________________________ ______________

Signature of the Research Participant Date

______________________________________ ______________

Signature of the Person obtaining consent Date

APPENDIX D

Interview Guide

ID number ___________ Date of Interview ___________

Demographic sheet

1. Date of birth______________

2. Gender: Male _________ Female ________

3. Education (of child)

    1. Attend school ____
    2. Does not attend school______
    3. Other: home school etc. _________

4. In what grade are you right now ______

5. Which of these groups would you say you and most of your family belong to?

a. White	b. African American
c. Hispanic	d. Asian
e. Native Hawaiian/Pacific Islander	f. American Indian, Alaska Native
g. Others, specify____	h. Do not know/Not sure
i. Multiracial but preferred race not asked	j. Refuse to answer

6. With whom do you live?

    a. Mom only _____
    b. Dad only _____
    c. Both mom and dad______
    d. Grandparents_______
    e. Others ________

7. Marital status (of parents)
Are you : 1. _____single 2. ____ married
3. ____ widowed 4. ____ divorced/separated

8. Employment status (of parents)
   a. Employed (full time) ______
   b. Employed (part time) ______
   c. Disabled, unable to work ______
   d. Homemaker ______
   e. Unemployed ______
   f. Retired ______
   g. Student ______
   h. Other (specify) ______

9. On a scale of 1 (very poor) to 5 (very rich), how would you describe your family's income/ money status:
   1. Very less money (very poor)
   2. Less money
   3. Enough money
   4. More than enough money
   5. Lots of money (very rich)

10. Since when have you had diabetes?

____

i. How often do you visit the doctor in a year?

____

MEDICATION

ii. Do you take insulin shots?
Yes(01) _____ No(02)_________ NA(3)_______

13a. Do you take diabetes tablets?
Yes (01) _____ No(02)_________ NA(3)_______

13b. Do you have any problems taking diabetes tablets when you are supposed to do so?
Yes (01) _____ No(02)_________ NA(3)_______

14c. What do you do if yes in 6b?
1. Take it later ________ 2. Wait until the next medicine time ________
3. Other (specify): __________

15. Other Medications? _________

MONITORING

16. How often do you check your blood sugar at home? ____________

17. Do you check it yourself? / Who helps you check your blood sugar?

____

18. What interferes with your blood sugar testing at home?

    a. I don't know how to do it
    b. It hurts
    c. I don't like it
    d. Other, specify _____________

Interview Questions based on research questions:

1) How do family/social factors facilitate or inhibit the management of diabetes?

Content	Interview questions
Structure	Who do you consider to be your family?
Family history of diabetes	Does anyone else in your family have diabetes? Or was there someone in your family who had diabetes?
Relationship with family	When you first found out you had diabetes, who in your family was helpful? Who in your family didn't understand? Can you give me an example? (Prompt- were they supportive of it? Did they help in your diabetes management? If so, how?) To whom do you turn for help or comfort when you need help with taking care of your diabetes?

2. How do the subjects values and behaviors influence self-care practices of diabetes?

Content	Interview questions
Behaviors	1. What has changed for you since you were diagnosed with diabetes? (diet, exercise, lifestyle) OR 1. How has having diabetes changed your life? (Prompt for mainly in terms of eating, sports, friends) OR 1. How has having diabetes changed things for you? 2.How has having diabetes changed how you act with friends? 3. What do you do differently now? (i.e. after being diagnosed with diabetes)
Beliefs/values	Who do admire and what do you admire most about them? What one quality would you like to have to make you "cool"? What are some of the things important to you now and why? Tell me one thing you do well about managing diabetes and Why? Is it important for you to manage your diabetes? Why?
Attitudes (barriers, facilitators)	What do you think is the best way for you to take care of yourself? Who in your family agree or disagree with you? What would you like to do to be healthy? What keeps you from taking care of yourself? What helps you in taking care of yourself?

3. How do institutions influence the aspects of diabetes self-care practices?

Content	Interview questions
Availability of resources (Physical education, medical assistance, dietary education)	Where and from where did you learn how to take care of yourself? From what organizations or groups do you get helpful information? What's been the most helpful resource or thing for you?
Barriers/ facilitators	What do you do on a daily basis to take care of yourself or your diabetes? Prompt for: exercise, medical care, diabetes education school. What are some of the difficulties in managing your diabetes? What are some things that helped you manage your diabetes? What do you think the role of diabetes centers/your doctor should be in helping you with your diabetes?

APPENDIX E

PHYSICAL ACTIVITY QUESTIONNAIRE

I. During the past week, how many times did you….

a) Do hobbies, such as collecting baseball cards, playing a musical instrument, reading, or doing arts and crafts?

   a. 0 – not at all
   b. 1 – 1 or 2 times
   c. 2 – 3 or 4 times
   d. 3 – 5 or > times
   e. 8 – don't know

   Duration - ______minutes

b) Watch television or videos, or play video games?

   i. 0 – not at all
   ii. 1 – 1 or 2 times
   iii. 2 – 3 or 4 times
   iv. 3 – 5 or > times
   v. 8 – don't know

   Duration - ______minutes

c) Go roller-blading, roller-skating, skate-boarding, or bicycling?

   i. 0 – not at all
   ii. 1 – 1 or 2 times
   iii. 2 – 3 or 4 times
   iv. 3 – 5 or > times
   v. 8 – don't know

   Duration - ______minutes

d) Play an active sport, such as baseball, softball, basketball, soccer, swimming, or football?

   i. 0 – not at all
   ii. 1 – 1 or 2 times
   iii. 2 – 3 or 4 times
   iv. 3 – 5 or > times
   v. 8 – don't know

   Duration - ______minutes

e) Exercise, such as jogging, walking, doing karate, jumping rope, doing gymnastics or dancing?

   i. 0 – not at all
   ii. 1 – 1 or 2 times
   iii. 2 – 3 or 4 times
   iv. 3 – 5 or > times
   v. 8 – don't know

   Duration - ______minutes

f) In your 24 – hour day how many hours do you spend sitting or lying down? Include time spent sleeping. _____________Hours

1. Do any of the following keep you from exercising as you think you should?

   1=YES   2= NO   NA= no applicable

i. Finding the time ______
ii. Finding a good place ______
iii. The inconvenience of going someplace and carrying equipment with me ______
iv. Problems with my health e.g. trouble seeing, heart condition, breathing problems _______
v. Forgetting _______
vi. Feeling sick _______
vii. Its too complicated _____
viii. Its too painful _______
ix. Being away from home (shopping, traveling etc.) ______
x. Changes in my routine ______
xi. The cost _____
xii. Special occasions (church, weddings, holidays, etc.) ______
xiii. Bad weather _____Other

Appendix F

24-Hour Diet Recall Protocol

- Record everything a person ate in a 24-hr period

- A list of WHAT, HOW, WHEN & WHERE food was consumed

  - Kind of food
  - Way it was prepared
  - How it was served
  - Portion size

Important to Include...

- Food

- Both meals & snacks
- All beverages (even water)

- Dietary supplements or vitamins & minerals

    - ***Include essentially everything that is eaten from a specific time period the day before until the same time the next day.***

Getting Started

- Break the ice

- Explain WHY the assessment is being done

- Reassure the subject this will be kept confidential

USDA Multiple Pass Method

- Three Main Passes

  - **Uninterrupted (Client talks): let them speak while you record**

  - **Food Details Probed (Interviewer talks)**

    - *Kind of food/beverage*
    - *Preparation of food*
    - *Portion size*
    - *How served*

- ***Review information with client; you are both talking here. Ask specific questions based on what they told you they ate.***

e. First Pass

- "What was the 1st thing you ate after you got up yesterday?
    - AVOID terms like breakfast or lunch
- Record only foods at this time; don't worry about portion sizes until later
- Allow extra space for adding things later
- Do NOT interrupt

f. Second Pass

- Your turn to talk
- Probe w/ open ended questions (How, What, Describe)
- Obtain 4 kinds of info about each food/beverage
- KIND OF FOOD/BEVERAGE
    - *Fresh, frozen, canned*
    - *Skim, 2%, whole*
- PREPARTION OF FOOD
    - *Fried or baked*
    - *Ingredients added*
- PORTION SIZE OF FOOD
    - *Participant may underestimate so use models or examples*
    - *Make sure EVERY item has some measuring unit*
- HOW SERVED
    - *Butter, gravy, or cream added?*
- If you are not sure about a food, ask the participant to describe it to you
    - For example, Joe tells you he has a Gatorade® every morning after breakfast
    - Find out what is Gatorade®…
        - *Is it a drink?*
        - *An energy bar?*
- Get details (color, ingredients, etc)
    - Your mom's BBQ is not going to be the same as his/her mom's
- Do not forget…
    - Condiments
    - Beverages
    - Alcohol
    - "Little bites" of food
- Frequently missed foods

g. Final Pass

- Review the day to them
- Ask the subject to tell you the time of day each food was eaten
- Ask if there are additions or corrections
- Record dietary supplement or vitamins/minerals
- "Do you have a problem with digesting fluid milk?" Yes or No
- "Was this a normal day?" Yes or No

Remember…

- Double check name on each dietary assessment form
- Check for completeness
- Remind them that they will be contacted again after the program

24- HOUR RECALL SHEET

TIME OF THE DAY	FOOD ITEMS	AMOUNT/ PORTION	WHAT WERE YOU DOING?	WHERE WERE YOU EATING?

Q 1. How many times/week do you eat meals with your family?

Q2. How many times/week do you eat breakfast?

APPENDIX G

University Committee on Research Involving Human Subjects (UCHRIS) Approval Letters

MICHIGAN STATE
UNIVERSITY

December 18, 2003

TO: Lorraine WEATHERSPOON
334 Trout FSHN Bldg
MSU

RE: **IRB# 03-829** CATEGORY: EXPEDITED 2-6, 2-7

APPROVAL DATE: December 16, 2003

EXPIRATION DATE November 16, 2004

TITLE: CHILDREN AND ADOLESCENTS DIAGNOSED WITH TYPE 2 DIABETES IN PEDIATRIC AND ADULT ENDOCRINOLOGY CLINICS IN MICHIGAN, GLYCEMIC CONTROL, AND ASSOCIATED FACTORS

The University Committee on Research Involving Human Subjects' (UCRIHS) review of this project is complete and I am pleased to advise that the rights and welfare of the human subjects appear to be adequately protected and methods to obtain informed consent are appropriate. Therefore, the **UCRIHS approved this project.**

RENEWALS: UCRIHS approval is valid until the expiration date listed above. Projects continuing beyond this date must be renewed with the renewal form. A maximum of four such expedited renewals are possible. Investigators wishing to continue a project beyond that time need to submit a 5-year application for a complete review.

REVISIONS: UCRIHS must review any changes in procedures involving human subjects, prior to initiation of the change. If this is done at the time of renewal, please include a revision form with the renewal. To revise an approved protocol at any other time during the year, send your written request with an attached revision cover sheet to the UCRIHS Chair, requesting revised approval and referencing the project's IRB# and title. Include in your request a description of the change and any revised instruments, consent forms or advertisements that are applicable.

PROBLEMS/CHANGES: Should either of the following arise during the course of the work, notify UCRIHS promptly: 1) problems (unexpected side effects, complaints, etc.) involving human subjects or 2) changes in the research environment or new information indicating greater risk to the human subjects than existed when the protocol was previously reviewed and approved.

If we can be of further assistance, please contact us at (517) 355-2180 or via email: UCRIHS@msu.edu. Please note that all UCRIHS forms are located on the web: http://www.humanresearch.msu.edu

Sincerely,

Peter Vasilenko, Ph.D.
UCRIHS Chair

PV: rt

cc: Deepa Handu
338 GM Trout FSHN Bldg

OFFICE OF
**ESEARCH
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NDARDS**
**ommittee on
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ian Subjects**
tate University
202 Olds Hall
st Lansing, MI
48824
517/355-2180
517/432-4503
lu/user/ucrihs
ihs@msu.edu

MICHIGAN STATE
UNIVERSITY

January 12, 2004

TO: Lorraine WEATHERSPOON
334 Trout FSHN Bldg
MSU

RE: **IRB #: 02-042** CATEGORY: 2-5 EXPEDITED

RENEWAL APPROVAL DATE: January 9, 2004

EXPIRATION DATE: December 9, 2004

TITLE: CHILDREN AND ADOLESCENTS DIAGNOSED WITH TYPE 2 DIABETES IN PEDIATRIC AND ADULT ENDOCRINOLOGY CLINICS IN MICHIGAN, GLYCEMIC CONTROL AND ASSOCIATED FACTORS

The University Committee on Research Involving Human Subjects' (UCRIHS) review of this project is complete and I am pleased to advise that the rights and welfare of the human subjects appear to be adequately protected and methods to obtain informed consent are appropriate. Therefore, the **UCRIHS APPROVED THIS PROJECT'S RENEWAL.**

This letter also notes approval for the the Waiver of Consent and Waiver of Authorization.

RENEWALS: UCRIHS approval is valid until the expiration date listed above. Projects continuing beyond this date must be renewed with the renewal form. A maximum of four such expedited renewals are possible. Investigators wishing to continue a project beyond that time need to submit a 5-year renewal application for complete review.

REVISIONS: UCRIHS must review any changes in procedures involving human subjects, prior to initiation of the change. If this is done at the time of renewal, please include a revision form with the renewal. To revise an approved protocol at any other time during the year, send your written request with an attached revision cover sheet to the UCRIHS Chair, requesting revised approval and referencing the project's IRB# and title. Include in your request a description of the change and any revised instruments, consent forms or advertisements that are applicable.

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If we can be of further assistance, please contact us at 517 355-2180 or via email: UCRIHS@msu.edu.

Sincerely,

Peter Vasilenko, Ph.D.
UCRIHS Chair

PV: rt

OFFICE OF
RESEARCH ETHICS AND STANDARDS

ersity Committee on Research Involving Human Subjects

chigan State University
202 Olds Hall
East Lansing, MI
48824

517/355-2180
FAX: 517/432-4503
w.msu.edu/user/ucrihs
Mail: ucrihs@msu.edu

Informed Consent Form

Participant/Guardian Consent Form

Children and Adolescents Diagnosed with Type 2 diabetes in Pediatric and Endocrinology Clinics in Michigan, Glycemic Control and Associated Factors.

Investigators: Lorraine Weatherspoon PhD, RD
(517) 355-8474 ext. 136

Deepa Handu MS
(517) 355-8474 ext. 164

Purpose: We invite you to participate in a research project designed to study the unique experiences and voices of youth with Type 2 diabetes regarding monitoring blood glucose, exercising regularly, dietary recommendations, food selection and eating patterns, social support, institutional support and the aspects of daily living that influence their diabetes self-management practices.

Type 2 diabetes mellitus (90-95% of all cases of diagnosed diabetes) has clearly been identified as a serious epidemic in our society, which can be prevented or ameliorated by self-managed lifestyle changes, especially diet and physical activity. Although the American Diabetes Association and other similar organizations have established target behaviors for management of the disease, the traditional medical model has been unsuccessful in effectively facilitating target behaviors. There is need for research that includes exploration of the individual's objectives and priorities for diabetes self-management education and care as they may differ from those of the health care team and published standards of care. This project will ask you questions about how you deal with diabetes management. Our purpose for this study is to learn more about your experiences so that we can be more helpful to families who have youth with the Type 2 diabetes.

Procedure/What you will be asked to do if you participate:

Your voluntary participation in this study will involve one meeting with the researcher which should take approximately 1- 1 ½ hours. We will be talking/discussing about doctor and health professional recommendations that help with blood sugar control and how easy or difficult it is to follow this advice and why. The procedures followed are: 1) you will be asked to participate in an interview with a researcher; and 2) A 24- hour dietary recall will be conducted by the researcher.

The purpose of this project is to help develop successful intervention for youth with Type 2 diabetes. Your participation in this research project is completely voluntary. You will continue to receive diabetes center services and medical care as you usually do whether or not you choose to participate in this research. You can refuse to answer any questions that you do not wish to answer. The interview or discussion will be audio-taped. The tape will be used for transcription purposes only and will be destroyed following transcription. Your name or any identifier will not appear on the transcription and will not be associated with the study findings in any way. You can withdraw your participation at any time. At the end of the interview, you will receive a $25 gift card to Meijer's/Best Buy/ Cash in appreciation for your participation. If for any reason, you decide to discontinue with the interview (dropout before it ends) you will only receive a pedometer in appreciation for your participation.

RISKS AND BENEFITS: There are no risks or discomforts associated with this research. You may feel tired during or after the evaluation. Some psychological discomfort may be experienced from revealing personal information or thinking about things that are related to you diabetes experiences. Keep in mind that you may take a break at any time and you can refuse to answer any questions that make you uncomfortable. There are no implied benefits for the participants in this study. However, the results from this study may be beneficial to youth who have Type 2 diabetes mellitus and their families in the future. If desired, you may learn of the study results by asking the investigators that the results be available to you when the study is completed

Confidentiality:

During and after this research, your privacy will be protected to the maximum extent of the law. All information that refers to you, or can be identified with you will remain confidential to the maximum extent permitted by law. If you choose to sign this consent form, you are also giving consent to have the interview audio-taped, so that the researchers have complete and correct information from the interview. You may request at any time to have the taping stopped and you can refuse to be taped at all. All data, including audio-tapes, will be kept for three years and then destroyed.

Other than this form, all data will be identified only with a code number. A list linking your name to the code will be kept in a locked file for the duration of the study. Once all the data are collected and analyzed, the list linking the names to the code numbers will be destroyed.

Who to contact for answers: If there are any questions you have at any time about this research project or your participation in it, please contact one of the investigators:

Lorraine Weatherspoon, PhD, RD
334 A GM Trout FSHN Bldg.

OR

Deepa Handu, MS
301 GM Trout FSHN Bldg.

Michigan State University
East Lansing, MI 48824

Michigan State University
East Lansing, MI 48824

If you have questions or concerns regarding your rights as a study participant, or are dissatisfied at any time with any aspect of this study, you may contact (anonymously, if you wish) – Ashir Kumar, M.D., Chair of the University Committee on Research Involving Human Subjects (UCRIHS) by phone: (517) 355-2180, fax: (517) 432-4503, email: UCRIHS@MSU.EDU, or regular mail: 202 Olds Hall, Michigan State University, East Lansing, MI 48824.

Your participation in this project is voluntary: Your participation in this study is voluntary. If you wish, you may decline to participate, simply by telling the project investigator. If you decide to participate in this study, and later decide that you do not wish to continue, you may at any time withdraw your consent and stop participation. You decision not to participate, or to participate and later withdraw from the study will not in any way result in a penalty to you, or a loss of benefits to which you are otherwise entitled.

Your signature below indicates your voluntary agreement to participate in this study.

Print Name of the Subject: ____

______________________________ ____________
Signature of Parent or Legal Guardian Date

______________________________ ____________
Signature of the Research Participant Date

______________________________ ____________
Signature of the Person obtaining consent Date

UCRIHS APPROVAL FOR
THIS project EXPIRES:

NOV 1 6 2004

SUBMIT RENEWAL APPLICATION
ONE MONTH PRIOR TO
ABOVE DATE TO CONTINUE

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REFERENCES

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