FACTORS ASSOCIATED WITH GLYCAEMIC CONTROL IN CHILDREN AND ADOLESCENTS WITH TYPE 1 DIABETES MELLITUS AT MUHIMBILI NATIONAL HOSPITAL, DAR ES SALAAM

By

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October 2011

CERTIFICATION

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DECLARATION AND COPYRIGHT

I, Mariam Nazir Noorani, declare that this dissertation is my own original work and that it has not been presented and will not be presented to any other University for a similar or any other degree award.

Signature …….

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DEDICATION

This work is dedicated to my father; in whose footsteps I hope to follow as a teacher

And

To all the children who suffer the burden of chronic diseases

ABSTRACT

Background: Type 1 Diabetes Mellitus (T1DM) is a rapidly growing problem in Tanzania and Africa as a whole. Its long term complications are devastating for individuals and families and impose a considerable burden to health care systems. Maintaining strict glycaemic control in type 1 diabetics has been shown to greatly reduce the incidence and progression of long term complications. Various risk factors have been found to be associated with poor glycaemic control. Children and adolescents with T1DM in Dar es Salaam have previously been found to have very poor glycaemic control and a high prevalence of chronic complications. Identification of factors associated with poor control in our setting is critical in order to institute appropriate interventions that will result in improved metabolic control and prevent chronic complications.

Objectives: To determine the mean glycaemic control and identify factors associated with poor control in children and adolescents with T1DM.

Materials and Methods: A cross sectional study was carried out at the diabetes clinic for children and adolescents at Muhimbili National Hospital. Children and adolescents attending the clinic were enrolled into the study after obtaining informed consent from the parent/guardian or assent from the adolescents themselves. A structured questionnaire was used to collect data from participants and parents/guardians. Glycaemic control was assessed by measurement of glycosylated haemoglobin (HbA1c). Data entry and analysis was done using Epi Info software version 3.5.1 and SPSS version 16.

Results: 75 participants were recruited into the study (51% males). The mean HbA1c was 11.1 ± 2.1%. Children aged < 10 years were found to have a significantly better glycaemic control (9.83%) as compared to 10 – 14 year olds (11.46%) and > 14 year olds (11.39%) (P value = 0.022). Sixty eight percent (68%) of patients had good adherence to insulin while good adherence to blood glucose monitoring regimen (BGM) and diet was 48% and 28% respectively. Younger children had better adherence to all treatment modalities and had optimal caregiver involvement in diabetes related tasks. Adherence to insulin injections was

better in children who had optimal caregiver involvement in the task of injecting insulin. Younger age, having the mother as the primary caregiver, better caregiver knowledge of T1DM, better adherence to blood glucose monitoring (BGM) regimen and diabetes duration of less than 1 year were associated with better glycaemic control.

In multivariate analysis, age of the child, adherence to BGM regimen and the mother as the primary caregiver were found to independently predict glycaemic control.(R^2 = 0.332, p value = 0.00). Sixty percent (60%) of children and adolescents reported a negative impact of T1DM on their daily lives. This was not related to glycaemic control.

Conclusions and Recommendations: Children and adolescents with T1DM in Dar es Salaam have very poor glycaemic control and poor adherence to treatment. Factors associated with poor control include older age, a caregiver other than the mother and poor adherence to BGM. There is also a high frequency of negative impact of the disease on daily life.

In order to improve metabolic control, more frequent BGM should be encouraged. Emphasis needs to be put on adherence counseling and active participation of caregivers in diabetes related tasks of their children. Close follow up of the adolescents is necessary as this group is the most vulnerable to poor control.

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ABBREVIATIONS

ADA	-	American Diabetic Association
BGM	-	Blood Glucose Monitoring
DCCT	-	Diabetes Control and Complications Trial
DKA	-	Diabetic Ketoacidosis
DM	-	Diabetes Mellitus
GADA	-	Glutamic acid decarboxylase antibodies
HbA1c	-	Glycosylated haemoglobin
IAA	-	Insulin autoantibodies
IA2A	-	Insulinoma antigen
ICA	-	Islet cell antibodies
IDF	-	International Diabetes Federation
MNH	-	Muhimbili National Hospital
MUHAS	-	Muhimbili University of Health and Allied Sciences
OGTT	-	Oral glucose tolerance test
SES	-	Socioeconomic status
T1DM	-	Type 1 Diabetes Mellitus
T2DM	-	Type 2 Diabetes Mellitus

1.0: INTRODUCTION AND LITERATURE REVIEW

1.1: BACKGROUND:

1.1.1: Definition and classification:

Diabetes mellitus (DM) is a group of metabolic diseases characterized by hyperglycaemia resulting from defects in insulin secretion, insulin action or both.(1) It is currently classified into 4 categories based on aetiology. These include type 1 diabetes mellitus (T1DM), type 2 diabetes mellitus (T2DM), gestational DM and other specific types which include drug or chemically induced DM.(1) T1DM is characterized by an absolute insulin deficiency and is the predominant type in children and adolescents. There seems to be a rise in the incidence of T2DM in this age group in the industrialized world due to the rising incidence of obesity.

1.1.2: Epidemiology:

The epidemiology of T1DM varies considerably based on geographic location. In the developed world, the prevalence has been found to be higher than that in Africa. However this may be due to higher diagnostic rates and surveillance in the developed world as compared to Africa.

In the USA, the estimated prevalence of diabetes (both T1DM and T2DM) in people younger than 20 years is 0.26%. This means that 1 in every 380 persons less than 20 years has diabetes. In the years 2002 – 2005, the annual incidence of T1DM was estimated at 19.7/100,000 in children < 10 years old and 18.6/100,000 in those between 10 and 20 years of age.(2)

In Europe, the annual incidence was found to be increasing in most countries from 1989 to 2003 with an overall annual increase of 3.9%. Highest incidence rates were found in Finland with an incidence of 52.6/100,000.(3)

In a study in Karnataka, India, the annual incidence was reported to be 0.32/100,000 per year based on a diabetes registry from 1995 to 2008.(4)

Few African studies have been done documenting the incidence and prevalence of T1DM, most of them being hospital based studies as opposed to population studies. The true

population prevalence hence remains unknown. Studies from North Africa have shown a varying incidence ranging from 4.4/100,000 in Algeria to 20/100,000 in Morocco.(5)

Only 2 countries from Sub Saharan Africa, Sudan and Tanzania, have documented the incidence of T1DM. In Sudan, the incidence increased from 9.5/100,000 in 1991 to 10.3/100,000 in 1995.(5)

In Tanzania, the incidence was estimated to be 1.5/100,000 per year.(6) This, however is data from 1991, follow up studies have not been done.

1.1.3: Pathophysiology of T1DM:

The absolute insulin deficiency in T1DM may result from an autoimmune destruction of the pancreatic beta cells that secrete insulin. Markers of this immune destruction include islet cell antibodies (ICA), insulinoma antigen 2 antibodies (IA2A), autoantibodies to insulin (IAA) and autoantibodies to glutamic acid decarboxylase (GADA). In Tanzania, it was found that 29.8% of type 1 diabetics had GADA and 21.3% had IA2A.(7) A study from Tunisia however found a higher prevalence of autoimmune markers with 90.7% having 1 or more autoantibodies.(8)

The autoimmune destruction has genetic predisposition as well as environmental influences. Some of the environmental risk factors that have been implicated include viral infections like enterovirus infection during pregnancy and early exposure to allergens such as cow's milk protein. These patients are also found to have other autoimmune diseases including hashimoto's thyroiditis, graves' disease and vitiligo. Breastfeeding and vitamin D supplementation have been found to be protective.(9)

Another form of T1DM is characterized as being idiopathic where there is an absolute insulin deficiency but no evidence of autoimmunity (type 1b). This type is thought to be more prevalent in patients of African and Asian origin.

Insulin is an essential hormone in the intermediary metabolism of carbohydrates. It is essential to facilitate glucose entry into most body cells; it also inhibits catabolism of fats and protein.

Deficiency results in failure of glucose utilization by most tissues and hyperglycaemia. Peripheral fat stores are catabolized with production of ketone bodies.

1.1.4: Clinical features and complications of T1DM:

The clinical features of T1DM arise due to hyperglycaemia, glycosuria and ketoacidosis. The patient presents with the classical symptoms of diabetes i.e. polyuria, polydypsia and weight loss. Other non specific features include malaise, headache and weakness. Some patients may present with Diabetic ketoacidosis (DKA) as the initial presentation. This manifests as dehydration, vomiting, abdominal pain, acidotic breathing, drowsiness and coma. In Tanzania, DKA was found to be the presenting feature in 75% of diabetic children and adolescents.(10)

The biochemical alterations in T1DM result in both acute and chronic complications. Acute complications include DKA and hypoglycaemia while chronic complications include retinopathy, neuropathy, nephropathy, growth disturbances, cardiovascular disease and diabetic foot ulceration. Most of the chronic complications are attributed to the non enzymatic glycosylation of protein residues in nerves, blood vessels and renal glomeruli.

The age of onset of chronic complications in T1DM is variable. In Tanzania, the prevalence of retinopathy was found to be 22.2% in children and adolescents with a higher frequency in the pre – pubertal age group. Microalbuminuria which is a marker of nephropathy had a prevalence of 29.3%.(10)

1.1.5: Diagnosis of T1DM:

Current guidelines by the American Diabetes Association (ADA) recommend making a diagnosis of DM based on any of the following criteria(1):

1. HbA1c $\geq$ 6.5%
2. Fasting plasma glucose $\geq$ 126 mg/dl (7.0 mmol/l). Fasting is defined as no caloric intake for at least 8 hours.
3. 2-hour plasma glucose $\geq$ 200 mg/dl (11.1 mmol/l) during an OGTT.
4. In a patient with classic symptoms of hyperglycemia or hyperglycemic crisis, a random plasma glucose $\geq$ 200 mg/dl (11.1 mmol/l).

The current World Health Organization (WHO) guidelines published in 2006 in consultation with the International Diabetes Federation (IDF) recommend using fasting plasma glucose of ≥ 7 mmol/l or a 2 hour plasma glucose of ≥ 11.1 mmol/l during an OGTT as diagnostic criteria.

1.1.6: Management of T1DM:

The mainstay of managing T1DM is diabetes education and insulin which is needed for survival due to the absolute deficiency seen in these patients. Current recommendations stress on the use of intensive insulin therapy which can either be administered by a continuous subcutaneous insulin infusion (CSII) or use of multiple insulin injections (3 – 4 injections per day of basal and prandial insulin).(11) Dietary and lifestyle modification also play an important role in the management.

1.1.7: Glycaemic control in T1DM:

Strict glycaemic control has been shown to reduce the long term complications of both type 1 and type 2 DM. This was observed in DCCT (Diabetes Control and Complication Trial), the landmark trial in type 1 diabetics which showed that intensive diabetes treatment delayed the onset and slowed the progression of chronic complications of T1DM such as nephropathy, neuropathy and retinopathy.(12)

Glycaemic control is routinely monitored by the use of glycosylated haemoglobin (HbA1c). This is the percentage of haemoglobin attached to a glucose moiety. It is formed by the non enzymatic linkage of glucose to the lysine and valine residues in the globin chain of hemoglobin. It measures the glycaemic control over the preceding 2 – 3 months which is the average life span of the RBC's. The normal level of HbA1c is < 6.5% of the total haemoglobin concentration.

In diabetics, current recommendations of the optimum value of HbA1c depend on the age group. The risk of hypoglycaemia has to be weighed against the benefits of strict glycaemic control especially in young children. The developing brain of infants and young children is very vulnerable to the detrimental effects of hypoglycaemia. In addition, infants and young

children exhibit hypoglycaemia unawareness because of the inability to communicate symptoms and a poor adrenergic response to low blood sugar. Hence it is recommended that their HbA1c be maintained at a higher level than the DCCT recommendations of < 7%. For children less than 6 years, the ADA recommends an HbA1c of between 7.5 and 8.5%. For those between 6 and 12 years, a level of < 8% is recommended while for those > 12 years, a level of < 7.5% is considered optimal. This is 0.5% higher than the recommendation for adults with T1DM because adolescence is a period of hormonal changes and achieving a lower HbA1c may be difficult.

HbA1c has its limitations for use as a marker of glycaemic control. Of importance is that it is not a reliable indicator in patients with severe anaemia giving falsely low readings. This potentially reduces its usefulness in sub-Saharan Africa where iron deficiency anaemia and other hemolytic anaemias like sickle cell anaemia are endemic.

There exists a wide variation in glycaemic control between Africa and the developed world. Studies from Africa have shown consistently poor glycaemic control in type 1 diabetics. In Sudan, the median HbA1c was reported to be 9.8% at puberty while a study done by Majaliwa et al in Tanzania reported the mean HbA1c to be 10.65%.(10) This poor control was attributed to lack of insulin supply, poor storage of insulin, inadequate dosing and lack of BGM.

Comparatively, data from Australia showed a median HbA1c of 8.2% (13) while in a study from France, the mean HbA1c was found to be 8.97%.(14) In a study in Denmark, the mean HbA1c dropped from 9.05% in 1997 to 8.2% in 2006.(15)

1.2: LITERATURE REVIEW:

1.2.1: Factors associated with glycaemic control:

In view of the benefits of strict glycaemic control, numerous studies have been done to explore variables that may be associated with poor control. Most of these studies however are from Europe and North America with minimal data available from Asia and the African continent. Some of the factors include:

1.2.1.1: Socioeconomic status: Socioeconomic variables such as family income, level of maternal education and family structure have been found to be predictors of glycaemic control. A study from Argentina found that single parent families and low levels of maternal education were predictive of poor glycaemic control.(16) Similarly, a study from the UK found that patients from deprived areas had poorer glycaemic control as compared to those from affluent areas.(17) In a study by Overstreet et al in USA, children from lower socioeconomic status were found to have an average glycaemic control which was 2.2% higher than those of middle SES and they also had higher incidence of hypoglycaemic blackouts.(18) A study from Belgium found parental marital and professional status to predict glycaemic control.(19) A study comparing glycaemic outcomes in children from single mother and 2 parent families found that those from single mother families had an average HbA1c of 1.2% higher than those from two parent families.(20) This was attributed to the fact that single mothers had lower levels of education and lower SES.

1.2.1.2: Family environment: Family support and involvement of parents and guardians in the care of diabetic children and adolescents has been found to promote adherence and hence result in better glycaemic control. A study by Anderson et al to investigate relationships between parental involvement in diabetes related tasks and glycaemic control found that more parental involvement in BGM improved adherence and this translated to better glycaemic control.(21) A study from Portugal found that support for female diabetics and those of lower social class resulted in higher adherence and better metabolic control while family conflict predicted poor glycaemic control in patients of upper social class.(22) In a study among Hispanic youth, better adherence was associated with lesser adolescent independent responsibility and more family support for diabetics.(23)

1.2.1.3: Insulin dose: The dose of insulin has been found to be associated with level of glycaemic control. Studies from Australia, New Zealand and France found a higher dose of insulin per kg body weight to be associated with poor glycaemic control.(13, 14, 24) However, a study from Sudan demonstrated no difference in glycaemic control with a higher dose of insulin.(25)

1.2.1.4: Age and duration of diabetes: Age of the patient, age at onset of DM and diabetes duration have been found to be significantly associated with glycaemic control. Older age and longer duration of DM was associated with poorer control in studies from UK and France. (14, 17) However, age was not associated with poor control in studies from Australia and New Zealand.(13, 17, 24) A study from Sudan showed an inverse relationship; with older age and longer duration of diabetes being associated with better control.(25) Possible explanations for this were that older patients with longer duration of DM may have more knowledge and experience to deal with their diabetes.

1.2.1.5: Adherence: Adherence to the treatment regimen has been found to play a major role in promoting optimal glycaemic control. A recent meta analysis by Hood et al of studies in type 1 diabetic children and adolescents demonstrated a negative correlation between adherence and HbA1c levels and this was found to be independent of socio demographic and other diabetes specific variables.(11) Mehta et al demonstrated that greater dietary adherence was associated with lower HbA1c levels in youth with diabetes.(26)

1.2.1.6: Blood glucose monitoring: Self monitoring of blood glucose is recommended 3 to 4 times a day for diabetics on intensive treatment.(11) Less frequent blood glucose monitoring has been found to be a predictor of poor glycaemic control.(13, 14) A study in Denmark showed improved glycaemic control with more frequent self monitoring of blood glucose.(15) Similarly, in Sudan, self monitoring in type 1 diabetics was associated with significantly better glycaemic control.(27)

1.2.1.7: Diabetes knowledge: Knowledge of diabetes and attitude of parents and care givers towards the care of children with diabetes have been found to predict glycaemic control. Better caregiver knowledge results in lower HbA1c levels as demonstrated by Tahirovic et al in Bosnia and Stallwood et al in USA.(28, 29) Similarly, Butler et al found that higher parental diabetes knowledge and less parental perceived burden towards the care of diabetic children were predictive of lower HbA1c levels.(30) In India, however, it was found that a planned educational intervention program on the knowledge, attitude and practices of type 1 diabetics

resulted in significant improvements in the knowledge and attitude but no change in the practice domain and hence no improvement in HbA1c levels.(31)

2.0: PROBLEM STATEMENT:

T1DM mellitus is a growing problem in sub-Saharan Africa. However, it has not been a research priority having been overshadowed by the burden of communicable and infectious diseases. The World Health Organization (WHO) recognizes that developing countries now face a double disease burden with the risks of both communicable and non communicable diseases. The non communicable diseases are being increasingly recognized as a major contributor of morbidity and mortality.

In Tanzania, existing evidence shows that type 1 diabetics have very poor glycaemic control and suffer from the chronic complications of diabetes at a very early age. However, no studies have been done to describe the risk factors associated with poor glycaemic control. Studies from different parts of the world have found a variety of risk factors that predict poor glycaemic control. Whether similar variables play a role in Tanzania and in other similar resource poor settings remains to be determined.

3.0: STUDY RATIONALE:

This study was done to identify the factors associated with glycaemic control in children and adolescents with T1DM in Dar es Salaam. The findings from this study will provide valuable information to guide targeted interventions aimed at improving glycaemic control in this country as well as in the region hence reducing the risk of complications at a young age.

In addition, this study will motivate further research into the field of diabetes in sub Saharan Africa and help improve the overall care and the quality of life in patients with T1DM.

4.0: OBJECTIVES:

4.1: Broad Objective:

To determine factors associated with glycaemic control in children and adolescents with T1DM mellitus in Dar es Salaam.

4.2: Specific Objectives:

1. To determine the mean glycaemic control in children and adolescents with T1DM at MNH in Dar es Salaam.
2. To determine socio demographic risk factors (age, sex, BMI, family structure, primary care giver and caregiver education) associated with glycaemic control in children and adolescents with T1DM.
3. To determine diabetes specific risk factors (duration of diabetes, insulin dose, insulin regimen, diabetes knowledge, adherence, care giver involvement in diabetes related tasks) associated with glycaemic control in children and adolescents with T1DM.
4. To describe the impact of T1DM on the daily life of children and adolescents and its association with glycaemic control.

5.0: METHODOLOGY:

5.1: Study design:

Cross sectional study.

5.2: Study population:

The target population was all children and adolescents up to 18 years inclusive attending the diabetes clinic at MNH, Dar es Salaam.

5.3: Study site and management of patients at the clinic:

This study was carried out at the diabetes clinic for children and adolescents at MNH in Dar es Salaam. This clinic runs once every week on Monday. Patients are managed by a team of 2 nurses, 2 paediatricians trained in endocrinology and 3 support staff. As of February 2011, 90 children and adolescents up to 18 years of age were registered at the clinic.

All children and adolescents attending the clinic are provided with insulin at no cost through the International Diabetes Federation (IDF) Life for a child program. In addition, they are provided with glucose monitors, strips and diaries for self monitoring and recording of blood glucose at home. They are encouraged to monitor their glucose at least 3 times a week at

specified times and to record the readings in their diaries. The blood glucose levels are then used by the clinicians to alter the insulin regimen appropriately.

The patients are either on a 2 daily injection regimen or on a multiple insulin dose regimen. The 2 daily injections consist of soluble and long acting insulin injected twice a day while the multiple insulin dose regimen consists of soluble insulin administered 3 times a day prior to main meals and NPH (lente, long acting) insulin once or twice a day.

On the first visit to the clinic, baseline lipid profiles, HbA1c, serum creatinine, thyroid function tests (TSH and fT4) and ophthalmologic examination are done for all patients. Thereafter, HbA1c is measured for all patients every 3 – 6 months and the other parameters are repeated yearly. Patients and guardians are also given diabetes education and advice on appropriate nutrition.

The nutritional guidelines given at the clinic consist of 3 components:

1. Meal frequency: 3 main meals and 3 snacks per day.
2. Meal content: carbohydrates, proteins and vitamins may be consumed with reduction of carbohydrate amount to two thirds of that usually eaten and an increase in vegetable quantity. Fruits may be consumed but only a portion of a fruit up to 3 times a day.
3. Forbidden foods: these include soft drinks, fruit juices (both homemade and commercial), candies, added sugar, honey, animal fat.

5.4: Study duration:

This study was carried out from October 2010 to March 2011.

5.5: Inclusion criteria:

1. Children and adolescents with T1DM up to 18 years inclusive.
2. Informed consent by the parents/guardians or assent by the adolescent.

5.6: Exclusion criteria:

1. Newly diagnosed type 1 diabetes or those on insulin treatment for less than 3 months.
2. Those who did not make any clinic visit during the study period.

5.7: Sample size calculation and recruitment of study participants:

The sample size was calculated using the formula for 2 independent means with equal group sizes:

$$(z_{1-\alpha/2} + z_{1-\beta})^2 \left\{ \frac{s_0^2}{n_0} + \frac{s_1^2}{n_1} \right\} = (\mu_1 - \mu_0)^2$$

Where:

α: type 1 error rate

β: type 2 error rate

s_1: standard deviation of the sample in group 1

s_2: standard deviation of the sample in group 2

n_0: sample size in group 1

n_1: sample size in group 2

μ_1: mean in group 1

μ_2: mean in group 2

Sample size was calculated based on the study by Anderson et al (21), who found that poor adherence to BGM resulted in a higher mean HbA1C of 1.6%, and estimating a ratio of 2:1 for poor versus good adherence. The type 2 error rate was fixed at 0.2 giving a power of 80%. The sample standard deviation for HbA1C was estimated at 2.52. This was based on data from the pediatric diabetic clinic of MNH from the year 2008. The sample size thus computed was 100 participants after adjusting for a 10% dropout rate.

However, the MNH clinic for diabetes did not have enough patients to meet this sample size and this clinic is the only centre for pediatric and adolescent diabetes in the region. Therefore,

all available and eligible children and adolescents at the MNH clinic were recruited into the study.

All children and adolescents attending the clinic who met the inclusion criteria were serially enrolled into the study after obtaining written informed consent from the parent/guardian. Those who came without a parent/guardian were encouraged to come with one during the subsequent visit. Adolescents who were unable to come with a parent/guardian were enrolled after obtaining assent. On average, five participants were enrolled every Monday until all eligible and available participants were recruited.

5.8: Data collection and instruments:

Data was collected by the Principal investigator using a structured questionnaire. (Appendix 1) This was administered to the child and caregiver together for children less than 10 years. For children greater than 10 years, one section of the questionnaire assessing diabetes knowledge was administered separately to the child and parent/guardian. The questionnaire was translated into Kiswahili (Appendix 2) and had the following 5 components:

1. Sociodemographic and background information
2. Diabetes knowledge of children/adolescents and caregivers
3. Diabetes related practices
4. Availability of insulin
5. Impact of T1DM on daily life

5.8.1: Sociodemographic and background information: This included age, gender, diabetes duration, insulin dose, family structure, primary caregiver and level of caregivers' education.

5.8.2: Diabetes knowledge of children and adolescents and their care givers: This was assessed by use of the Michigan Diabetes Research and Training Center's brief diabetes knowledge test.(32) This is a multiple choice questionnaire which was modified and translated into Kiswahili. A total of 14 questions out of the 23 item questionnaire were used. 9 questions

were omitted because they were not applicable to our patient population. The results of the test were scored based on percentage of correct responses.

5.8.3: Diabetes related practices: The practices evaluated were adherence, caregiver involvement in diabetes related tasks and insulin storage.

5.8.3.1: Insulin adherence: This was determined by the number of insulin doses missed in the last 1 week: none, between 1 and 3 and greater than 3 doses. Adherence was then graded as:
Good – no missed doses
Average – between 1 and 3 missed doses
Poor - > 3 missed doses

5.8.3.2: Dietary adherence: This was assessed by use of a 24 hour dietary recall. All meals and snacks eaten in the last 24 hours prior to the clinic visit were documented and adherence was graded based on a score derived from the dietary guidelines given at the clinic:

Dietary adherence score:

Component:	**Score**
Meal frequency:	
3 meals and 3 snacks OR 3 meals and 2 snacks	4
3 meals and 1 snack	3
3 meals only	2
< 3 meals	1
Meal content: (lunch and dinner)- score each meal separately then divide by 2	
All components (carbohydrates, proteins, vegetables)	4
Carbohydrates and vegetables	3
Carbohydrates and protein	2
Only carbohydrates	1
Forbidden foods: Each time a forbidden food is consumed	-1

Interpretation:
Maximum score: 8
< 4 – poor
4 – 6 – average
> 6 – good

5.8.3.3: BGM adherence: This was classified as: 3 or more times a week, 1 – 2 times a week or none. This was subsequently graded as:

Good - ≥ 3 times a week

Average – 1 – 2 times a week

Poor - none

5.8.3.4: Family involvement in diabetes related tasks: The level of involvement of parents or caregivers in insulin administration and blood glucose monitoring was assessed by using a scale graded as minimal, moderate or optimal involvement. This was modified from the scale used in the study by Anderson et al.(21)

Involvement in insulin injections was determined by the number of doses in the last 24 hours injected or supervised by the caregiver.

Involvement	**Number of injections supervised in the last 24 hours**
Minimal	None
Moderate	1 - for those on a 2 injection regimen 1 or 2 - for those on a multiple dose regimen
Optimal	All injections

Involvement in BGM was determined by the degree of participation of the caregiver in the task.

Involvement	Participation of caregiver
Minimal	No participation
Moderate	Reminds the child to check blood glucose Enters glucose level in the diary Asks child about the blood glucose level
Optimal	Sets up the meter Does the finger prick Supervises the task

5.8.3.5: Method of insulin storage: This was classified as refrigeration, storage in a pot of cold water or storage at room temperature.

5.8.4: Availability of insulin: This was assessed by determining the frequency of missed insulin supplies from the hospital in the last 3 months prior to the study. This was classified as never missed, missed every month or once or twice in 3 months. The ability to purchase insulin if unavailable at the clinic was also determined.

5.8.5: Impact of diabetes on daily life: This was determined by specific questions on missed school days and hindrance to participation in sports. In addition, free conversation with the parent/caregiver and child/adolescent was undertaken to reveal any other impact.

5.9: Lab investigation:

Glycaemic control was determined by measurement of glycosylated hemoglobin levels (HbA1c). This was determined on all children and adolescents from January to March 2011. Blood was obtained by finger prick using a sterile lancet after cleansing the skin with an 70% alcohol swab. This was collected using a capillary tube which was then entered into a reagent cartridge. The cartridge was inserted into the analyzer which is a DCA 2000 + machine. Automated results were read from the machine after a processing time of six minutes.

Quality control of the DCA 2000 + analyzer was done routinely after analysis of 10 blood samples. Each set of 10 reagent cartridges has a Quality control card which was used to measure the quality control.

5.10: Weight and height measurements:

Each participant was weighed in order to accurately determine the insulin dose per kilogram body weight and to calculate the body mass index (BMI). This was done using a seca scale with the patient having light clothes and no shoes. Weight was measured up to the nearest 100 grams.

Height was measured using a standard height board with the participant having no shoes. The head piece was gradually lowered until it reached the patients head and was at a 90˚ angle with the measuring scale. The measurement was then taken to the nearest1 cm.

5.10: Research assistants and training:

A nurse at the clinic and 1 member of the support staff were selected as research assistants for this study. They were trained on how to use the weight and height scales accurately as well as on use of the HbA1c analyzer. They assisted in measurements of weights and heights of the study participants and measuring the level of HbA1c.

5.11: Piloting the questionnaire:

This was carried out for two weeks prior to actual data collection to test the effectiveness of the questionnaire. Questions which were misunderstood were corrected so as to bring out the intended information.

5.12: Data analysis:

Data was entered, cleaned and analyzed using Epi Info software version 3.5.1 and SPSS (Software Package for Statistical Sciences) version 16. Patients' socio demographic characteristics and diabetes specific variables were summarized using frequency distribution tables. Mean and median was calculated for continuous data. Association between variables was tested by use of chi square and fishers' exact tests. Means were compared using students' t test and ANOVA (analysis of variance). Multivariate linear regression analysis was

performed to determine factors independently associated with glycaemic control. A p value of less than or equal to 0.05 was considered statistically significant.

6.0: ETHICAL CONSIDERATIONS AND CLEARANCE:

The aims of the study and expected outcomes and utility of knowledge derived from this study was explained to patients and guardians. Study participants were enrolled after obtaining written informed consent from the guardian or assent from the adolescent in the absence of a guardian.

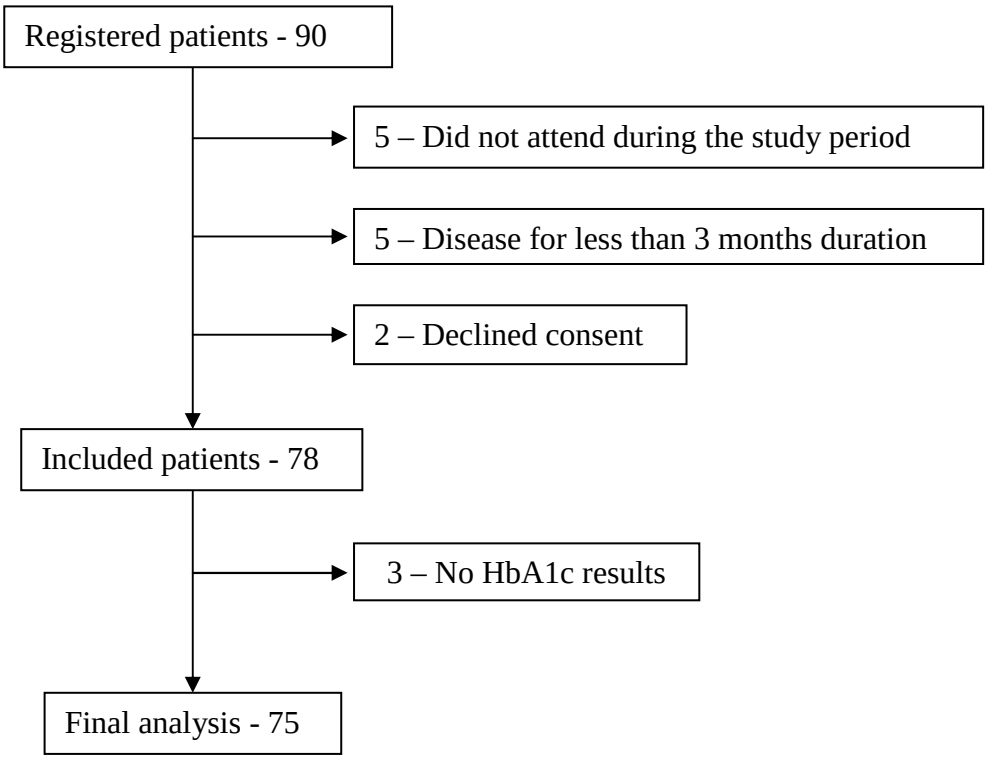
All data collected during the study was treated with strict confidence. HbA1c values were communicated to the patients/guardians and the results explained to them.

Ethical clearance to carry out this study was obtained from the Research and Publications Committee of MUHAS and The Director of Clinical Services of MNH.

7.0: RESULTS:

During the study period (October 2010 to March 2011), 90 children and adolescents aged up to 18 years inclusive were registered at the clinic. The flow diagram of the study population is shown in figure 1. Three participants did not attend the clinic during the period of measuring HbA1c and were excluded from final data analysis.

FIGURE 1: FLOW DIAGRAM OF STUDY PARTICIPANTS



The calculated power of this study having 75 participants was 72.5%.

Twelve (12) adolescents were unable to come along with the primary caregiver; hence the parent component of the diabetes knowledge test was not administered.

The mean age was 13.37 ± 3.9 years (median: 14.08, range: 3.5 – 18.9 years) with an almost equal sex distribution (50.7% males). Thirty eight (50.7%) children were > 14 years of age. Most of the children (68%) were on a multiple daily insulin injection regimen. The socio demographic and diabetes specific characteristics of study participants are summarized in table 1.

TABLE 1: SOCIODEMOGRAPHIC AND DIABETES SPECIFIC CHARACTERISTICS OF PATIENTS

Characteristics	Frequency		Median (range)
	N = 75	%	
Age (years)			14.1(3.5, 18.9)
<10	17	22.7	
10 – 14	20	26.7	
>14	38	50.7	
Sex			
Male	38	50.7	
Female	37	49.3	
BMI (kg/m^2)			17.8(12.1, 26.7)
<18.5 (underweight)	41	54.7	
18.5 – 25 (normal)	30	40.0	
>25 (overweight)	4	5.3	
Family structure			
2 parent family	47	62.7	
Single parent	17	22.7	
Not living with parents	7	9.3	
Orphan	4	5.3	
Primary caregiver			
Mother	50	66.7	
Father	10	13.3	
Sibling	5	6.7	
Other	10	13.3	
Caregiver education			
No formal education	7	9.3	
Primary	39	52.0	
Secondary	13	17.3	
Tertiary	16	21.3	
Duration of DM (years)			3.17(0.33,11.2)
<1	10	13.3	
1 - 5	46	61.3	
>5	19	25.3	
Insulin dose (units/kg body wt/day)			1.0(0.24,2.0)
Insulin regimen			
2 daily injections	24	32.0	
Multiple daily injections	51	68.0	

The mean HbA1c was **11.05 ± 2.11%.** There was no difference in the mean HbA1c between males and females. However, children in the younger age group (<10 years) had a significantly lower mean HbA1c as compared to the older children.

Children with mothers as the primary caregivers had a significantly lower mean HbA1c as compared to those whose caregivers were a father, a sibling or another family member. The family structure of the patient and the education level of the caregiver were not significantly associated with glycaemic control. (Table 2)

TABLE 2: ASSOCIATION BETWEEN SOCIODEMOGRAPHIC CHARACTERISTICS OF PATIENTS AND HbA1c

Characteristics	**Mean HbA1c (% ± 2SD)**	**P value**[1]
Age group		
<10years	9.83 ± 1.99	0.022[2]
10 – 14 years	11.46 ± 2.09	
>14 years	11.39 ± 2.02	
Sex		
Male	11.03 ± 2.28	0.907
Female	11.08 ± 1.96	
BMI		
< 18.5	11.15 ± 2.21	0.560
18.5 – 25	11.07 ± 2.05	
> 25	9.95 ± 1.48	
Family structure		
2 parent family	10.89 ± 2.07	0.377
Other	11.34 ± 2.20	
Primary caregiver		
Mother	10.67 ± 2.07	0.025[2]
Other	11.82 ± 2.03	
Caregiver education		
None/Primary	11.27 ± 2.11	0.26
Secondary/tertiary	10.71 ± 2.11	

[1] Calculated using students' t test and ANOVA

[2] Statistically significant

Pair-wise analysis of age groups was done after applying bonferroni adjustment to the P value to reduce the error of multiplicity (P value = 0.05/3 = 0.017). The mean HbA1c was significantly lower in the age group < 10 as compared to age group 14 – 18 (p value = 0.012). (Table 3)

Shorter duration of disease was associated with significantly lower HbA1c levels. Children who had T1DM for less than 1 year had a mean HbA1c that was 2% lower than those with disease for a longer duration (p value = 0.011). Pair-wise analysis is shown in table 3. The median HbA1c in those with duration of < 1 year was 9.5% with a narrow range between 8.1 and 10.1% (Figure 2).

FIGURE 2: HbA1c DISTRIBUTION BY DURATION OF DIABETES

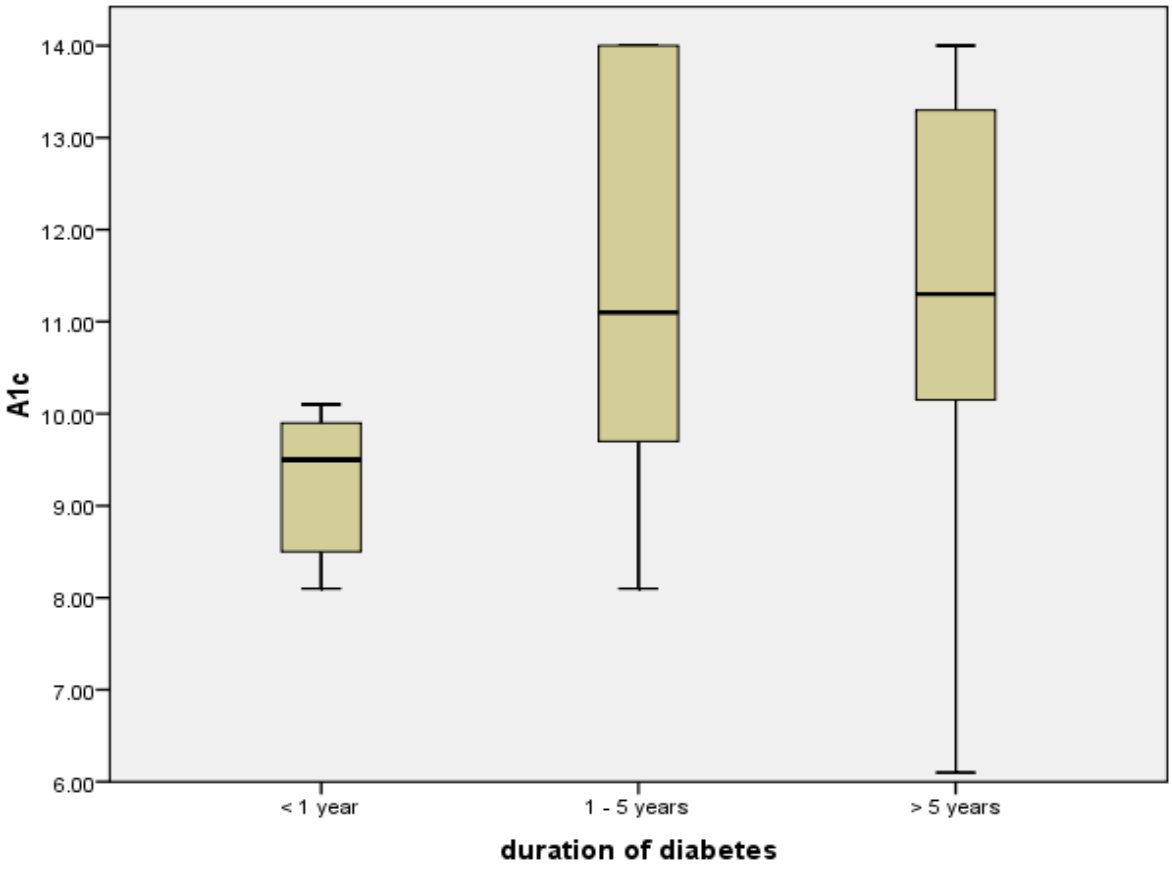


TABLE 3: PAIR-WISE ANALYSIS OF HbA1c BY AGE OF PATIENT AND DURATION OF DIABETES

	Mean HbA1c (% ± 2SD)	P value[1]
Age groups:		
< 10 years	9.83 ± 1.99	0.02
10 – 14 years	11.46 ± 2.09	
< 10 years	9.83 ± 1.99	0.012[2]
14 – 18 years	11.39 ± 2.02	
Duration of DM:		
< 1year	9.23 ± 0.78	0.002[2]
1 – 5 years	11.37 ± 2.06	
< 1 year	9.23 ± 0.78	0.013[2]
>5 years	11.24 ± 2.31	

[1] Calculated using student's t test

[2] Statistically significant at p value < 0.017

The insulin regimen used did not influence the HbA1c. Children who were on the multiple daily insulin injection regimen had an equal mean HbA1c as compared to those who were on 2 daily injections. (P value 0.9)

The mean daily dose of insulin/kg body weight/day was 1.06 ± 0.38 (table 1). This did not differ significantly with the duration of diabetes. However, there was a significant dose difference with age. The mean daily dose was lowest in those greater than 14 years (P value = 0.03). The mean daily dose was significantly lower in those on 2 daily injections as compared to those on a multiple dose regimen (p value = 0.0004) (Table 4)

TABLE 4: DAILY DOSE OF INSULIN IN PATIENTS

	Mean daily dose (U/kg/day ± 2SD)	P value[1]
Age		
<10 years	1.01 ± 0.32	0.03[2]
10 – 14 years	1.25 ± 0.45	
>14 years	0.98 ± 0.33	
Duration of DM		
<1 year	0.92 ± 0.22	0.455
1 – 5 years	1.08 ± 0.41	
>5 years	1.1 ± 0.37	
Insulin regimen		
2 daily injections	0.86 ± 0.24	0.000[3]
Multiple daily injections	1.16 ± 0.4	

[1] Calculated using students' t test

[2] Pair-wise analysis shows a significant difference between 10 – 14 years and > 14 years at a significance level of 0.017 (p value = 0.013).

[3] Statistically significant

The mean diabetes knowledge score of parents/caregivers was 70 ± 15%. The scores showed an increasing trend with increase in duration of diabetes, though this was not significant. Mean parent knowledge scores were higher for children < 10 years as compared to older children.

Assessment of diabetes knowledge of the adolescent revealed a mean score of 70.3 ± 15.9%. Caregivers of children less than 10 years old had significantly higher knowledge scores as compared to those of older children. The mean scores were also higher in those who had diabetes for a longer duration but this did not show statistical significance. The assessment of diabetes knowledge is summarized in table 5.

TABLE 5: DIABETES KNOWLEDGE SCORES OF CHILDREN AND CAREGIVERS

	AGE GROUPS			
Mean knowledge scores	**< 10 years**	**10 – 14 years**	**>14 years**	**P value[1]**
Parent	78.17 ± 11.65	67.6 ± 18.52	66.38 ± 12.18	0.025[2]
Child	-	64.65 ± 15.51	73.32 ± 15.5	0.06
	DIABETES DURATION			
Mean knowledge scores	**<1 year**	**1 – 5 years**	**>5 years**	**P value[1]**
Parent	62.43 ± 24.3	69.74 ± 13.19	73.53 ± 14.2	0.259
Child	59.5 ± 12.57	69.44 ± 14.95	76.38 ± 17.34	0.072

[1] Calculated using ANOVA

[2] Statistically significant

Simple linear regression analysis found diabetes knowledge of caregivers to be significantly associated with HbA1c. (r^2= 0.07, p value = 0.036). Knowledge of children was not associated with HbA1c (p value = 0.868)

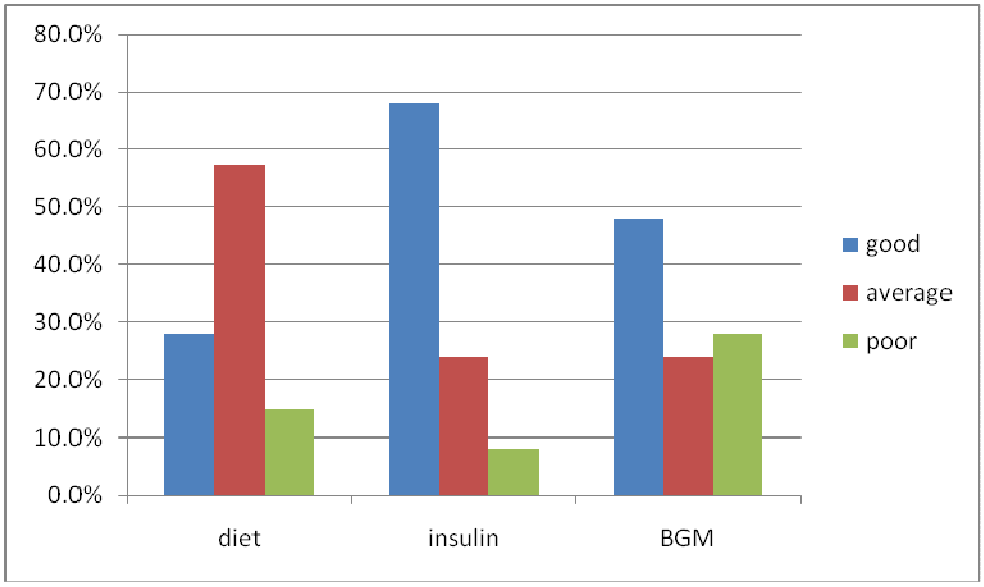
Only 22% of caregivers and 29% of children > 10 years had knowledge about HbA1c and its importance in the management of T1DM. The education level of the caregiver was not related to HbA1c knowledge ($\chi 2$ = 2.293, p value = 0.13). Knowledge of HbA1c was not significantly associated with glycaemic control.

Adherence to the insulin regimen was found to be good in majority of study participants (68%). Only 8% reported poor adherence. Reasons cited for poor adherence included forgetfulness and inconvenience in injecting insulin at school and other public places.

48% of children reported good adherence to the BGM regimen prescribed at the clinic while 24% and 28% reported average and poor adherence respectively. The most common reason for poor adherence was unavailability of BGM strips.

Dietary adherence was average in most of the patients (57.3%). Difficulty in reducing carbohydrate quantity was a common problem encountered by most adolescents. Figure 3 shows the frequency of adherence to the different treatment modalities.

FIGURE 3: TREATMENT ADHERENCE IN CHILDREN AND ADOLESCENTS WITH T1DM



Adherence varied with age with the oldest age group (>14 years) having poorer adherence to all treatment modalities while children less than 10 years demonstrated higher levels of adherence. This however did not demonstrate statistical significance. (Table 6)

TABLE 6: ADHERENCE TO TREATMENT IN DIFFERENT AGE GROUPS

	<10 Years		**10 – 14 years**		**>14 years**		**TOTAL**		**P value[1]**
	N=17	**(22.7%)**	**N=20**	**(26.7%)**	**N=38**	**(50.7%)**	**N=75**		
Insulin:									
Good	14	(82.4)	17	(85)	20	(52.6)	51	(68)	0.055
Average	2	(11.8)	3	(15)	13	(34.2)	18	(24)	
Poor	1	(5.90)	0	(0)	5	(13.2)	6	(8)	
BGM:									
Good	11	(64.7)	12	(60)	13	(34.2)	36	(48)	0.13
Average	4	(23.5)	4	(20)	10	(26.3)	18	(24)	
Poor	2	(11.8)	4	(20)	15	(39.5)	21	(28)	
Diet:									
Good	7	(41.2)	5	(25)	9	(23.7)	21	(28)	0.633
Average	8	(47.1)	13	(65)	22	(57.9)	43	(57.3)	
Poor	2	(11.8)	2	(10)	7	(18.4)	11	(14.7)	

The type of insulin regimen used, whether 2 daily injections or multiple daily injections did not have an effect on adherence (p value = 0.726).

Caregiver involvement in diabetes related tasks of the child varied with the type of task. In the task of insulin injection, 44% of caregivers exhibited optimal involvement as compared to only 29.3% in the task of BGM.

The level of involvement varied significantly with the age of the child. In those less than 10 years of age, only 5.9% of caregivers had minimal involvement in insulin injections as compared to 65.8% in those > 14 years (p value = 0.00). This was also reflected in the task of BGM; 5.9% vs 47.4% in the <10 years and > 14 year olds respectively (p value = 0.00).

Optimal caregiver involvement in the task of injecting insulin was related to better adherence to the insulin regimen. This association however was not seen in the task of BGM (table 7).

TABLE 7: ASSOCIATION BETWEEN CAREGIVER INVOLVEMENT IN DIABETES RELATED TASKS AND ADHERENCE

	Insulin adherence						
	Good		Average/Poor		Total		P value[1]
Involvement	N=51	(68%)	N = 24	(32%)	N=75		
Minimal	12	(42.9)	16	(57.1)	28	(37.3)	0.001[2]
Moderate	10	(71.4)	4	(28.6)	14	(18.7)	
Optimal	29	(87.9)	4	(12.1)	33	(44)	

	BGM adherence								
	Good		Average		Poor		Total		P value[1]
Involvement	N=36	(48%)	N=18	(24%)	N=21	(28%)	N=75		
Minimal	10	(45.5)	5	(22.7)	7	(31.8)	22	(29.3)	0.984
Moderate	16	(51.6)	7	(22.6)	8	(25.8)	31	(41.3)	
Optimal	10	(45.5)	6	(27.3)	6	(27.3)	22	(29.3)	

[1] Calculated using exact chi square test

2 Statistically significant

The mean HbA1c did not differ with adherence to diet and insulin. Adherence to BGM regimen was associated with lower mean HbA1c in those with average adherence as compared to those with poor adherence (Table 8). Caregiver involvement in diabetes related tasks was not significantly associated with HbA1c.

TABLE 8: ASSOCIATION BETWEEN ADHERENCE AND GLYCAEMIC CONTROL

	MEAN HBA1C			
	GOOD	**AVERAGE**	**POOR**	**P VALUE[1]**
DIET	10.75 ± 2.41	11.27 ± 2.09	10.81 ± 1.62	0.604
BGM	11.12 ± 2.02	10.14 ± 2.06	11.71 ± 2.12	0.065
INSULIN	10.76 ± 2.12	11.68 ± 2.07	11.67 ± 2.01	0.224

[1] Calculated using ANOVA

65.3% of children stored their insulin in a fridge; either their own or a neighbours. 32% stored it in a pot of water while the remaining 2.7% kept the vials at room temperature. The difference in the mean HbA1c between those who stored insulin in the fridge and in a pot of water was not statistically significant (11.06% vs 11.11%, p value=0.85).

Insulin was not universally available to all the patients from the clinic. 40% of patients reported missing their insulin supply from the clinic at least once in the 3 months prior to the study. Most of the patients reported having the ability to purchase their own insulin in the absence of clinic supplies. Only 7 patients (9.3%) said they would be unable to buy insulin in case of clinic shortage.

There was a varied impact of T1DM on the daily life of children and adolescents. 64% of children reported that diabetes had a significant impact on their life. 3 children (4%) reported a positive impact of the disease, making them more tolerant and responsible. 60% reported a negative impact on their lives. This was higher in those greater than 10 years, with highest prevalence in the 10 – 14 year olds (70%). A higher percentage of females (70.3%) reported a negative impact as compared to males (57.9%). School absence and dietary difficulties were the most commonly reported problems. Depression was described in 8% of children and adolescents (table 9).

TABLE 9: IMPACT OF T1DM ON DAILY LIFE

IMPACT	N	(%)
Regular school absence/cessation of school	18	(24)
Diet restriction	17	(22.7)
Sports restriction	10	(13.3)
Poor school performance	11	(14.7)
Depressed mood	6	(8)
Increased responsibility	5	(6.7)
Social isolation	3	(4)
Positive impact	3	(4)

Children who reported a negative impact on their lives had a marginally higher mean HbA1c (11.03%) as compared to those who had no impact (10.95%). This difference was not statistically significant.

To determine predictors of glycaemic control, a multivariate regression analysis was performed using variables that had a significant association with HbA1c ($p < 0.05$) and those that approached statistical significance ($P < 0.1$) in bi-variate analysis The variables tested in the multivariate analysis were: age of the child, primary caregiver, diabetes knowledge of caregiver, duration of disease and adherence to BGM regimen. Results of the multivariate analysis are shown in table 10.

TABLE 10: PREDICTORS OF HbA1c IN MULTIVARIATE ANALYSIS

VARIABLE	B (unstandardised coefficients)	BETA (standardized coefficients)	P VALUE	95% CI for significant values of B
Constant	6.617		0.00	(4.782,8.452)
Age of patient	0.232	0.404	0.002[1]	(0.110,0.354)
Duration of DM	-0.174	-0.144	0.184	
Primary caregiver (mother/other)	1.395	0.312	0.005[1]	(0.439,2.351)
Adherence to BGM regimen (poor/good)	0.015	0.016	0.908	
Adherence to BGM regimen (poor/average)	-1.098	-0.234	0.03[1]	(-2.085,-0.112)
Diabetes knowledge of caregiver	-0.102	-0.086	0.439	

[1] Statistically significant

The independent variables in the model predicted 33.2% of the variance in HbA1c ($R^2 = 0.332$, p value = 0.000)

8.0: DISCUSSION

Management of T1DM in children and adolescents is a challenge for health care workers, patients and their families. Current management standards focus on optimizing glycaemic control to reduce the risks of long term complications.(33)

The mean glycaemic control in this study was 11.05 ± 2.11%. This is a marginal increase from the mean of 10.65 ± 2.09 which was reported at the same centre by Majaliwa et al in 2006.(10)

This increase is alarming because the previous study was done in the setting of very poor insulin supplies and unavailability of BGM at home. Despite major progress in the availability of insulin and blood glucose monitors, glycaemic control shows no improvement. This points to the existence of other underlying factors which have yet to be identified that are contributing to poor glycaemic control.

Very few studies have been done in Africa documenting glycaemic control. A study by Pillay et al from South Africa documented a mean glycaemic control of 9.7% in children with T1DM aged 6 – 10 years.(34) This is similar to the mean HbA1c in children < 10 years in the current study (9.83%). Younger age has consistently been found to be associated with better glycaemic control in many studies.(14, 17) This may be attributed to more parental supervision in this age group. A study from Sudan however reported an inverse correlation between HbA1c and age.(25) This study included type 1 diabetics up to the age of 60 years and the inverse correlation was attributed to poor compliance to treatment in younger diabetics.

Adolescents with T1DM have been reported to have poor glycaemic control in some studies.(21) The poor glycaemic control with increasing age as demonstrated in the current study may be due to the onset of puberty and the contribution of pubertal hormones. In addition, psychological and social stressors in this age group may result in poor compliance to treatment.

The role of the family in the management of T1DM in children and adolescents has been described. In a study by Thompson et al, children from single parent families had a significantly higher HbA1c as compared to those from 2 parent families.(20) This was also demonstrated in a study by Araujo et al in Argentina.(16) In the current study, children from 2 parent families did not have significantly better glycaemic control. This could be explained by the role that parents play in caring for a sick child in the African societies, where it is the primary responsibility of the mother to care for sick children. Indeed this was demonstrated by the significantly lower mean HbA1c (10.79%) in children whose primary caregiver was the mother as compared to 12.12% in those who had a primary caregiver other than the mother.

The mean duration of diabetes in our population was 3.74 years. Children with duration of < 1 year had significantly better mean HbA1c compared to those with duration > 1 year. This is a common finding in newly diagnosed diabetics due to the "honeymoon effect"; this is a period of relatively good glycaemic control that occurs due to residual beta cell function in the 1st year following diagnosis and initiation of treatment. In multivariate analysis, however, duration of DM did not significantly predict HbA1c. This is contrary to many studies which have reported diabetes duration as a significant predictor of HbA1c.(13, 14, 17)

In the current study, majority of the children (68%) were on a multiple insulin injection regimen. This is currently one of the recommended modes of treatment of T1DM, the other being the continuous subcutaneous insulin infusion (CSII). However, the mean HbA1c in this group did not differ from those on the conventional 2 daily insulin injection regimen. This finding is surprising given the important role of prandial insulin in lowering blood glucose. It could be explained by the poor adherence in our diabetic population.

The mean daily dose of insulin was 1.06units/kg/day with the older children (14 – 18 year olds) having a lower mean daily dose. This difference may be seen because many children in this age group were on a 2 daily injection regimen which resulted in a lower daily insulin dose.

Diabetes education is a key component in the management of T1DM. Education of both the caregiver and the child is important to ensure adherence to the multiple diabetes related tasks. In the current study, population the mean parental knowledge score was 70 ± 15%. This indicates a significant deficit in knowledge. There was a significant association between parental diabetes knowledge and younger age of the child and this may mediate the better metabolic control seen in this age group.

Higher parent diabetes knowledge scores were associated with a significantly lower HbA1c. These results were similar to those in a study by Butler et al where higher parental diabetes specific knowledge was significantly correlated with a lower HbA1c.(30) In another study by Stallwood et al, parental diabetes knowledge was tested using the Michigan Diabetes Research and Training Centre's brief knowledge test using all the 23 items in the questionnaire unlike

the current study where we used 14 out of 23. The mean parental score in that study was 74% and higher scores were correlated to lower HbA1c's.(29)

The mean diabetes knowledge score of the youth was similar to that of the parents but did not show association with age or with HbA1c. This finding emphasizes the key role of optimizing parental knowledge to achieve better control in the child.

Despite the importance of HbA1c in the management of T1DM, less than one third of parents and children had knowledge on this measurement. Although knowledge of HbA1c was not associated with glycaemic control, understanding the risk of micro vascular complications with increasing HbA1c levels is important to motivate parents and children to optimize their glycaemic control.

The multi modal treatment approach in T1DM which encompasses dietary management, multiple injections and regular BGM poses a considerable burden to children and their families. Adherence to these multiple, complex tasks is challenging for many young diabetics especially the adolescents who are more independent with reduced reliance on caregivers.

The current study demonstrates varying adherence to the different treatment modalities. Best adherence was observed to the insulin regimen (68%) followed by BGM (48%) and lastly diet (28%). This reflects the underlying importance patients given to insulin administration and the relative complacency to the other modes of treatment.

Adherence to all 3 modalities was better in children < 10 years as compared to older children. Improved adherence in younger children can be attributed to better caregiver involvement in this age group. 88.2% of children < 10 years had optimal involvement from caregiver in the task of insulin injection as only 13% in those > 14 years.

Irrespective of age, this study has found out that better caregiver involvement in insulin injections was associated with better adherence to the insulin regimen. For the task of BGM, caregiver involvement was not associated with better adherence. This is in contrast to the study by Anderson et al where more parental involvement in BGM resulted in higher

adherence and this translated to lower HbA1c levels.(21) The absence of this association in the current study may be explained by the reasons for poor adherence to BGM in our population, the commonest being lack of availability of test strips. In the absence of adequate supplies, caregiver involvement is unlikely to contribute to adherence.

Overall, better adherence in the diet and insulin regimen domains did not translate to better glycaemic control. However, adherence to BGM was significantly associated with HbA1c in multivariate analysis.

The adherence – glycaemic control link has been examined in several studies including a meta - analysis carried out by Hood et al.(11) This meta - analysis demonstrated an effect size of -0.28 (CI -0.32, -0.24). This implies that better adherence leads to lower HbA1c. This meta-analysis failed to demonstrate any association between Sociodemographic or disease specific variables on the overall effect size. This suggests that improving adherence results in improved glycaemic control across all populations irrespective of different Sociodemographic or disease specific characteristics.

A study by Mehta et al examining dietary adherence showed that a higher dietary score was associated with lower HbA1c.(26) The absence of significant association between HbA1c and adherence to insulin and diet in the current study may be explained by the method used to assess adherence which was primarily self reporting. This method is prone to recall bias and misreporting and this may have resulted in falsely elevated adherence levels. Other studies have used caloric counting to assess dietary adherence; this however is not applicable in our population. BGM adherence can be determined by data from blood glucose meter downloads. In the current study population however, this was not practical because most patients did not carry meters to the clinic during visits.

The recommended method of insulin storage is refrigeration at a temperature of 2 - 8^0C for unopened vials of insulin. Open vials may be kept at room temperature but must be used within 1 month.(35) Due to the low availability of refrigerators, our diabetics store their insulin in a pot of water which is kept cool by use of charcoal to absorb heat. In the current

study, a large proportion (32%) of children and adolescents stored insulin using a pot of water. 2 patients stored it at room temperature; the reason being lack of knowledge on proper storage. The method of insulin storage did not significantly affect glycaemic control. This may be explained on the basis of the limited insulin stocks available to the patients which usually do not last more than 1 month.

Despite efforts to make insulin regularly and freely available to all children and adolescents with T1DM, shortages were frequently noted with 40% of children missing insulin at least once in 3 months. Although this is a large proportion, it shows improvement from what was reported by Majaliwa et al at the same clinic 5 years ago where 63% of children regularly missed insulin.(5) Most of the participants in the current study (90.7%) reported having the financial ability to buy insulin in case of clinic shortage. This may contribute to the lack of difference in HbA1c between children who missed insulin and those who did not.

Adolescents with T1DM especially females have been found to have unique challenges. One review by Jack classified these challenges into psychological disturbances such as depression, biological influences such as puberty and social stressors such as peer pressure.(36) These influences may worsen glycaemic control in the adolescent age group.

The association between glycaemic control and psychosocial factors was examined in a study by Krishnavathana et al who found depression in 9.5% of poorly controlled subjects as compared to only 3% of children with good glycaemic control.(37) This study also found that quality of life deteriorated with poor glycaemic control.

The current study has found out that 60% of children and adolescents described a negative impact of T1DM on their daily life. There was no significant difference in mean HbA1c between those with a negative impact and those without. This may be attributed to the method used to determine the impact which was the perception of the parent and child. Objective assessment of depression and quality of life were beyond the scope of this study.

Multivariate analysis of variables associated with glycaemic control found 3 main predictors of HbA1c: age, primary caregiver and adherence to BGM regimen. This multivariate model

can be applied to actual clinical scenarios using the regression equation and an estimate of the expected HbA1c of a given patient can be calculated.

The best case scenario would have the following profile: A child aged 7 years who has had diabetes for 9 months whose primary caregiver is the mother and she has good knowledge of diabetes (scores 80% on our knowledge test). The blood glucose of this child is monitored at home at least once or twice a week. The calculated HbA1c in this patient is 6.93%. This is in contrast to a 16 year old adolescent who has been diabetic for 5 years with an uncle as the primary caregiver and he scores 50% on the diabetes knowledge test. This patient does not monitor blood glucose at home. The calculated HbA1c is 10.81%.

The former patient has an HbA1c value which is almost 4% lower than the latter and hence an overall reduced risk of long term complications. Results of the DCCT demonstrated that every 1% decrease in HbA1c results in a 40% reduced risk of developing retinopathy.(38) The importance of lowering the level of HbA1c in our population of type 1 diabetics cannot be overemphasized.

9.0: STUDY LIMITATIONS:

Adherence to treatment modalities may have been overestimated by the self reporting method used. In addition, dietary adherence was assessed in the 24 hours prior to the study while adherence to insulin and BGM was assessed for one week prior to the study; this may not be representative of overall adherence.

The small population size at our clinic may have failed to demonstrate some significant associations.

10.0: CONCLUSION:

- Glycaemic control in children and adolescents with T1DM attending the MNH clinic for diabetes has remained very poor despite measures to improve insulin availability and self monitoring of blood glucose at home.

- There was a deficit in the diabetes knowledge of both caregivers and children with lack of knowledge specific to HbA1c. Poor adherence was common especially to dietary

guidelines. Older children had minimal involvement of caregivers in their diabetes management and this group demonstrated poor adherence to all treatment modalities. The disease was associated with a significant negative impact on daily life.

- Age, primary caregiver and adherence to BGM regimen were found to be independent predictors of glycaemic control.

11.0: RECOMMENDATIONS:

- Caregivers of children and adolescents with T1DM should receive regular diabetes education and specific knowledge about HbA1c should be imparted to all patients and caregivers.
- Adolescents with T1DM need close follow up with emphasis on adherence counseling. Incentives to those who show improving glycaemic control may be used to promote adherence in this group of diabetics.
- Active participation of caregivers in diabetes related tasks of children should be encouraged.

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13.0: APPENDICES:

Appendix 1: Questionnaire English:

PART 1: SOCIODEMOGRAPHIC DATA AND BACKGROUND INFORMATION:

1. Serial number: _____
2. Name: _____
3. Telephone contact _____
4. Date of birth (dd/mm/yy): _____
5. Sex: ☐ M ☐ F
6. Date of diagnosis of DM (dd/mm/yy):_____
7. Body weight (Kg) _____
8. Height (m) _____
9. BMI(kg/m^2)_____
10. Daily insulin dose (per kg body weight)_____
11. Insulin regimen:
    - ☐ 2 daily injections
    - ☐ Multiple daily injections
12. Primary caregiver
    - ☐ Mother
    - ☐ Father
    - ☐ Sibling
    - ☐ Other – specify _____
13. Highest level of education completed by the primary caregiver (select one):
    - ☐ No formal education
    - ☐ Primary
    - ☐ Secondary
    - ☐ Tertiary
14. Family structure (select one):
    - ☐ Both parents living together
    - ☐ Single parent

☐ Not living with either parent

☐ Orphan

PART 2: KNOWLEDGE ASSESSMENT OF PATIENTS AND CAREGIVERS:

A. KNOWLEDGE ASSESSMENT OF CAREGIVERS:

1. Which of the following is highest in carbohydrates?
    a. Chicken
    b. Milk
    c. Potato
    d. Butter
2. Which of the following is highest in fats?
    a. Milk
    b. Orange juice
    c. Maize
    d. Honey
3. Which is the best method for testing your child's glucose?
    a. Urine testing
    b. Blood testing
    c. Both are equally good
4. What effect does unsweetened fruit juice have on your child's blood glucose?
    a. Lowers it
    b. Raises it
    c. Has no effect
5. What effect does exercise have on blood glucose?
    a. Lowers it
    b. Raises it
    c. Has no effect
6. Infection is likely to cause:
    a. An increase in blood glucose

b. A decrease in blood glucose
c. No change in blood glucose

7. Numbness and tingling may be symptoms of:
    a. Kidney disease
    b. Nerve disease
    c. Eye disease
    d. Liver disease
8. Which of the following is usually not associated with diabetes?
    a. Eye problems
    b. Kidney problems
    c. Nerve problems
    d. Lung problems
9. Signs of ketoacidosis (very high blood sugar) include:
    a. Shakiness
    b. Sweating
    c. Vomiting
10. If your child is sick with the flu, which of the following changes would you tell her/him to make?
    a. Take less insulin
    b. Drink less liquids
    c. Eat more proteins
    d. Test for blood glucose more often
11. You realize just before lunch time that your child forgot to take his/her insulin before breakfast. What should you advise him to do now?
    a. Skip lunch to lower blood glucose
    b. Take the insulin that he/she usually takes at breakfast
    c. Take twice as much insulin as he/she usually takes at breakfast
    d. Check his/her blood glucose level to decide how much insulin to take
12. Low blood glucose may be caused by:

a. Too much insulin
b. Too little insulin
c. Too much food
d. Too little exercise

13. If your child takes morning insulin but skips breakfast, his/her blood glucose level will usually:
    a. Increase
    b. Decrease
    c. Remain the same
14. High blood glucose may be caused by:
    a. Not enough insulin
    b. Skipping meals
    c. Delaying your food

What was your last HbA1c level? _____

What is the importance of HbA1c? _____

B. KNOWLEDGE ASSESSMENT OF CHILD/ADOLESCENT:

1. Which of the following is highest in carbohydrates?
    a. Chicken
    b. Milk
    c. Potato
    d. Butter
2. Which of the following is highest in fats?
    a. Milk
    b. Orange juice
    c. Maize
    d. Honey
3. Which is the best method for testing glucose?
    a. Urine testing

b. Blood testing
c. Both are equally good

4. What effect does unsweetened fruit juice have on blood glucose?
    a. Lowers it
    b. Raises it
    c. Has no effect
5. What effect does exercise have on blood glucose?
    a. Lowers it
    b. Raises it
    c. Has no effect
6. Infection is likely to cause?
    a. An increase in blood glucose
    b. A decrease in blood glucose
    c. No change in blood glucose
7. Numbness and tingling may be symptoms of?
    a. Kidney disease
    b. Nerve disease
    c. Eye disease
    d. Liver disease
8. Which of the following is usually not associated with diabetes?
    a. Eye problems
    b. Kidney problems
    c. Nerve problems
    d. Lung problems
9. Signs of ketoacidosis (very high blood sugar) include?
    a. Shakiness
    b. Sweating
    c. Vomiting
10. If you are sick with the flu, which of the following changes should you make?

a. Take less insulin
b. Drink less liquids
c. Eat more proteins
d. Test for glucose more often

11. You realize just before lunch time that you forgot to take your insulin before breakfast. What should you do now?
    a. Skip lunch to lower your blood glucose
    b. Take the insulin that you usually take at breakfast
    c. Take twice as much insulin as you usually take at breakfast
    d. Check your blood glucose level to decide how much insulin to take
12. Low blood glucose may be caused by?
    a. Too much insulin
    b. Too little insulin
    c. Too much food
    d. Too little exercise
13. If you take your morning insulin but skip breakfast your blood glucose level will usually?
    a. Increase
    b. Decrease
    c. Remain the same
14. High blood glucose may be caused by?
    a. Not enough insulin
    b. Skipping meals
    c. Delaying your food

What was your last HbA1c level? _____

What is the importance of HbA1c? _____

PART 3: PRACTICES OF PATIENT/CAREGIVER ON DIABETES:

1. How many doses of insulin have you missed in the last one week?

- ☐ None
- ☐ Between 1 – 3
- ☐ >3

2. How many times have you monitored glucose at home in the last one week?
   - ☐ ≥ 3 times a week
   - ☐ 1 – 2 times a week
   - ☐ < Once a week
3. What did you eat in the last 24 hours?

Breakfast _____

Lunch _____

Dinner _____

Snacks (how many times) _____

4. How do you store your insulin?
   - ☐ Refrigerator
   - ☐ Pot of cold water
   - ☐ Room temperature
5. In the last 24 hours, how many times did the parent/caregiver inject or supervise the insulin injection?
   - ☐ None
   - ☐ Once or twice
   - ☐ All the injections
6. How involved is the parent/caregiver in the monitoring of the child's blood glucose?
   - ☐ No involvement
   - ☐ Reminds the child to monitor glucose or logs in the level in the diary or asks about the blood glucose level
   - ☐ Sets up the meter and does the finger prick

PART 4: AVAILABILITY OF INSULIN

1. In the last 3 months, have you ever missed getting your prescribed insulin from the hospital?
   - ☐ Yes
   - ☐ No
2. If yes to number 7, how frequently have you missed your supplies?
   - ☐ Every month
   - ☐ Once or twice in 3 months
3. When you miss your supplies of insulin or syringes, what do you usually do?
   - ☐ Buy your own
   - ☐ Wait till supplies are available from the hospital

PART 5: IMPACT OF DIABETES ON DAILY LIFE:

1. Does the child frequently miss school due to diabetes and related complications?
   - ☐ Yes
   - ☐ No
2. If yes, in the last 1 month, how many missed days of school? _____
3. Does having diabetes restrict the child from regular sports?
   - ☐ Yes
   - ☐ No
4. Are there any other ways that having a chronic disease like diabetes affects the daily life of the child?

   _____

   _____

   _____

Appendix 2: Questionnaire Kiswahili:

DEMOGRAPHIC DATA AND BACKGROUND INFORMATION:

1. Namba: _____
2. Jina: _____
3. Namba ya simu _____
4. Tarehe ya kuzaliwa (sk/mwz/mwk): _____
5. Jinsia: ☐ Mme ☐ Mke
6. Tarehe ya kukugunduliwa ugonjwa wa kisukari (sk/mwz/mwk): _____
7. Uzito _____
8. Urefu _____
9. BMI _____
10. Dozi ya insulini kwa siku (kwa uzito wa mwili)_____
11. Aina ya matibabu:
    - ☐ Sindano mbili kwa siku
    - ☐ Sindano zaidi ya mbili kwa siku
12. Uhusiano wa mgonjwa na anayemhudumia nyumbani
    - ☐ Mama
    - ☐ Baba
    - ☐ Kaka/Dada
    - ☐ Mwingine-Ainisha _____
13. Je, mzazi/mlezi amefikia kiwango gani cha elimu (chagua moja):
    - ☐ Hajaenda Shule
    - ☐ Elimu ya Msingi
    - ☐ Elimu ya Sekondari
    - ☐ Elimu ya Juu
14. Familia (Chagua moja):
    - ☐ Wazazi wote wanaishi pamoja
    - ☐ Mzazi mmoja
    - ☐ Haishi na wazazi

☐ Mkiwa

PART 2: KNOWLEDGE ASSESSMENT OF PATIENTS/CAREGIVERS:

A. KNOWLEDGE ASSESSMENT OF CAREGIVERS:

1. Chakula gani kina wanga kwa wingi zaidi?
    a. Kuku
    b. Maziwa
    c. Viazi
    d. Siagi
2. Je,chakula gani kina mafuta kwa wingi?
    a. Maziwa
    b. Juisi ya machungwa
    c. Mahindi
    d. Asali
3. Je, kipi ni kipimo bora cha sukari cha mwanao?
    a. Kipimo cha mkojo
    b. Kipimo cha damu
    c. Vyote viko sawa
4. Juisi ya matunda isiyo na sukari inabadilisha vipi kiwango cha sukari ya mwanao?
    a. Inaongeza
    b. Inapunguza
    c. Haibadilishi
5. Mazoezi yanabadilisha vipi kiwango cha sukari?
    a. Yanaongeza
    b. Yanapunguza
    c. Hayabadilishi
6. Uambukizi unasababisha:
    a. Kiwango cha sukari kuongezeka
    b. Kiwango cha sukari kupungua
    c. Haubadilishi kiwango cha sukari

7. Ganzi ni dalili ya:
    a. Ugonjwa wa figo
    b. Ugonjwa wa mishipa ya fahamu
    c. Ugonjwa wa macho
    d. Ugonjwa wa ini
8. Mojawapo wa yafuatayo hauhusiani na ugonjwa wa kisukari
    a. Matatizo ya kuona
    b. Matatizo ya figo
    c. Matatizo ya mishipa ya fahamu
    d. Matatizo ya mapafu
9. Dalili za kitoasidosis/kuoengezeka kwa sukari kwa mwili ni:
    a. Kutetemeka
    b. Kutoka jasho jingi
    c. Kutapika
10. Je, mtoto wako akipata mafua utamwambia afanye nini?
    a. Atumie insulin kidogo
    b. Anywe maji kidogo
    c. Atumie vyakula vya protini kwa wingi
    d. Apime kiwango cha sukari mara nyingi zaidi
11. Kabla ya chakula cha mchana unagundua mtoto wako alisahau kuchoma insulini kabla ya chakula cha asubuhi. Utamwambia afanye nini?
    a. Asile chakula cha mchana kupunguza kiwango cha sukari
    b. Achome insulin kiasi anayochoma kabla ya chakula cha asubuhi
    c. Achome insulin mara mbili ya anayochoma wakati wa chakula cha asubuhi
    d. Apime kiwango cha sukari kwenye damu ili kuamua achome insulin kiasi gani
12. Kupungua kwa sukari kwenye damu husababishwa na:
    a. Insulini kwa wingi
    b. Insulini kidogo sana
    c. Chakula kwa wingi

d. Mazoezi kidogo sana

13. Iwapo mtoto wako atachoma insulin asubuhi lakini asipate chakula, kiwango cha sukari kwenye damu kitakuwaje?
    a. Kitaongezeka
    b. Kitapungua
    c. Hakitabadilika
14. Kuzidi kwa sukari kwenye mwili husababishwa na:
    a. Insulin isiyotosha
    b. Kuacha kula
    c. Kuchelewa kula

HbA1c ya mtoto ya mwisho ilikuwa kiasi gani? _____

Kipimo cha HbA1c (kipimo cha miezi mitatu) kina umuhimu gani?

_____

B. KNOWLEDGE ASSESSMENT OF CHILD/ADOLESCENT:

1. Chakula gani kina wanga kwa wingi zaidi?
    a. Kuku
    b. Maziwa
    c. Viazi
    d. Siagi
2. Je, chakula gani kina mafuta kwa wingi?
    a. Maziwa
    b. Juisi ya machungwa
    c. Mahindi
    d. Asali
3. Je, kipi ni kipimo bora cha sukari chako?
    a. Kipimo cha mkojo
    b. Kipimo cha damu
    c. Vyote viko sawa

4. Juisi ya matunda isiyo na sukari inabadilisha vipi kiwango cha sukari chako?
    a. Inaongeza
    b. Inapunguza
    c. Haibadilishi
5. Kwa mtu mwenye kiwango kizuri cha sukari, mazoezi yanabadilisha vipi kiwango cha sukari?
    a. Yanaongeza
    b. Yanapunguza
    c. Hayabadilishi
6. Uambukizi unasababisha:
    a. Kiwango cha sukari kuongezeka
    b. Kiwango cha sukari kupungua
    c. Haubadilishi kiwango cha sukari
7. Ganzi ni dalili ya:
    a. Ugonjwa wa figo
    b. Ugonjwa wa mishipa ya fahamu
    c. Ugonjwa wa macho
    d. Ugonjwa wa ini
8. Mojawapo wa yafuatayo hauhusiani na ugonjwa wa kisukari
    a. Matatizo ya kuona
    b. Matatizo ya figo
    c. Matatizo ya mishipa ya fahamu
    d. Matatizo ya mapafu
9. Dalili za kitoasidosis/kuongezeka kwa sukari ni:
    a. Kutetemeka
    b. Kutoka jasho jingi
    c. Kutapika
10. Je, ukipata mafua, utafanya nini?
    a. Utumie insulin kidogo

b. Unywe maji kidogo
c. Utumie vyakula vya protini kwa wingi
d. Upime kiwango cha sukari mara nyingi zaidi

11. Kabla ya chakula cha mchana unagundua ulisahau kuchoma insulini kabla ya chakula cha asubuhi. Utafanya nini?
    a. Usile chakula cha mchana kupunguza kiwango cha sukari
    b. Uchome insulin kiasi unayochoma kabla ya chakula cha asubuhi
    c. Uchome insulin mara mbili ya unayochoma wakati wa chakula cha asubuhi
    d. Upime kiwango cha sukari kwenye damu ili kuamua uchome insulin kiasi gani
12. Kupungua kwa sukari kwenye damu husababishwa na:
    a. Insulini kwa wingi
    b. Insulini kidogo sana
    c. Chakula kwa wingi
    d. Mazoezi kidogo sana
13. Iwapo utachoma insulin asubuhi lakini usipate chakula, kiwango cha sukari kwenye damu kitakuwaje?
    a. Kitaongezeka
    b. Kitapungua
    c. Hakitabadilika
14. Kuzidi kwa sukari kwenye mwili husababishwa na:
    a. Insulin isiyotosha
    b. Kuacha kula
    c. Kuchelewa kula

HbA1c yako ya mwisho ilikuwa kiasi gani? _____

Kipimo cha HbA1c (kipimo cha miezi mitatu) kina umuhimu gani?

_____

PART 3: PRACTICES OF PATIENT/CAREGIVER ON DIABETES:

1. Dozi ngapi za insulin ulikosa wiki iliyopita?
   - ☐ Hakuna
   - ☐ Kati ya 1 – 3
   - ☐ Zaidi ya 3
2. Umejipima kiwango cha sukari mara ngapi (wiki iliyopita)
   - ☐ Mara 3 au zaidi kwa wiki
   - ☐ Mara 1-2 kwa wiki
   - ☐ Sijapima
3. Umekula vyakula vipi kwenye masaa ishirini na manne yaliyopita?

Staftahi _____

Chakula cha mchana _____

Chakula cha usiku _____

Vitafunwa (saa ngapi) _____

4. Unahifadhi vipi insulin?
   - ☐ Jokofu/friji
   - ☐ Chungu cha maji baridi
   - ☐ Joto la kawaida chumbani
5. Katika masaa 24 yaliyopita, mzazi/anayekuhudumia nyumbani alikuchoma au alihakikisha unachomwa insulin?
   - ☐ Hakuna
   - ☐ Mara moja au mbili
   - ☐ Sindano zote
6. Mzazi/anayekuhudulia nyumbani anahusika katika kuangalia kiwango cha sukari kwenye damu?
   - ☐ Hahusiki
   - ☐ Humkumbusha mtoto kuangalia kiwango cha sukari au kuandika kiwango kwenye dayari au kumwuliza mtoto kiwango
   - ☐ Huwasha kipimo na kumtoa damu ya kidole

PART 4: AVAILABILITY OF INSULIN

1. Katika miezi 3 iliyopita, umewahi kukosa insulin yako hapa hospitalini?
   - ☐ Ndiyo
   - ☐ Hapana
2. Kama jibu la swali iliyopita ni Ndiyo, Je umekosa mara ngapi?
   - ☐ Kila mwezi
   - ☐ Mara moja au mbili katika miezi 3
3. Ukikosa insulin au sindano huwa unafanya nini?
   - ☐ Nanunua mwenyewe
   - ☐ Nasubiri mpaka nipate kutoka hospitali

PART 5: IMPACT OF DIABETES ON DAILY LIFE:

1. Je mtoto huwa anakosa kwenda shule mara kwa mara kwa sababu ya kisukari na matatizo yake?
   - ☐ Ndiyo
   - ☐ Hapana
2. Kama ndiyo, katika mwezi uliopita alikosa siku ngapi za shule? _____
3. Je kuwa na kisukari kumemzuia mtoto kushiriki michezo?
   - ☐ Ndiyo
   - ☐ Hapana
4. Je kuwa na ugonjwa sugu kama kisukari kumeathiri vipi maisha ya kawaida ya mtoto?

   _____

   _____

   _____

Appendix 3: Consent form: English

TITLE OF THE STUDY: FACTORS ASSOCIATED WITH GLYCAEMIC CONTROL IN CHILDREN AND ADOLESCENTS WITH TYPE 1 DIABETES MELLITUS AT MUHIMBILI NATIONAL HOSPITAL, DAR ES SALAAM

My name is Dr. Mariam Noorani, a 2nd year resident in the department of Paediatrics and Child Health at Muhimbili University of Health and Allied Sciences (MUHAS).

I am conducting a study with the above title as part of my study program.

Aims of the study:

This study aims to determine the average blood sugar control in children and adolescents with type 1 diabetes and to find out what factors are associated with poor control of blood sugar. In addition, it will also describe the impact of diabetes on the daily life of children and adolescents with type 1 diabetes.

Participation in this study:

Your child can participate in this study if he/she is 18 years old or less and has been on insulin treatment for type 1 diabetes for at least 3 months.

The study mainly involves responding to a questionnaire which has general questions about the child's demographic characteristics, your family's socioeconomic status and a section on questions related to diabetes. Both you and your child will answer the questions together if your child is less than 10 years and separately if the child is older than 10 years.

In addition, the child's HbA1c level will be measured as part of routine care at the clinic and this level will be used in the study.

If you choose not to participate in this study, your child will continue to receive the normal care at the diabetic clinic and will not be compromised in any way.

Risks:

We do not anticipate any risks involved in participating in the study

Benefits:

By participating in this study, you will know your child's glucose control as measured by HbA1c and the level will be interpreted for you and hence you will be able to take measures to improve the control or maintain it if it is within normal levels.

Confidentiality:

All information collected during this study will be kept strictly confidential and will not be revealed to anybody outside the research team.

Cost:

You will not be required to make any payments to participate in this study and no payment will be made to you.

For further information, questions or queries, you can contact:

1. The Principal Investigator,
   Dr. Mariam Noorani,
   Department of Paediatrics and Child Health,
   MUHAS
   P. O. Box 65001,
   Dar es Salaam.
   Cell no: +255 784 238687
   Email: mariamnoorani@yahoo.com
2. Prof. Karim Manji,
   Dean, School of Medicine,
   MUHAS.
   P. O. Box 65001
   Dar es Salaam

3. Dr. Kaushik Ramaiya,
   Hindu Mandal Hospital,
   P. O. Box 581
   Dar es Salaam
4. Prof. E. Lyamuya,
   Director of Research and Publications,
   MUHAS.
   Tel No: +255 22 2152489.

I, _____, have read/been told of the contents of this form and have understood its meaning. I agree for me and my child to participate in this study.

Signature of parent/guardian/adolescent _____

Signature of Researcher _____

Date _____

Appendix 4: Consent form: Kiswahili

FOMU YA RIDHAA YA KUSHIRIKI KATIKA UTAFITI

Jina langu ni Dr. Mariam Noorani, mwanafunzi wa udaktari bingwa wa watoto katika chuo kikuu cha afya na sayansi shirikishi Muhimbili (MUHAS). Ninafanya utafiti kuangalia **Mambo yanayohusiana na kiwango cha sukari kwenye watoto na vijana wenye aina moja wa ugonjwa wa kisukari katika hospitali ya Taifa, Muhimbili, Dar es Salaam.**

Madhumuni ya utafiti:

Utafiti huu unalenga kujua kiasi ya sukari kwa miezi miwili iliyopita kwenye watoto na vijana wenye aina moja wa ugonjwa wa kisukari na kujua sababu zinazohusiana na kuzidi kwa kiasi hicho. Pia, utafiti huu utaangalia vile ugonjwa wa kisukari inaathiri maisha ya watoto na vijana hao.

Ushiriki katika utafiti:

Mtoto wako anaweza kushiriki katika utafiti huu kama ana umri wa miaka 18 au chini na amekuwa akipata matibabu ya insulin kwa angalau miezi mitatu.

Utafiti huo hasa unahusu kujibu maswali kuhusu mtoto, kiuchumi ya familia yako na sehemu ya maswali kuhusiana na ugonjwa wa kisukari. Utajibu maswala hayo pamoja na mtoto wako kama yeye ana umri wa chini ya miaka 10 na kama anazidi miaka 10, mtayajibu tofauti.

Pia, sampuli ya damu kutoka kidole itatolewa ili kujua kiasi ya HbA1c.

Kama ukiamua kutoshiriki katika utafiti huu, mtoto wako ataendelea kupata huduma ya kawaida kwenye kliniki ya wagonjwa wa kisukari na hataathirika kwa njia yoyote.

Hatari:

Hatutarajii kwamba utakuwa na hatari zinazohusika kwa kushiriki katika utafiti huu.

Faida za utafiti:

Kwa kushiriki katika utafiti huu, utajua kiasi ya sukari ya mtoto wako kwa kipimo cha HbA1c na hii itakusaidia kuchukua hatua za kuboresha kiasi ya sukari yake au kuidumisha kama ni katika ngazi ya kawaida.

Usiri:

Taarifa zote zitakazokusanywa katika utafiti huu zitakuwa siri, hivyo ushiriki wako hautajulikana na mtu.

Taarifa hizi zitajulikana kwenye timu ya watafiti tu.

Malipo:

Kwa kushiriki kwenye utafiti huu, hautalipwa wala hautalipa chochote.

Ukiwa na swali au tatizo lolote, unaweza kuwasiliana na wafuatao:

1. Mtafiti Mkuu,
   Dr. Mariam Noorani
   Idara ya Afya na Magonjwa ya watoto
   MUHAS
   P. O. Box 65001,
   Dar es Salaam.
   Simu: +255 784 238687
   Email: mariamnoorani@yahoo.com

2. Prof. Karim Manji,
   Dean, School of Medicine,
   MUHAS.
   P. O. Box 65001
   Dar es Salaam

3. Dr. Kaushik Ramaiya,
   Hindu Mandal Hospital,
   P. O. Box 581
   Dar es Salaam

4. Prof. E. Lyamuya,
   Director of Research and Publications,
   MUHAS.
   Tel No: +255 22 2152489

Mimi, _____, nimesoma/nimesomewa maelezo yote yaliyomo kwenye fomu hii na nimeelewa. Nakubali mimi na mtoto wangu kushiriki katika utafiti huu.

Sahihi ya mzazi/mlezi/kijana _____

Sahihi ya Mtafiti _____

Tarehe _____