

**QUALITY OF LIFE IN CHILDREN WITH
DIABETES AT KENYATTA NATIONAL
HOSPITAL**

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MBCChB, NAIROBI

H58/82355/2012

**A DISSERTATION SUBMITTED IN PARTIAL FULFILLMENT
OF THE DEGREE OF MASTER OF MEDICINE IN
PAEDIATRICS' AND CHILD HEALTH AT THE UNIVERSITY
OF NAIROBI**

NOVEMBER, 2014

DECLARATION

This dissertation is my original work and has not been submitted for a degree in any other university.

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This dissertation has been submitted to the ethical and research committee and approved my supervisors.

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DEDICATION

I dedicate this work to my dear husband Dr. Walter Nalyanya for being there for me, my sons Lesley, Michael and Reilly for their patience and endurance, my parents Mr. Herman Musabi and Mrs Elimina Musabi , brothers and sisters with special thanks to my dear sister Millycent for their support and prayers .

Special dedication to all children with diabetes in Kenya with the ultimate goal of improving their quality of life.

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ABBREVIATIONS

CDC – Center for Disease Control

BMI – Body Mass Index

DRQOL – Diabetes related quality of life

HRQOL – Health Related Quality of life

PedsQL - Pediatric related Quality of life

QOL – Quality of Life

WHO–World Health Organization

STUDY DEFINITIONS

Caregiver - A caregiver is someone over age 18 that provides care for another.

Child - The United Nations Convention on the Rights of the Child defines a child as "a human being below the age of 18 years unless under the law applicable to the child, majority is attained earlier" In Kenya, 'a child is any human being below the age of eighteen years' (Chapter 586 Laws of Kenya, 2001)

Quality of Life (QOL) – individual's perceptions of their position in life in the context of the culture and value systems in which they live and in relation to their goals, expectations, standards and concerns

Health-related quality of life (HRQOL) - is a multi-dimensional concept that includes domains related to physical, mental, emotional and social functioning

ACKNOWLEDGEMENT

I thank God for His grace that enabled me to complete this work despite the challenges.

I wish to thank my supervisors and mentors Dr. Yuko- Jowi, Dr. Lucy Wainaina -Mungai and Dr. Boniface Osano for their guidance, constant support and commitment despite their busy schedules they still found time to contribute to this research.

Many thanks to the entire staff of Kenyatta National Hospital Paediatric Endocrinology Clinic for their assistance with recruitment of children with diabetes. Special thanks to Mrs. Purity Munene.

I am also grateful to the staff in the University of Nairobi Paediatric Department Laboratory for their support.

Special thanks to Mr. Phillip Ayieko from Kenya Medical Research Institute for assisting me with data analysis, your support was invaluable. I would also like to thank Professor Wagner for enabling me carry out HbA1C analysis by availing the test kits without which I wouldn't have been able to assess the glycemetic control of the diabetic patients.

Special thanks to the children and parents who participated in this research for their time and cooperation.

Thanks to Dr. James W. Varni for allowing me to use the questionnaires.

ABSTRACT

Introduction: Health related quality of life of an individual includes domains related to physical, mental, social and emotional functioning with regard to their health status. Diabetes mellitus is the commonest paediatric endocrinology disease and children with diabetes face challenges of adjusting their lifestyle and adherence to the treatment plan which might affect their quality of life.

Objective: Assess Quality of Life in children with diabetes compared to their non diabetic peers.

Methodology: This was a comparative cross sectional study that included 156 children aged 2 – 18 years (78 diabetic children at Kenyatta National Hospital endocrinology clinic and 78 controls matched for sex age and residence). Questionnaires (PedsQL version 4.0 for both the groups and PedsQL diabetes module version 3.0 for diabetics) were administered for the diabetic group and telephone interviews were conducted for the control group. Parent proxy reports were also obtained in all the groups. Data was analyzed using SPSS 17.0

Results: Mean age was 11.7 ± 4.3 for children with diabetes and 11.7 ± 4.2 for controls. Mean duration of diabetes was 35.02 ± 32 months. Diabetic patients were found to have a lower quality of life than their non diabetic peers ($p < 0.05$). Older age, male gender, self administration of insulin and adherence to insulin therapy were associated with better HRQOL in children with diabetes. Older age was also associated with better diabetic related QOL. Age at diagnosis, duration of treatment and compliance to follow up, glycemic control level of education of parent, residence, family setting and did not affect quality of life.

Conclusion: Children with diabetes have a lower quality of life compared to their non diabetic peers.

Recommendation: Children with diabetes should be followed up keenly to achieve better quality of life.

BACKGROUND

Introduction

World Health Organization (WHO) defines health as ‘a state of complete physical, mental and social well being and not merely the absence of disease or infirmity’ (WHO, 1948)¹. It is from this definition that quality of life has been derived. The WHO defines “Quality of Life” (QOL) as “individuals' perceptions of their position in life in the context of the culture and value systems in which they live and in relation to their goals, expectations, standards and concerns.”² It's a subjective report of what the patient perceives about their health status.

Health-related quality of life (HRQOL) is a multi-dimensional concept that includes domains related to physical, mental, emotional and social functioning. It goes beyond direct measures of population health, life expectancy and causes of death, and focuses on the impact health status has on quality of life.

Patrick et al (1993) defined “Health-related quality of life as the value assigned to duration of life as modified by, impairments, functional states, perceptions, and social opportunities that are influenced by disease, injury, treatment, or policy.”³

Chronic illnesses like asthma, cancer, cardiac diseases and diabetes have been shown to lower the quality of life. Quality of life assessment in diabetic children provides valuable information on the impact of diabetes on the quality of life. Diabetes mellitus is a demanding disease that affects a person's health- related quality of life, a person's ability to function and to derive satisfaction from doing so^{4,5,6}.

Diabetes Mellitus in children

Type 1 diabetes mellitus Diabetes mellitus is a group of metabolic diseases characterized by hyperglycemia resulting from defects in insulin secretion, insulin action, or both⁷. International

Diabetes Federation (IDF) estimates that there are over 78,000 new cases of diabetes in children globally annually⁸. Diabetes is a chronic disease and a major contributor to morbidity and mortality among the non-communicable diseases in Kenya. Most children die early even before they are diagnosed ⁸and even those who are diagnosed have limited access to care and so they die early from complications (Majaliwa et al 2007)⁹.

Children with diabetes are constantly reminded of the disease on a daily basis because they have to eat carefully, exercise, test their blood glucose and they have to schedule their next meal or medication based on the glucose levels. Furthermore, they often have to stop and check for symptoms of hypoglycemia or hyperglycemia as well as deal with the fears of the possibility of long term complications of the disease and this can affect their quality of life.

However, when children with diabetes receive the right treatment and follow up, they are able to live a near normal to normal life as their counterparts without diabetes. At present, follow up of diabetic children emphasizes on glyceemic control by assessing HbA1c every three months¹⁰. However, follow up of diabetic children should go beyond glyceemic control and encompass routine QOL assessments as better glyceemic control may not necessarily correlate to better QOL as there may be other factors affecting the QOL other than diabetes.

LITERATURE REVIEW

Quality of life studies carried out in diabetic children have shown that diabetic children have a lower quality of life than their non diabetic counterparts^{11,12,13,14}. However, other studies did not find a difference between the two groups^{15,16}. In fact, Emmanoulidou et al in Greece found diabetic children to have better social functioning than the healthy children¹⁵. However, no study has been done on quality of life in children with diabetes and limited studies have been done in Africa

Factors associated with QOL in diabetics

1. Socio-demographic factors

Age

Children are wholly dependent on an adult (parent/care giver) in their health seeking behavior and compliance to treatment as the parent or care giver has the economic power over the child, and younger children have their insulin injections administered by an older person.

Most children present in diabetic ketoacidosis (Majaliwa et al, 2007)⁹ at diagnosis and glycemic control is a challenge as they keep alternating between hypoglycemia and hyperglycemia.¹⁷ .Diabetic children of a younger age have been found to have better glucose self monitoring thus better QOL.

Adolescents are faced with many challenges including demands from school work, peer influence, societal and family expectations. A study done in 2008 in the United States by Michelle et al in selected populations, older girls were found to have a lower QOL.¹¹

Sex

The pubertal peak in onset of Type 1 Diabetes Mellitus occurs earlier in girls than boys and this may contribute to accelerated onset of type 1 DM in genetically susceptible females¹⁷. A study done in Greece by Kalyva et al found that onset of diabetes at an older age and the male gender were associated with better QOL compared with the female gender.¹⁸

The female gender among diabetic children and adolescents was found to be associated with a lower QOL^{19,20}. However, other studies have found no sex differences in QOL in diabetic children²¹.

Education

When a family member is diagnosed with diabetes, it is not easy for the family members to cope. There's denial and self-blame. The patient and the family members need to be educated on diabetes for them to understand that it is a chronic disease and total lifestyle change is mandatory and not an option for optimal care. Education on adherence to insulin dosage and injections and glycemic control in order to prevent acute and chronic complications; how to recognize symptoms of hyperglycemia and hypoglycemia and the necessary interventions, nutritional counseling and psychological support is necessary.

Diabetes education helps patients acquire the knowledge, information, self-care practices, coping skills and attitudes required for the effective self-management of diabetes and this facilitates the development of diabetes self-management skills which can improve QOL^{19,20}.

Mothers are key players in diabetic care for their children. They have to prepare or ensure food is prepared for the child and the child has had medication. Level of education of the mother is important as it enables her have better understanding. Ann et al found that children whose mothers had a higher level of education and stronger perception of social limitation influence had a lower HbA1c thus better glycemic control and QOL²².

2. Medical factors

Glycemic control

Follow up of diabetic patients aims at having good glycemic control and prevention of complications (acute and chronic). Glycemic control is monitored by measuring the levels of HbA1c every 2-3 months. Optimal HbA_{1c} goals for children are less than 8% for those aged 8 to

12 years, less than 7.5% for those aged 13 to 18 years, and less than 7% for those 18 years and older.²³

At the Kenyatta National Hospital diabetic children are followed up at the endocrinology clinic where they are given insulin and a glucometer for monitoring blood sugars at home. Access to insulin and glucose monitoring has led to improvement in glycemic control. In 2010 (Amolo et al) 50.9% of diabetic children had poor glycemic control compared to 2004 (Ngwiri et al) where 78% had poor glycemic control^{24,25}.

Studies show that a higher HbA1c is related to low HRQOL^{13,18, 19, 26}.

Number of admissions

Younger children are at risk of repeated hospital admissions due to hypoglycemia or hyperglycemia. Admission to hospital deprives children and adolescents time spent with their family members, play groups and school. A study done in Egypt by Mostafa et al showed that HRQOL was lower in children who had multiple admissions in a span of 6 months²⁷. In the United States, Michelle et al found that a lower HRQOL was associated with at least two or more visits to the emergency unit.¹¹

Type of medication

Diabetic children and adolescents face a challenge with medication as they have to keep injecting themselves up to three times a day. They bear the pain and their medication all the time. This limits their level of activity as many fear the consequences of going into hypoglycemia or hyperglycemia. In our setting, patients rely mostly on injectable insulin. In centers where patients have access to insulin pump, studies have shown that children and adolescents who use the insulin pump had a better QOL compared to those who use the injection. A study conducted by Hillard E et al diabetic children showed an improvement in their QOL after being transitioned from injectable insulin to the insulin pump²⁸

Co-morbidities

In diabetes, co-morbidities can be physical, due to complications of diabetes or psychological. A survey in Canada by Maddigan et al concluded that the illness burden experienced by individuals with diabetes is not only associated with diabetes itself, but largely with co-morbid medical conditions and the more the co-morbidities one has, the worse the QOL. Patients who had more than three co-morbidities had a worse HRQOL than those with a single co-morbidity (stroke, arthritis, obesity).²⁹

Adherence

Non adherence is common among adolescents. Deliberate overdosage with insulin, resulting in hypoglycemia, or omission of insulin with excesses in nutritional intake resulting in ketoacidosis with frequent admissions to the hospital for ketoacidosis or hypoglycemia should arouse suspicion of an underlying emotional conflict as this has adverse effects on HRQOL¹⁷.

Health related beliefs

Health Belief Model (Janz et al) focuses on a framework of understanding patient adherence to health behaviors and it focuses on two aspects of a person's conceptualization of health and health behavior. According to Health Belief Model, the likelihood of patients adhering to medical treatment is determined by 5 factors: susceptibility, severity, benefits, barriers and cues³⁰. Poorer diabetes related quality of life also appears to be associated with youths' perceptions that diabetes is upsetting, difficult to manage, and stressful, and is related to higher levels of self-reported depression which leads to lower HQOL³¹

Quality of life Studies

Several studies done have been done to assess quality of life in diabetic children (Table 1)

TABLE 1: Quality of Life studies in diabetic children.

Author	Study title	Type of study	Sample size	Findings
Michelle et al,2008,USA¹¹	HRQL of Children and Adolescents with Type 1/Type 2 Diabetes Mellitus	Cross sectional	2445	Adolescence girls and poor glycemic control were associated with lower HRQOL
Kylie et al,2004 Australia¹²	HRQOL & Metabolic Control in Children with Type 1 Diabetes Mellitus	Prospective cohort study	83	Adolescents reported lower HRQOL and poor physical functioning is associated with poor metabolic control
Lawrence et al, 2012 ,USA¹³	Demographic and clinical correlates of diabetes-related quality of life among youth with type 1 diabetes	Cross sectional	2602	Poor DRQOL associated with younger age, parent without college degree, female sex, medical co morbidities, poor glycemic control
Nijat et al, 2011,Gazi, Turkey¹⁴	Evaluation of Factors Affecting Quality of Life in Children with Type 1 Diabetes Mellitus	Cross sectional	61	Diabetic children had a lower QOL compared to their health peers
Ausili et al,2007 Italy³²	Multidimensional study on quality of life in children with type 1 diabetes	Prospective	33	Metabolic control, younger age, earlier onset of Diabetes Mellitus was associated with better physical and psychosocial functioning of QOL
Emmanoulidou et al 2007 Greek¹⁵	QOL of children and adolescents with diabetes of Northern Greek origin	Cross sectional	89	No difference in QOL among diabetics compared to non diabetics. In fact diabetics showed better social functioning compared to non diabetics.
Lori et al,2007 USA¹⁶	General QOL in Youth With Type 1 Diabetes Mellitus	Cross sectional	100	Youth with type 1Diabetes Mellitus reported similar QOL to the non diabetic youth.

Measures of quality of life

The QOL is measured using several tools. The tools used must fulfill certain psychometric requirements which are: acceptability, reliability, validity and responsiveness.

Practical criteria: The measure should be appropriate or relevant, brief and simple to administer and can be adapted easily for routine use.

The tools used can be either generic scores (can be used in the healthy population as well as the diseased) or disease specific modules (only used for those diseased and it assesses the impact of disease on the quality of life). There are several internationally accepted tools for measuring quality of life.

The Pediatric Quality of Life (PedsQL) modules were applied for this study as they have been internationally tested for reliability and validity and also include a wide range of pediatric age group including the toddlers and they are easy to administer and takes 5-10 minutes

PedsQL Generic Core Scales version 4.0

The 23-item PedsQL Generic Core Scales version 4 encompasses: Physical functioning, Emotional functioning, Social functioning, School functioning (Refer Appendix 1- 3)

They were developed through focus groups, cognitive interviews, pretesting, and field testing measurement development protocols.^{33,34}

Child self-report includes ages 5–18 years, and parent proxy-report includes ages 2–18 years.

The instructions asked how much of a problem each item had been during the past 1 month. A five-point response scale is used (0 = never a problem, 4 = almost always a problem). Items are reverse-scored and linearly transformed to a 0–100 scale (0 = 100, 1 = 75, 2 = 50, 3 = 25, and 4 = 0), so that higher scores indicate better HRQOL. Scale scores are computed as the sum of the items divided by the number of items answered. If >50% of the items in the scale are missing, the scale score is not computed³⁵.

The PedsQL Type 1 Diabetes Module Version 3.0.

It is a 28-item multidimensional module that encompasses five scales: Diabetes symptoms, Treatment barriers, Treatment adherence, Worries, Communication (Refer Appendix 4 – 6)

The format, instructions, Likert-type response scale, and scoring method are identical to the PedsQL 4.0, with higher scores indicating fewer symptoms or problems. The PedsQL 3.0 Diabetes Module development consisted of a review of the literature, patient and parent focus groups and individual focus interviews, item generation, cognitive interviewing, pretesting, and subsequent field testing.³⁶

JUSTIFICATION

Over the years, there has been change in pattern in the management of diabetes children locally. Currently there's a paediatric endocrinologist and there is a fellowship programme in endocrinology which has led to doctors graduating from medical school both at postgraduate and undergraduate level with better knowledge and experience on how to diagnose diabetes promptly and manage them optimally. Early diagnosis and better management has led to increased survival unlike earlier on when the diabetic children would die early.

At Kenyatta National Hospital, there are approximately 250 diabetic patients on follow up at the paediatric endocrinology clinic.

With improved survival and care of diabetes children, it is of value to assess the QOL in this group of children.

The results will not only be useful in improving service provision gearing towards better QOL in diabetic patients but will also serve as a basis for further research.

OBJECTIVES

Research question

1. What is the Quality of Life in diabetic children at the Kenyatta National Hospital?
2. How does it differ with that of normal children?

Primary Objectives

1. To assess Quality of Life in diabetic children with comparison to their non diabetic peers.
2. To assess Diabetic Related Quality of Life of diabetic children.

Secondary objective

To assess the socio-demographic factors associated with quality of life in diabetic children.

STUDY METHODOLOGY

Study design

Comparative cross sectional study.

Study Period

The study was conducted from August 2013 to February, 2014.

Study site

The study was carried out at the Kenyatta National Teaching and Referral Hospital paediatric endocrinology clinic which has approximately 250 diabetic patients. The children with diabetes are brought to the clinic by their parents on appointment. The clinic day is every Tuesday morning. The patients are attended to by doctors on fellowship programme, the resident doctors and the pediatric endocrinologist being the overall doctor. There is a nurse, counselor and a dietician.

Study population

Children with diabetes aged 2-18 years diagnosed with diabetes mellitus and had been on follow up for at least 3 months. The controls were healthy children from the same school and the same class as each diabetic patient recruited matched for sex and age. Those that were not going to school (2- 4years) controls were from the child welfare clinic Kenyatta National Hospital. Parent proxy reports were also filled.

Sampling and sample size.

Sample size was calculated by the formula below for comparative cross section study:

$$n = \frac{2\sigma^2\{Z_{\alpha} + Z_{1-\beta}\}^2}{\Delta^2}$$

n = minimum sample size from each group (diabetic and control)

σ = standard deviation (10.69 in a study done in Northern Greece 2008. This was used as limited studies have been done in Africa)

Z_{α} significance level = 1.96

$Z_{1-\beta}$ is the power = 0.84

Δ Difference in quality of life = 5

$$N = \frac{2 \times 10.69^2 (1.96 + 0.84)^2}{5^2} = \frac{2 \times 10.69 \times 10.69 \times 2.8 \times 2.8}{5 \times 5} = \frac{1791.8492}{25} = 71.6740$$

The minimum sample size from each group (diabetic and controls) was 72 children.

Consecutive recruitment of the study subjects and their controls was applied.

Patient selection

Inclusion criteria

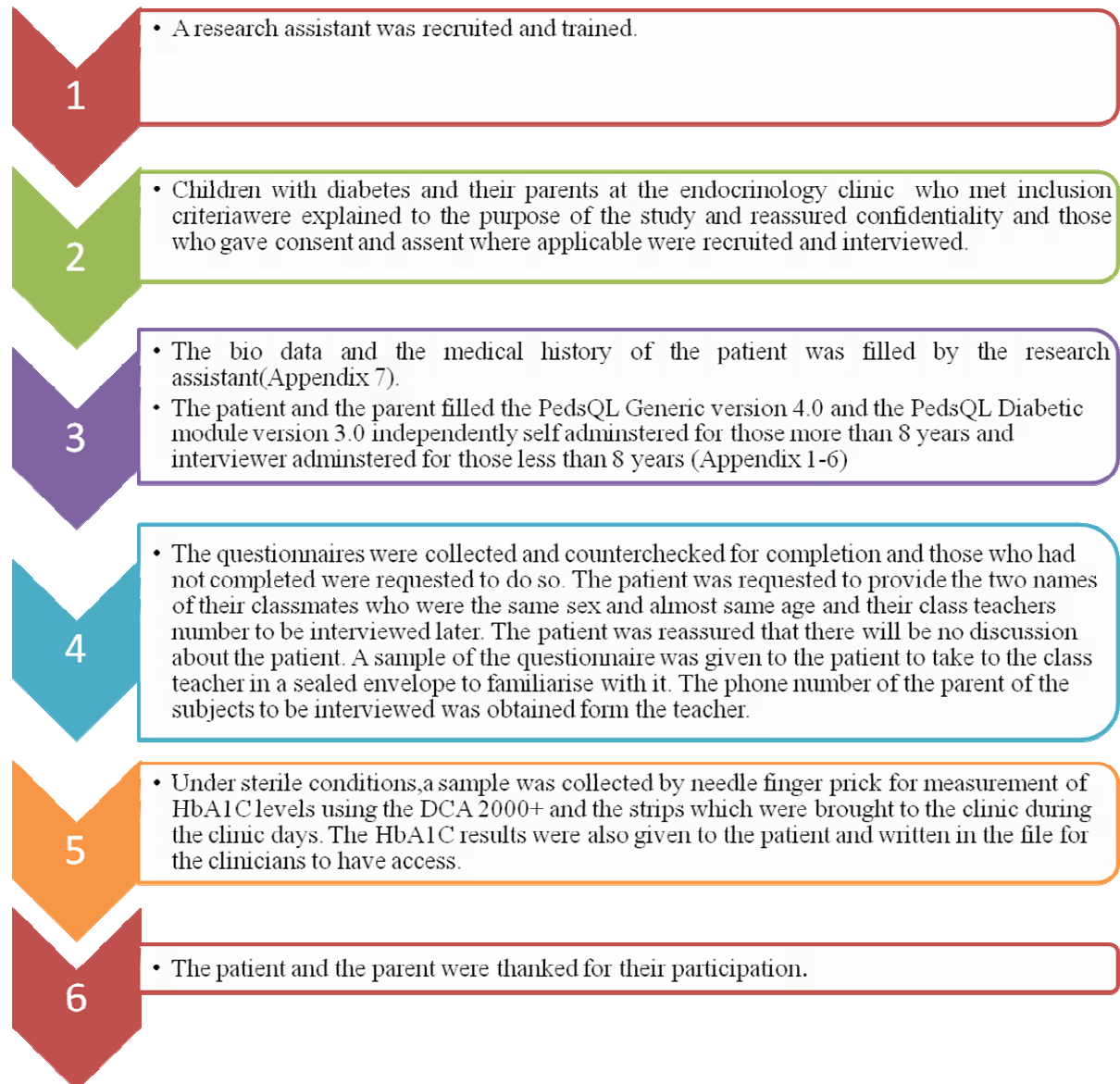
1. Diabetic patients aged 2-18 years had been on follow up for at least 3 or more months.
2. Duly filled informed consent form by parent or care giver and assent form filled by children above 7 years.
3. The controls were healthy children without any acute or chronic disease.

Exclusion criteria

1. Critically ill children who were unable to read or write.
2. Newly diagnosed diabetic patients who had been in care for less than 3months.

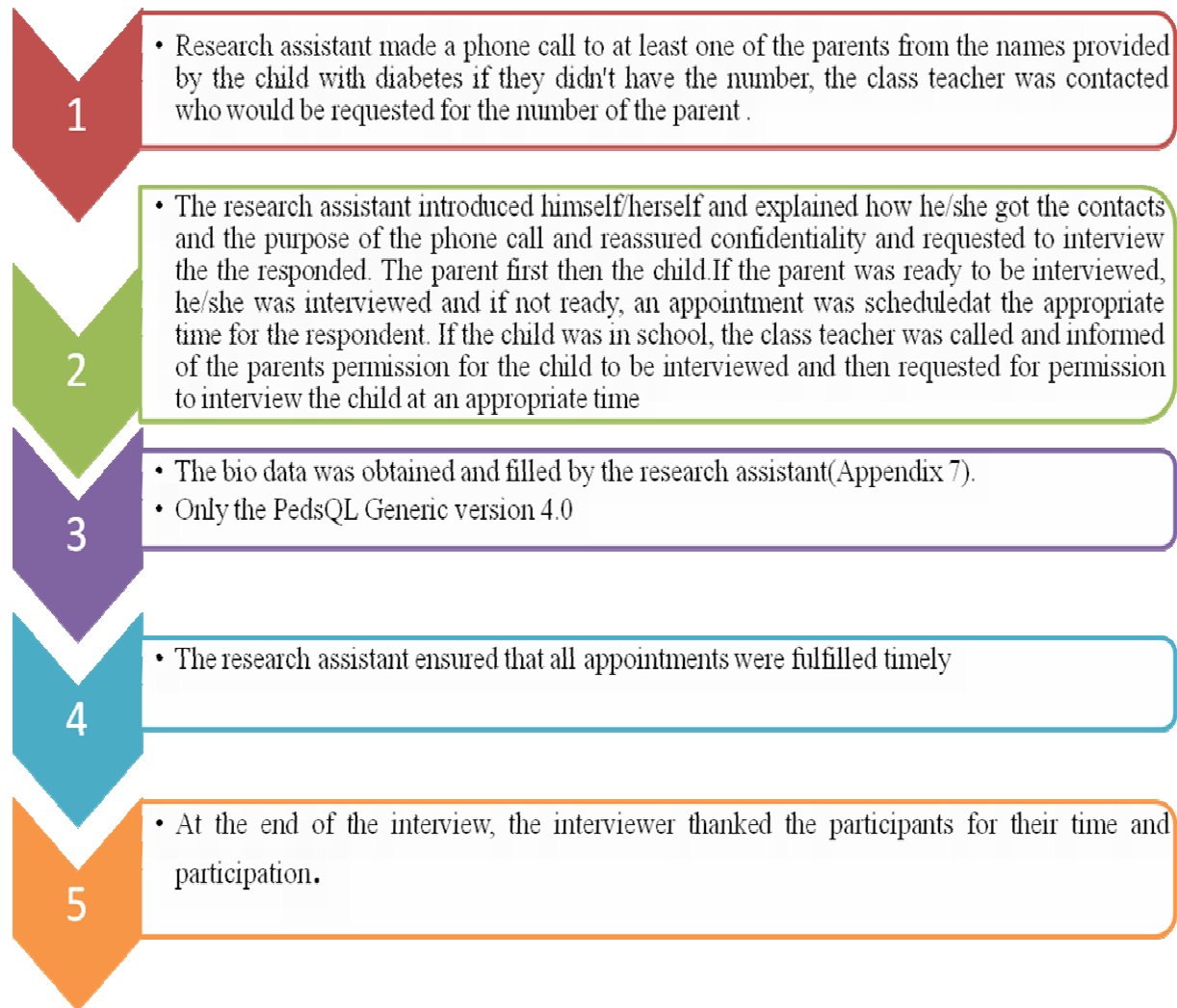
Screening and recruitment

Figure 1: Flow chart for screening and recruitment of diabetic subjects



For the control group

Figure 2: Flow chart for recruitment of the control group



DATA COLLECTION

Data was collected stepwise (Fig 1&2above). The questionnaires were filled at the endocrinology clinic on Tuesdays. Questionnaires were coded for confidentiality. Socio-demographic data and medical history was obtained using a structured questionnaire (Appendix 7). Patient's medical records were reviewed for information regarding age at diagnosis, duration of diabetes and insulin dosage. Both child and parent proxy reports were filled for the PedsQL generic module version 4.0 for both the diabetic and the controls. The diabetic group also filled

the PedsQL diabetic module version 3.0. Children aged 5- 18 years were interviewed with 5 -7 years having the questionnaires administered and above 8 years self administered. There was no discussion between the parent and the child as they filled the questionnaires independently. For the toddlers (2-4years) only the parent filled the questionnaires. The diabetic patients were requested to provide at least two names of their classmates who were of the same sex and same age and their parents and/or class teacher's contacts. HbA1C was measured at the end of the interview as the machine was brought to the clinic. A sample of the questionnaire was given to the child to take to the teacher so that he/she could be aware of the nature of the study.

For the control, the information was obtained by phone call interviews to the numbers provided by the child with diabetes. The teacher was called and explained to the nature of the study. Where there were no numbers of the parents, the teacher provided the phone number of the parent from the school records. The parent was called and explained to the purpose of the phone call and how his/her phone number was obtained. They were assured of confidentiality. If the parent was ready to be interviewed, the questionnaire was administered through phone call and the interviewee was allowed to ask for a repetition so that he/ she could get clarification. Information regarding bio data was recorded in the bio data form (Appendix 7) and then coded PedsQL version 4.0 forms were filled. If the interviewee was not ready, an appointment was scheduled at their time of convenience. The parent and if possible the child were interviewed one after the other. If the child was in school, the class teacher was called and informed on the purpose of the call and informed that permission had been obtained from the parent to have the child interviewed. The interviewer requested to be allowed to interview the student at the appropriate time. The child was allowed to ask for clarification. The responses were entered in

coded PedsQL version 4.0 questionnaires. Both the parent, class teacher and the student were thanked for participation.

Clinical methods

For the child with diabetes, height was measured to the nearest 5 mm using a stadiometer against the wall patient standing straight and without shoes. Weight was measured without shoes and heavy clothing using an electronic weighing scale to the nearest 50g. BMI was calculated using Quetelet equation (weight in kilograms divided by height in meters squared. BMI percentiles for age and sex were determined using the CDC 2000 BMI for age charts and Interpreted as per table 2 below.

TABLE 2: CDC 2000 BMI for age weight status

Percentile Range	Weight status category
< 5 th percentile	Underweight
5 th to < 85 th percentile	Normal
85 th to < 95 th percentile	Overweight
>95 th percentile	Obese

Laboratory methods

For the child with diabetes, HbA1C was determined using the BAYER DCA 2000+ from the University of Nairobi, Department Paediatrics and Child Health Laboratory which was brought to the endocrinology clinic every Tuesday.

The finger was cleaned using alcohol swab. Using a lancet, the finger was pricked and 1 µL blood sample was obtained from a finger prick at the time of the determination and filled into the capillary tube of the test kit and the analysis begun within 5 minutes. Test was 6 minutes and the results were displayed as percent HbA1c. (Range for the DCA 2000+ 2.5% to 14.0%).

Results were recorded in the testing log, and in the patient's chart interpreted as per the Diabetes Control and Clinical Trials with those with HbA1c <8% having good glyceemic control and those with HbA1c >8% having poor glyceemic control.

Waste was handled as highly infectious and discarded as per the hospitals laboratory standards.

Limitations of the procedure:

- The results are accurate over a range of total hemoglobin of 7 to 24 g/dl.
- This test does not detect glycosylated hemoglobin F.
- Because of shortened red cell survival, results from patients with hemolytic anemia, polycythemia and homozygous HbS and HbC cannot accurately reflect long term glyceemic control.

Data management and statistical analysis

Data was entered into database using access 2007 then exported to Statistical Package for the Social Sciences (SPSS) version 17 and analyzed accordingly. General health related quality of life was measured using all the reports (Child, parent, teens and young child) of the Pediatric Quality of Life inventory (PedsQL). The PedsQL comprised of two summary scales: physical QOL and psychosocial QOL. The total QOL score consisted of both summary scales, and was computed as the sum of the items divided by the number of items answered. All scale scores range from 0 to 100, by which higher scores indicate better QOL. The items were scored using a five-point Likert scale (0=never a problem to 4=almost always a problem) and were reversed and linearly transformed to a 0-100 scale. The diabetics module which consisted of 28 items each scored using a five-point Likert scale (0=never a problem to 4=almost always a problem) were reversed and linearly transformed to a 0-100 scale. The total scale (computed as the sum of the

items divided by the number of items answered) showed an internal consistency as measured by Cronbach's alpha. The same applied for the PedsQL diabetic module

As a preliminary analysis frequencies and means were used to present the available demographics of the data for both diabetic cases and control cases. Chi square tests (Fishers exact and Pearson chi square tests) were used to compare categorical variables (gender, BMI, residence). Continuous variables were compared using student t-test (age).

Ethical consideration

1. Study was conducted after written approval by the Department of Paediatrics and Child Health, University of Nairobi and the Kenyatta National Hospital Scientific and Ethical Review Committee.
2. The study was carried out on children whose parents gave written informed consent after being explained to the nature of the study and why the study was being carried out.
3. Information gathered was handled with confidentiality.
4. Laboratory results were availed to the clinician attending to the patient and the parent/care giver was informed too.
5. There was no added cost as the cost of the research was met by the principal investigator.

RESULTS

Demographic characteristics

A total of 166 children (86 diabetics and 80 controls) were enrolled in the study out of which 78 in the diabetic group and 78 in the control group completed the questionnaires (overall response rate of 94 %; adequate for analysis). This was over the minimum sample size.

The mean age (SD) of participants in the two groups were 11.7 ± 4.3 and 11.7 ± 4.2 in the diabetic and the controls respectively with most participants (47.4% diabetics and 50% controls) being teenagers (Table 3). There were slightly more males (52.6% in the diabetic group and 50% in the control group) than females (47.4% in the diabetic group and 50 % in the control giving an overall Male-to-Female ratio of 1.05: 1. Most of the subjects were from the urban area (56.4% of the diabetics and 55% of the controls) while the rest were from either rural (20%) or peri-urban areas (23%). Majority of the participants reported that they were living with both parents (59% in diabetics and 83.3% of the controls) although single parent families were also common especially among diabetics 39.7% compared 15.4% in the control group. Of the 46 fathers interviewed, 76% versus 84% for the diabetic and the control group respectively had attained secondary level of education and above compared to 60% versus 73 % of mothers in the diabetic group and the control group respectively.

The diabetic group and the control group were comparable as most of the variables were not found to be significantly associated with any group except for employment status of the mother and single parent family which were statistically significant ($p < 0.05$) as shown in table 3.

Table 3: Baseline characteristics of study subjects

ITEM	CATEGORY	DIABETIC (N=78) Frequency %	COMPARISON GROUP(N=78) Frequency %	P-value
Sex	Male	41(52.6%)	39(50%)	0.75
	Female	37(47.4%)	39(50%)	
Age group	2 – 4	6(7.7%)	6(7.7%)	Referent
	5 – 7	10(12.8%)	9(11.5%)	0.89
	8 – 12	25(32.1%)	24(30.8%)	0.95
	13 – 19	37(47.4%)	39(50%)	0.93
Residence	Periurban	18(23.1%)	19(24.4%)	0.84
	Rural	16(20.5%)	16(20.5%)	0.96
	Urban	44(56.4%)	43(55.1%)	Referent
Family setting	Both parents	46(59%)	65(83.3%)	Referent
	Single parent	31(39.7%)	12(15.4%)	0.04
	Orphaned	1(1.3%)	1(1.3%)	1.00
Level of education of Father	None	1(2.2%)	1(1.7%)	0.73
	Primary	10(21.7%)	15 (25%)	Referent
	Secondary	20(43.5%)	22(36.7%)	0.51
	Tertiary	9(19.6%)	14(23.3%)	0.16
	University	6(13%)	8(13.3 %)	0.38
Level of education of Mother	None	2(2.6%)	2(2.6%)	0.67
	Primary	28(36.4%)	18(23.4%)	Referent
	Secondary	22(28.6%)	30(39%)	0.07
	Tertiary	19(24.7%)	21(27.3%)	0.22
	University	6(7.8%)	6(7.8%)	0.50
Employment status(Father)	Formal	14(30%)	26(43.3%)	Referent
	Informal	29(62%)	32(53.3%)	0.57
	Not employed	4(9%)	2(33.3%)	0.10
Employment status(Mother)	Formal	14(18%)	18(23%)	Referent
	Informal	43(56%)	47(61%)	0.70
	None	20(26%)	9(12%)	0.05

CLINICAL CHARACTERISTICS

Table 4 presents data on the clinical aspects of diabetes among the 78 diabetics participating in the study. The mean age of patients at the point of diagnosis with diabetes was 8.57 ± 4.25 years and the mean duration of diabetes was 35.02 ± 32.72 months.

Seventy percent of the participants were on short acting insulin (Humulin R) & intermediate acting insulin (NPH) while 30% were on premixed insulin (mixtard). Most of the participants injected themselves (74%) while 26% were injected by either the parents or caregivers. Thirty three percent of the diabetic patients reported having been on alternative therapy. About 50% of the patients had been previously admitted due to diabetes ketoacidosis. Eighty seven percent of the diabetic patient had poor glycemic control (HBA1c above 8%). Self report for compliance to diet, treatment and follow up was quite good with a score of over 70%. However, in objective assessment compliance was poor as reflected by glycemic control.

The mean insulin dosage was 0.66 IU/kg body weight.

Table 4: Clinical characteristics of study subjects

ITEM	DIABETIC (N = 78)	
Age at diagnosis in years	8.57 ±4.25	
Mean duration of treatment in months (± SD)	35.02±32.72	
Mean insulin dosage (IU/Kg)	0.66 ± 0.21	
Type of insulin	Premixed	23(30%)
	Rapid & intermediate	54(70%)
Self report for compliance	Diet	57 (73%)
	Treatment	66 (85%)
	Follow up	60 (77%)
Person who injects the insulin	Parent	19(24.3%)
	Self	58(74.4%)
	Caregiver	1(1.3%)
Complimentary therapy	26 (33%)	
Previous admissions for diabetic ketoacidosis in the past 6 months	38 (49%)	
HBA1c	< 8% (good glycemic control)	10 (12.6%)
	>8% (poor glycemic control)	68(87.4%)
BMI	Underweight	15(19%)
	Normal	58(73%)
	Overweight	4(5%)
	Obese	2(3%)

QUALITY OF LIFE SCORES

The total QOL score ($\alpha=.905$) consisted of five summary scales, and was computed as the sum of the items divided by the number of items answered. Scores within each scale range from 0 to 100, with higher scores indicating better QOL. Reliability analyses were performed to determine the internal consistency of the items and the Cronbach's alpha (α) was 0.72 which is above the expected score of 70%. It is a measure of how well the sum score on the selected items capture the expected score in the entire domain. The next section shows the comparison of quality of life between the diabetics and the healthy children.

Health related Quality of life

Overall, children with diabetes had a lower QOL compared to their non-diabetic peers. Based on scores computed from responses provided by children in the paediatric module of the QOL tool, children with diabetes scored lower percentage mean score 65.1 ± 10.9 compared to their non diabetic peer's percentage mean score 72.9 ± 9.3 ($p < 0.05$). In Table 5 below, domain specific QOL scores for children with diabetes were lower compared to that of controls in all domains (physical functioning, emotional functioning, social functioning, school functioning and psychosocial functioning) p value < 0.05 .

Table 5: Quality of Life scores as per Child reports

Child report of PedsQL module Subscales	Comparison of quality of Life between diabetic and control					
	Diabetic(N=72)		Control (N=72)		Comparison	
	Mean	SD	Mean	SD	Difference	P value
Physical functioning	67.6	11.5	73.2	9.3	5.6	0.002
Emotional functioning	60.8	15.5	72.1	11.9	11.3	<0.001
Social functioning	67.7	12.9	72.6	11.4	4.9	0.017
School functioning	62.6	13	73.7	8.9	11.1	<0.001
Psychosocial functioning	63.7	11.8	72.8	9.6	9.1	<0.001
Total (physical and psychosocial functioning)	65.1	10.9	72.9	9.3	7.9	<0.001

In table 6 below, Parental proxy reports just like child reports, showed that overall, diabetic children had lower total quality of life scores compared to their non diabetic peers with percentage mean scores of 62.2 ± 15.7 and 72 ± 9.6 , respectively (p value < 0.05). Similarly, quality of life scores for diabetics were consistently lower across all five domains compared to non-diabetic group ($p < 0.05$).

Table 6: Quality of life scores as per Parent proxy reports

Parent report of PedsQL module subscales	Comparison of quality of Life between					
	Diabetic (N=78)		Control (N=78)		Comparison	
	% Mean	SD	% Mean	SD	Difference	P value
Physical functioning	64.2	17	72.9	9.1	8.7	0.001
Emotional functioning	59	17.7	70.1	15.8	11.1	<0.001
Social functioning	68.7	15.3	74	8.5	5.3	0.008
School functioning	55.6	21.2	70.4	17.4	14.8	<0.001
Psychosocial functioning	61.1	15.7	71.5	10.5	10.4	<0.001
Total(physical functioning and psychosocial functioning)	62.2	15.7	72	9.6	9.8	<0.001

Diabetes Related Quality Of Life

Quality of life scores related to diabetes specific aspects are shown in Table 7.

The lowest scored aspect of DRQOL by both children with diabetes and their parents was worrying about the illness with a mean 50 ± 20.1 and 49.4 ± 19.4 for children and parents respectively. They worried about the short term and long term complications of diabetes and whether the medications would work or not. Experiencing diabetic symptoms and adherence to treatment were also consistently scored lower than other domains by both parents (mean = 57 and 56.8, respectively) and children (mean = 56.9 and 56.2, respectively).

Table 7: Diabetes Related Quality of Life

PedsQL Diabetic Module version 3.0 Subscales	Child reports (N=72)		Parent proxy report (N= 78)	
	Mean %	SD	Mean %	SD
Symptoms related to diabetes	57	9.3	56.9	27.3
Barriers to treatment	63.3	15.3	61.1	14.3
Adherence to treatment plan	56.8	8.9	56.2	10.1
Worrying about short term and long term complications of diabetes and effectiveness of the medication.	50	20.1	49.4	19.4
Communication	64.4	14.8	60.1	20.2
Total mean scores	57.9	8.3	56.9	8.4

MULTIVARIATE ANALYSIS**Factors associated with health related quality of life**

Table 8 shows the findings of the multivariate linear regression analysis of participant characteristics on QOL. The model had an R-squared (R^2) of 0.6 implying that the included independent variables (case-control status, age, gender, residence and family setting) explained 60% of the variability in quality of life based on the paediatric module tool. Among these independent variables three factors – child’s age ($p < 0.05$), diabetes diagnosis ($p = 0.01$) and male gender ($p = 0.02$) were independently associated with QOL. On average the QOL of diabetic patients was lower than that of non-diabetics after adjusting for the effect of age, gender, residence and family setting ($p = 0.01$; 95% CI -13.12 to -1.68).

QOL increased with increasing age after accounting for diagnosis of diabetic, gender, residence and family setting ($p < 0.05$ 95% CI 1.79 to 3.20). Poor adherence to medication was also

associated with poor QOL ($p < 0.05$). Self injection of insulin was associated with better QOL ($p = 0.02$) Table 8 below.

Table 8: Factors associated with health related Quality of life.

VARIABLE	P value	95% CI	
Diabetic vs. control	0.01	-13.12	-1.68
Age (years)	0.00	1.79	3.20
Male	0.02	0.91	12.86
Residence:			
Rural	0.12	-1.47	13.45
Urban	0.16	-2.01	12.11
Family setting:			
Single parent	0.37	-3.23	8.55
Orphaned	0.61	-19.23	32.55
Intercept	0.00	10.09	38.35
Duration of treatment (in years)	0.30	-1.31	0.41
Rapid and intermediate acting insulin compliance with follow-up	0.73	-3.75	5.32
Adherence to treatment plan	0.98	-5.53	5.65
HbA1c (> 8%)	0.04	-14.22	-0.45
Self injection	0.91	-0.93	1.05
Body Mass Index :			
Overweight	0.88	-17.67	20.48
Risk of overweight	0.09	-1.39	17.99
Underweight	0.68	-4.85	7.38
Intercept	0	49.58	82.05

Association between diabetes related quality of life (DRQOL) and the demographic and medical characteristics

In Table 9 below, multivariable linear regression analysis showed that DRQOL was significantly associated with patient age ($p < 0.05$) and not other characteristics as shown. DRQOL increased with increasing age just like the findings of analysis in HRQOL ($p < 0.05$; 95 % CI 1.43 to 3.50). Other factors like family setting, glycemic control, self report for compliance, duration of illness and type of insulin did not affect the DRQOL.

Table 9: Factors associated with diabetes related Quality of Life

Variable	P value	95% CI	
Age (years)	0.00	1.43	3.50
Female	0.22	-3.01	12.74
Residence:			
Rural	0.77	-11.56	8.60
Urban	0.21	-3.57	15.78
Family setting :			
Single parent	0.35	-4.07	11.35
Orphaned	0.43	-19.49	45.51
Duration of treatment (years)	0.61	-1.82	1.08
Type of insulin	0.48	-6.09	12.75
BMI	0.40	-4.81	1.96
Complimentary therapy	0.84	-7.33	8.98
HbA1C	0.44	-2.04	0.90
Compliance follow up	0.79	-13.02	9.93
Compliance medication	0.89	-12.62	14.58
Intercept	0.40	-22.36	55.04

DISCUSSION

In this study, children with diabetes had a lower HRQOL compared to their non diabetic peers. Similar findings have been found by other studies on QOL in children with diabetes compared to their non diabetic counterparts^{11, 12, 14, 27}. However, some studies have found no difference in QOL between the two groups. A study done in Greece by Emmanoulidou et al found no difference in QOL between the two group¹⁵. In another study in USA by Lori et al, found no difference in QOL between the two groups and the children with diabetes were found to have a better psychosocial functioning compared to their non diabetic peers¹⁶.

The age difference between the diabetes group and the control group was almost the same. This is because of the minimum age entry to school is 6 years for standard one and children rarely repeat thus children are likely to be in the same age group in a particular class. Older children had better HRQOL and DRQOL. Also seen in a study done in Greece by Kalyva et al, older age was associated with better QOL¹⁸. This shows that children diagnosed with diabetes at a younger age should be followed up closely so that they can be assisted to adjust within the shortest time so as to cope with their school work, psychosocial adjustments and challenges that come with diabetes care. However, in a multicentre study in USA by Michelle et al, older children were found to have a lower QOL and this could be because both type 1 and type 2 diabetic children up to 22 years were included in the study unlike our study in which the study subjects were type 1 diabetic children up to 18 years¹¹.

There were slightly more male than female in the study (male: female 1.05: 1) though the difference was not significant. In this study, boys were likely to have a better HRQOL compared to the girls. However, gender did not have an effect on the DRQOL. Similar to other studies,

teenage girls were found to have a lower HRQOL than the boys^{11, 13, 18, 20}. However, in Turkey, a study done by Bas et al found no effect of gender on QOL though the sample size was slightly smaller with a narrow range of the age (61 subjects aged 7-16 years)¹⁹.

It was not possible to obtain height and weight in the control group due to the phone based interview thus only the body mass index (BMI) for the diabetics was computed.

In this study, majority of diabetic children had normal BMI which had no effect on the diabetic related QOL which was the case with other studies done QOL in children with type 1 diabetes mellitus^{12, 14, 15}. This is because type 1 diabetes mellitus is due to insulin deficiency or antibodies to insulin unlike to type 2 diabetes mellitus which is due to poor lifestyle and studies have associated high BMI with poor QOL in patients with type 2 diabetes mellitus.³⁷

Majority of the subjects (56.4%) were from the urban setting with the rest representing the rural and peri-urban population (43.6%). This may be explained by the fact that Kenyatta National Hospital is the largest government Teaching and Referral Hospital with an endocrinologist within Nairobi which is an urban place hence patients would be from the nearby. In this study, residence did not affect QOL. In other studies as such as Emmanoulidou et al in Greece, residence did not affect the QOL¹⁵.

There was no association between family setting and QOL in this study. This is in keeping with a Greek study by Emmanoulidou et al¹⁵. However, the prevalence of single parenthood was lower at 7.9% in the diabetic group in the Greek study compared to this study where it was 40% in the diabetic group. This study did not elicit whether the parents had separated after the child had

been diagnosed with diabetes or before. Of note, a study done by Delamater, it was found that youths from single parent families experienced lower QOL³¹.

The level of education of the parent did not affect the HRQOL and the DRQOL. This is because despite their level of education, parents at the endocrinology clinic have been educated on diabetes care to their level of understanding. Lori et al did not find any association between level of education of parent and QOL¹⁶. A study done by Ausili et al in Italy (2007) did not find any association between level of education of the mother and the QOL³². However, a cross sectional study done by Lawrence et al (USA, 2012) on 2,602 diabetic children found that children whose parents had no college degree had a lower QOL¹³ and this could be because this was a multicentre study with a larger sample size compared to this study.

The employment status determines the socioeconomic status of the family as it is a source of income. Diabetes mellitus is a chronic disease and comes with economic challenges to the family. In this study, employment status of the parent did not affect the QOL. This could be because diabetic children at the endocrinology clinic at Kenyatta National Hospital are provided with free insulin, a glucometer and glucosticks and this relieves the economic burden associated with diabetes mellitus. One months' insulin dosage could cost a family on average two thousands Kenyan shillings. Similar to our findings, Lori et al did not find any association between level of education of parent and QOL¹⁶. However, in a study done in Bosnia by Tahirovic H et al on the impact of socioeconomic status on HRQOL in diabetic children, children with type 1 diabetes mellitus from families of low and middle socioeconomic status had a lower HRQOL compared to the non diabetic children from similar socioeconomic background³⁸. In another study by

Delamater et al, youths from families of lower socioeconomic status were found to have a lower QOL³¹.

Age at diagnosis had no impact on QOL which was similar to a study in Turkey by Bas et al¹⁹. However, Ausili et al found earlier onset of diabetes to be associated with better QOL.³²

Duration of treatment did not affect the QOL. However, most of the patients had been on follow up for a shorter duration and QOL might change over time as the long term complications of diabetes set in. Other studies found no association between QOL and duration of treatment^{16,19}.

Diabetic children and adolescents face a challenge with medication as they have to keep injecting themselves up to four times a day. They have to bear with the pain of the injections and adjust their lifestyles so as not to forget or miss taking the insulin. This limits their level of activity as many fear the consequences of going into hypoglycemia or ketoacidosis. In the endocrinology clinic at the Kenyatta National referral and teaching Hospital, children with diabetes rely on injectable insulin and majority (70%) of the children was on intensified insulin therapy (> 3 injections per day). This study found no impact of insulin therapy on QOL. This finding is similar to findings in other studies^{15, 16, 19, 31}. However, intensified insulin therapy has been associated with better QOL^{28, 39}.

In centers where patients have access to insulin pump, studies have shown that children and adolescents who use the insulin pump have a better QOL compared to those who use the injection. A study conducted by Hillard et al, where children were transitioned from the injectable insulin to the insulin pump then followed up; they showed an improvement in the

health related QOL after being transitioned to the insulin pump²⁸ hence injections were expected to be associated with a lower QOL.

From this study, 26 % of children were on complimentary therapy. Some of the complimentary therapies used were nutritional supplements, herbs and quail eggs. Whether a child was on complimentary therapy or not, it did not affect the QOL. This is because as much as they were on complimentary therapy, they still continued with the insulin. Other studies did not factor in the impact of complimentary therapy on QOL.

The study subjects were on mean insulin dosage of 0.66 ± 0.21 IU/kg / which is within the required dose of upto 1.2 IU/kg/day. Insulin dosage did not affect the QOL. Lori et al did not find insulin dosage to have an impact on QOL¹⁶

Adherence to diet did not affect the HRQOL. However, adherence to follow up affected QOL in that children who were more adherent to follow up plan and not missing appointments had a better QOL compared to those who were not adherent to follow up. Those who administered insulin by themselves had better QOL. This is may be explained by the fact that when children take charge, they stick to their schedule and they can even carry the insulin to school rather than relying on the parent's schedule which may lead to non compliance as the parent might be away or at work. Lori et al found no association between QOL and compliance or parent involvement in care¹⁶.

Follow up of diabetic patients aims at having good glycemic control and prevention of complications (acute and chronic). Glycemic control is monitored by measuring the levels of HbA1c every 2-3 months. According to Diabetes Control Clinical Trial, good control is defined as having HbA1C less than 8 %. Due to improved care and access to insulin at the Kenyatta National Hospital, glycemic control has improved over the years. In 2010, Amolo et al found 50.9 % of diabetic patients to have poor glycemic control compared to poor glycemic control in 78% of diabetic children as reported by Ngwiri et al in 2004. However, in this study 87.4 % of children had poor glycemic control. Diabetic children at Kenyatta National Hospital are given insulin, a glucometer and glucose test strips and this has led to better glycemic control. However, since October 2013, there was lack of access to the free insulin which was the duration this study was carried out and this could explain the poor glycemic control.

There was no effect of glycemic control on QOL. Just like this study, Bas et al did not find any association between QOL and glycemic control though 57.4 % of the participants had good glycemic control¹⁹. However, other studies done show that a high HbA1C is associated with poor QOL^{11, 16, 18, 28, 39}

Previous admissions in the past 6 months due to diabetes ketoacidosis did not affect the QOL. However, a study done by Mostafa et al in Egypt showed that HRQOL was lower in children who had multiple admissions in a span of 6 months²⁷. Michelle et al also found that two or more visits to the emergency unit was associated with lower QOL and this could be because the study subjects had a longer mean duration of diabetes of 73.3 ± 43.1 months and the sample size was larger compared to our study¹¹.

STUDY LIMITATIONS

This study had some limitations which might minimally affect the power of its results

1. Field test for the study tools wasn't done in a larger population due to time factor.
2. Asynchronous communication of place, the interviewer had no view on the situation in which the interviewee in the control group was situated thus the interviewer had lesser possibilities of creating a good interview ambience.
3. There might be other factors that could have affected quality of life that may have not been explored in this study such as family conflict, relationship with other family members.
4. There was no Kiswahili/ local language questionnaires as the user agreement did not permit translation and therefore the respondent might have had a different understanding of the questions as interpreted by the interviewer.

CONCLUSIONS

1. Children with diabetes had a lower QOL compared to their non diabetic peers.
2. Male gender, compliance to medication and insulin injections by self were associated with better HRQOL.
3. Diabetic children had lower DRQOL with majority worrying about the short term and long term complications of diabetes and whether the medications would work or not.
4. Age was an important predictor of both HRQOL and DRQOL as QOL would improve as one grows older. Other sociodemographic and medical factors did not affect the quality of life.

RECOMMENDATIONS

1. Girls and children diagnosed at a younger age should be followed up keenly so as to achieve better QOL. This could be achieved through psychosocial support and formation of support groups.

2. Diabetic children and their families should be offered diabetic education and psychosocial support so that they are more confident about preventing short- and long-term complications of diabetes.
3. A longitudinal study should be carried out to assess the QOL over a longer period of time where QOL is assessed at enrollment and reassessed later to evaluate impact of treatment and complications of the disease on QOL.
4. Other factors that could affect QOL in children with diabetes beyond what we examined by this study could warrant further exploration.

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APPENDICES

APPENDIX 1: PEDSQL VERSION 4.0 (YOUNG CHILD)

TITLE: QUALITY OF LIFE IN DIABETIC CHILDREN AT THE KENYATTA NATIONAL HOSPITAL

SERIAL NUMBER -----

DATE-----

YOUNG CHILD REPORT (ages 5-7)

Instructions for interviewer:

I am going to ask you some questions about things that might be a problem for some children.

I want to know how much of a problem any of these things might be for you.




Show the child the template and point to the responses as you read.

If it is not at all a problem for you, point to the smiling face

If it is sometimes a problem for you, point to the middle face

If it is a problem for you a lot, point to the frowning face

I will read each question. Point to the pictures to show me how much of a problem it is for you. Let's try a practice one first.

	Not at all	Sometimes	A lot
Is it hard for you to snap your fingers			

Ask the child to demonstrate snapping his or her fingers to determine whether or not the question was answered correctly. Repeat the question if the child demonstrates a response that is different from his or her action.

APPENDIX 1 : PEDSQLversion 4.0 (YOUNG CHILD)

Think about how you have been doing for the last few weeks. Please listen carefully to each sentence and tell me how much of a problem this is for you.

After reading the item, gesture to the template. If the child hesitates or does not seem to understand how to answer, read the response options while pointing at the faces.

PHYSICAL FUNCTIONING (PROBLEMS WITH...)	Not at all	Some-times	A lot
1. Is it hard for you to walk	0	2	4
2. Is it hard for you to run	0	2	4
3. Is it hard for you to play sports or exercise	0	2	4
4. Is it hard for you to pick up big things	0	2	4
5. Is it hard for you to take a bath or shower	0	2	4
6. Is it hard for you to do chores (like pick up your toys)	0	2	4
7. Do you have hurts or aches (<i>Where?</i> _____)	0	2	4
8. Do you ever feel too tired to play	0	2	4

Remember, tell me how much of a problem this has been for you for the last few weeks.

EMOTIONAL FUNCTIONING (PROBLEMS WITH...)	Not at all	Some-times	A lot
1. Do you feel scared	0	2	4
2. Do you feel sad	0	2	4
3. Do you feel mad	0	2	4
4. Do you have trouble sleeping	0	2	4
5. Do you worry about what will happen to you	0	2	4

SOCIAL FUNCTIONING (PROBLEMS WITH...)	Not at all	Some-times	A lot
1. Is it hard for you to get along with other kids	0	2	4
2. Do other kids say they do not want to play with you	0	2	4
3. Do other kids tease you	0	2	4
4. Can other kids do things that you cannot do	0	2	4
5. Is it hard for you to keep up when you play with other Kids	0	2	4

School Functioning (PROBLEMS WITH...)	Not at all	Some-times	A lot
1. Is it hard for you to pay attention in school	0	2	4
2. Do you forget things	0	2	4
3. Is it hard to keep up with schoolwork	0	2	4
4. Do you miss school because of not feeling good	0	2	4
5. Do you miss school because you have to go to the doctor's or hospital	0	2	4

APPENDIX 2: PEDSQL PEDIATRIC QUALITY OF LIFE INVENTORY VERSION 4.0

TITLE: QUALITY OF LIFE IN DIABETIC CHILDREN AT THE KENYATTA NATIONAL HOSPITAL

SERIAL NUMBER -----

DATE-----

CHILD'S / TEENS REPORT(8- 18 YEARS)

DIRECTIONS

On the following page is a list of things that might be a problem for you.

Please tell us how much of a problem each of them has been for you during the past **ONEMONTH** by circling:

0 if it is **never** a problem

1 if it is **almost never** a problem

2 if it is **sometimes** a problem

3 if it is **often** a problem

4 if it is **almost always** a problem

There is no right or wrong answer.

If you do not understand a question, please feel free to ask for help

APPENDIX 2: PEDSQL PEDIATRIC QUALITY OF LIFE INVENTORY VERSION 4.0
(CHILD / TEEN REPORT)

In the past **ONE MONTH**, how much of a **problem** has this been for you?

ABOUT MY HEALTH AND ACTIVITIES (problems with..)	Never	Almost never	someti mes	often	Almost always
1. It is hard for me to walk more than one block	0	1	2	3	4
2.It is hard for me to run	0	1	2	3	4
3.it is hard for me to do sports activity or exercise	0	1	2	3	4
4.It is hard for me to lift something heavy	0	1	2	3	4
5. It is hard for me to take a bath or shower by myself	0	1	2	3	4
6. It is hard for me to do chores around the house	0	1	2	3	4
7.I hurt or I ache	0	1	2	3	4
8. I have low energy	0	1	2	3	4

ABOUT MY FEELINGS (problems with..)	Never	Almost never	someti mes	often	Almost always
1. I feel afraid or scared	0	1	2	3	4
2.I feel sad	0	1	2	3	4
3. I feel angry	0	1	2	3	4
4. I have trouble sleeping	0	1	2	3	4
5. I worry about what will happen to me	0	1	2	3	4

HOW I GET ALONG WITH OTHERS (problems with..)	Never	Almost never	someti mes	often	Almost always
1.I have trouble getting along other peers	0	1	2	3	4
2.Other peers don't want to be my friend	0	1	2	3	4
3.Other peers tease me	0	1	2	3	4
4. I can't do things other peers my age do	0	1	2	3	4
5. It is hard to keep up with my peers	0	1	2	3	4

ABOUT SCHOOL (problems with..)	Never	Almost never	Someti mes	often	Almost always
1.It is hard to pay attention in class	0	1	2	3	4
2.I forget things	0	1	2	3	4
3.I have trouble keeping up with schoolwork	0	1	2	3	4
4. I miss school because of being unwell	0	1	2	3	4
5.I miss school to go to the hospital	0	1	2	3	4

APPENDIX 3: PEDSQL PEDIATRIC QUALITY OF LIFE INVENTORY VERSION 4.0

TITLE: QUALITY OF LIFE IN DIABETIC CHILDREN AT THE KENYATTA NATIONAL HOSPITAL

SERIAL NUMBER -----

DATE-----

PARENT REPORT

DIRECTIONS

On the following page is a list of things that might be a problem for **your child**.

Please tell us how much of a problem each of them has been for **your child** during the past **ONEMONTH** by circling:

0 if it is **never** a problem

1 if it is **almost never** a problem

2 if it is **sometimes** a problem

3 if it is **often** a problem

4 if it is **almost always** a problem

There is no right or wrong answer.

If you do not understand a question, please feel free to ask for help

APPENDIX 3: PEDSQL PEDIATRIC QUALITY OF LIFE INVENTORY VERSION 4.0 (PARENT REPORT)

In the past **ONE MONTH**, how much of a **problem** has this been for your child?

PHYSICAL FUNCTIONING (problems with..)	Never	Almost never	someti mes	often	Almost always
1. Walking more than one block	0	1	2	3	4
2. Running	0	1	2	3	4
3. Participating in sports activity /exercise	0	1	2	3	4
4. Lifting something heavy	0	1	2	3	4
5. Taking a bath or shower by him/herself	0	1	2	3	4
6. Doing chores around the house	0	1	2	3	4
7. Having hurts or I aches	0	1	2	3	4
8. Low energy	0	1	2	3	4

EMOTIONAL FUNCTIONING (problems with..)	Never	Almost never	someti mes	often	Almost always
1. Feeling afraid or scared	0	1	2	3	4
2. Feeling sad	0	1	2	3	4
3. Feeling angry	0	1	2	3	4
4. I have trouble sleeping	0	1	2	3	4
5. Worrying about what will happen to him/her	0	1	2	3	4

SOCIAL FUNCTIONING (problems with..)	Never	Almost never	someti mes	often	Almost always
1. Trouble getting along other peers	0	1	2	3	4
2. Other peers not wanting to be his/her friend	0	1	2	3	4
3. Getting teased other peers	0	1	2	3	4
4. Not able to do things other peers his/her age can do	0	1	2	3	4
5. Keeping up when playing with his/her peers	0	1	2	3	4

SCHOOL FUNCTIONING (problems with..)	Never	Almost never	someti mes	often	Almost always
1. Paying attention in class	0	1	2	3	4
2. Forgetting things	0	1	2	3	4
3. Keeping up with schoolwork	0	1	2	3	4
4. Missing school because of being unwell	0	1	2	3	4
5. Missing school to go to the hospital	0	1	2	3	4

APPENDIX 4: PEDSQL DIABETES MODULEVERSION 3.0 (YOUNG CHILD)

TITLE: QUALITY OF LIFE IN DIABETIC CHILDREN AT THE KENYATTA NATIONAL HOSPITAL

SERIAL NUMBER -----

DATE-----

YOUNG CHILD (5 – 7YEARS)

YOUNG CHILD REPORT (ages 5-7)

Instructions for interviewer:

I am going to ask you some questions about things that might be a problem for some children.

I want to know how much of a problem any of these things might be for you.




Show the child the template and point to the responses as you read.

If it is not at all a problem for you, point to the smiling face

If it is sometimes a problem for you, point to the middle face

If it is a problem for you a lot, point to the frowning face

I will read each question. Point to the pictures to show me how much of a problem it is for you. Let's try a practice one first.

	Not at all	Sometimes	A lot
Is it hard for you to snap your fingers			

Ask the child to demonstrate snapping his or her fingers to determine whether or not the question was answered correctly. Repeat the question if the child demonstrates a response that is different from his or her action.

APPENDIX 4: PEDSQL DIABETES MODULE VERSION 3.0 (YOUNG CHILD)

Think about how you have been doing for the last few weeks. Please listen carefully to each sentence and tell me how much of a problem this is for you?

After reading the item, gesture to the template. If the child hesitates or does not seem to understand how to answer, read the response options while pointing at the faces.

Symptoms of DIABETES(<i>PROBLEMS WITH...</i>)	Not at all	Some-times	A lot
1. Do you feel hungry	0	2	4
2. Do you feel thirsty	0	2	4
3. Do you have to go to the bathroom alot	0	2	4
4. Do you have sotmachaches	0	2	4
5. Do you have headaches	0	2	4
6. Do you go 'low'	0	2	4
7. Do you feel tired or fatigued	0	2	4
8. Do you get shaky	0	2	4
9. Do you get sweaty	0	2	4
10.Do you have trouble sleeping	0	2	4
11. Do you get irritable	0	2	4

TREATMENT- I(<i>PROBLEMS WITH...</i>)	Not at all	Some-times	A lot
1. Does it hurt to prick your finger and give insulin shots	0	2	4
2. Are you embarrassed about having diabetes	0	2	4
3. Do you and your parents argue about diabetes care	0	2	4
4. Is it hard for you to stick to diabetes care plan	0	2	4

Whether you do these things **on your own or with the help of your parents**, please answer how hard these things were hard to do in the past **ONE MONTH**

TREATMENT- II(<i>PROBLEMS WITH...</i>)	Not at all	Some-times	A lot
1. Is it hard for you take blood glucose tests	0	2	4
2. Is it hard for you to take insulin shots	0	2	4
3. Is it hard for you to exercise	0	2	4
4. Is it hard for you to keep track of carbohydrates	0	2	4
5. Is it hard for you to wear your ID	0	2	4
6. Is it hard for you to carry a fast acting carbohydrate	0	2	4
7. Is it hard for you to eat snacks	0	2	4

APPENDIX 4: PEDSQL DIABETES MODULE VERSION 3.0 (YOUNG CHILD)

Think about how you have been doing for the last few weeks. Please listen carefully to each sentence and tell me how much of a problem this is for you.

After reading the item, gesture to the template. If the child hesitates or does not seem to understand how to answer, read the response options while pointing at the faces.

WORRY (<i>PROBLEMS WITH...</i>)	Not at all	Some-times	A lot
1. Do you worry about 'going low'	0	2	4
2. Do you worry whether or not your medical treatments are working	0	2	4
3. Do you worry about having problems from diabetes	0	2	4

COMMUNICATION (<i>PROBLEMS WITH...</i>)	Not at all	Some-times	A lot
1. Is it hard for you to tell the doctors and nurses how you feel	0	2	4
2. . Is it hard for you to ask the doctors and nurses questions	0	2	4
3. Is it hard for you to explain your illness to other people	0	2	4

APPENDIX 5: PEDSQL DIABETIC MODULE VERSION 3.0

TITLE: QUALITY OF LIFE IN DIABETIC CHILDREN AT THE KENYATTA NATIONAL HOSPITAL

SERIAL NUMBER -----

DATE-----

CHILD / TEEN REPORT (8 – 18 YEARS)

DIRECTIONS

Children with diabetes sometimes have special problems. On the following page is a list of things that might be a problem for **you**. Please tell us how **much of a problem** each of them has been for **you** during the past **ONEMONTH** by circling:

0 if it is **never** a problem

1 if it is **almost never** a problem

2 if it is **sometimes** a problem

3 if it is **often** a problem

4 if it is **almost always** a problem

There is no right or wrong answer.

If you do not understand a question, please feel free to ask for help

APPENDIX 5: PEDSQL DIABETIS MODULE VERSION 3.0 (CHILD / TEEN REPORT)

In the past **ONE MONTH**, how much of a **problem** has this been for you?

ABOUT MY DIABETES (problems with)	Never	Almost never	Someti mes	Often	Almost Always
1. I feel hungry	0	1	2	3	4
2. I feel thirsty	0	1	2	3	4
3. I have to go to the bathroom too often	0	1	2	3	4
4. I have stomachaches	0	1	2	3	4
5. I have headaches	0	1	2	3	4
6. I go "low"	0	1	2	3	4
7. I feel tired or fatigued	0	1	2	3	4
8. I get shaky	0	1	2	3	4
9. I get sweaty	0	1	2	3	4
10. I have trouble sleeping	0	1	2	3	4
11. I get irritable	0	1	2	3	4

TREATMENT- I (problems with)	Never	Almost never	Someti mes	Often	Almost Always
1. It hurts to prick my finger/give insulin shots	0	1	2	3	4
2. I am embarrassed about having diabetes	0	1	2	3	4
3. My parents and I argue about my diabetes care	0	1	2	3	4
4. It is hard for me to stick to my diabetes care plan	0	1	2	3	4

Whether you do these things **on your own or with the help of your parents**, please answer how hard these things were hard to do in the past **ONE MONTH**

TREATMENT - II (problems with)	Never	Almost never	Someti mes	Often	Almost Always
1. It is hard for me to take glucose tests	0	1	2	3	4
2. It is hard for me to take insulin shots	0	1	2	3	4
3. It is hard for me to exercise	0	1	2	3	4
4. It is hard for me to keep track of carbohydrates	0	1	2	3	4
5. It is hard for me to wear my diabetic ID	0	1	2	3	4
6. It is hard for me to carry a fast acting carbohydrate	0	1	2	3	4
7. It is hard for me to eat snacks	0	1	2	3	4

WORRY (problems with)	Never	Almost never	Someti mes	Often	Almost Always
1. I worry about 'going low'	0	1	2	3	4
2. I worry whether or not medical treatment are working	0	1	2	3	4
3. I worry about long term complications diabetes	0	1	2	3	4

APPENDIX 5: PEDSQL DIABETIS MODULE VERSION 3.0 (CHILD / TEEN REPORT)

In the past **ONE MONTH**, how much of a **problem** has this been for you?

COMMUNICATION (problems with)	Never	Almost never	Someti mes	Often	Almost Always
1. It is hard for me to tell the doctors and nurses how I feel	0	1	2	3	4
2. It is hard for me to ask the doctors and nurses questions	0	1	2	3	4
3. It is hard for me to explain my illness to other people	0	1	2	3	4

APPENDIX 6: PEDSQL DIABETIC MODULE VERSION 3.0

TITLE: QUALITY OF LIFE IN DIABETIC CHILDREN AT THE KENYATTA NATIONAL HOSPITAL

SERIAL NUMBER -----

DATE-----

PARENT REPORT

DIRECTIONS

Children with diabetes sometimes have special problems. On the following page is a list of things that might be a problem for **you**. Please tell us how **much of a problem** each of them has been for **your child** during the past **ONEMONTH** by circling:

- 0 if it is **never** a problem
- 1 if it is **almost never** a problem
- 2 if it is **sometimes** a problem
- 3 if it is **often** a problem
- 4 if it is **almost always** a problem

There is no right or wrong answer.

If you do not understand a question, please feel free to ask for help

APPENDIX 6: PEDSQL DIABETIS MODULE VERSION 3.0 (PARENT REPORT)

In the past **ONE MONTH**, how much of a **problem** has this been for your child?

DIABETES (problems with)	Never	Almost never	Someti mes	Often	Almost Always
1. Feeling hungry	0	1	2	3	4
2. Feeling thirsty	0	1	2	3	4
3. Having to go to the bathroom too often	0	1	2	3	4
4. Having stomachaches	0	1	2	3	4
5. Having headaches	0	1	2	3	4
6. Going “low”	0	1	2	3	4
7. Feeling tired or fatigued	0	1	2	3	4
8. Getting shaky	0	1	2	3	4
9. Getting sweaty	0	1	2	3	4
10. Having trouble sleeping	0	1	2	3	4
11. Getting irritable	0	1	2	3	4

TREATMENT- I (problems with)	Never	Almost never	Someti mes	Often	Almost Always
1. Needle sticks (injections/blood tests) causing him/her pain	0	1	2	3	4
2. Getting embarrassed about having diabetes	0	1	2	3	4
3. Arguing with my spouse about diabetes care	0	1	2	3	4
4. Sticking to his/her diabetes care plan	0	1	2	3	4

Whether you do these things **independently or with your help**, please answer how difficult these things were to do in the past **ONE MONTH**

TREATMENT - II (problems with)	Never	Almost never	Someti mes	Often	Almost Always
1. It is hard for him/her to take glucose tests	0	1	2	3	4
2. It is hard for him/her to take insulin shots	0	1	2	3	4
3. It is hard for him/her to exercise	0	1	2	3	4
4. It is hard for him/her to keep track of carbohydrates	0	1	2	3	4
5. It is hard for him/her to wear my diabetic ID	0	1	2	3	4
6. It is hard for him/her to carry a fast acting carbohydrate	0	1	2	3	4
7. It is hard for him/her to eat snacks	0	1	2	3	4

APPENDIX 6: PEDSQL DIABETIS MODULE VERSION 3.0 (PARENT REPORT)

WORRY (problems with)	Never	Almost never	Sometimes	Often	Almost Always
1. Worrying about 'going low'	0	1	2	3	4
2. Worrying whether or not medical treatment are working	0	1	2	3	4
3. Worrying about long term complications diabetes	0	1	2	3	4

PEDSQL DIABETIS MODULE VERSION 3.0 (CHILD / TEEN REPORT)

In the past **ONE MONTH**, how much of a **problem** has this been for you?

COMMUNICATION (problems with)	Never	Almost never	Sometimes	Often	Almost Always
1. It is hard for him/her to tell the doctors and nurses how I feel	0	1	2	3	4
2. It is hard for him/her to ask the doctors and nurses questions	0	1	2	3	4
3. It is hard for him/her to explain my illness to other people	0	1	2	3	4

APPENDIX 7 :PATIENT’S PROFILE

QUALITY OF LIFE IN CHILDREN WITH DIABETES AT THE KENYATTA NATIONAL HOSPITAL

SERIAL NUMBER.....

DATE.....

A. DEMOGRAPHIC DATA

i) Bio data

Age (years).....Sex:Male Female Weight (Kg)..... Height(M).....

BMI..... RBS.....

Residence.....School level (Indicate particular class).....

ii) Family Setting: Who do you live with?

- Lives with both parents
- Single parent: Lives with mother Lives with father
- Orphaned: who is the primary care giver (specify).....
- Other (specify).....

iii) Level of education of (TICK ONE)

Father: Primary Secondary Tertiary University None

Mother: Primary Secondary Tertiary University None

Care giver: Primary Secondary Tertiary University None

iv) Employment status(Tick if employed and specify whether formal or informal)

Father: Employed Formal employment Informal employment Not employed

Mother: Employed Formal employment Informal employment Not employed

Care giver: Employed Formal employment Informal employment Not employed

B) Medical History

i) At what age was the patient diagnosed?

ii) How long has he/she been on medication/follow up?.....

iii) Medication (Tick where appropriate)

a) Type of Insulin.....dosage.....

b) Who injects you? Self Parent Care giver

d) Any other medications (specify).....

e) Have you been on alternative therapy? Yes No

If yes (Specify eg traditional, herbal, prayers, nutritional supplements).....

iv) Compliance to

Diet Yes No if no why?

Medication: Yes No if no why?

Follow-up: Yes No if no why?

v) Previous HBA_{1c} levels (check from the records and record at least 3 if available and the dates if none the patient to have it taken- only the current will be used for analysis)

1).....%Date taken.....2).....%Date taken.....

3)..... %Date taken.....

vi) Have you been admitted in the previous 6 months?

Yes how many times? NO

Reasons for admissions?.....

Class teachers phone number.....

Parent's name and phone number of a pupil in the same class.....

APPENDIX 8: INFORMATION TO THE PARTICIPANT

Background

You are being asked to participate in a research study. Before you decide, it is important for you to understand why the research is being done and what it will involve. Read the following information carefully and ask us if there is anything that is not clear or if you would like more information. Please take time to decide whether you want your child to volunteer to take part in this study.

The purpose of this study is to find out Quality Of Life of diabetic children. Our study is for research purposes but we hope that the information obtained will be used to formulate policies which will result in improved healthcare service delivery to diabetic children and adolescents.

Study Procedure

The study involves filling out a questionnaire capturing your bio data and answering questions appropriately. Your responses will not be linked to you or the child and are completely anonymous and confidential. There are no right or wrong answers.

Risks and benefits

There are no risks of this study except for the pain during sample collection for HbA1C levels and there are no direct medical benefits to your child for participating in this study. A potential benefit of the study will be improved healthcare service delivery in diabetic patients.

Alternative Procedures

You may choose your child not to participate in this study and it will not affect the health care that will be provided to you.

Confidentiality

This research will be conducted in accordance with all the Kenyan laws and regulations that protect rights of human research subjects. All records and other information obtained will be

kept strictly confidential and your child's protected health information will not be used without permission. All data collection tools will be identified by number or otherwise coded to protect any information that could be used to identify your child. Results of this study may be published, but no names or other identifying information will be released.

Person to contact: If you have questions, complaints or concerns about this study, you can contact the principal investigator Dr. Musabi S Melab 0724846944 University of Nairobi, Department of Child Health and Paediatrics, Postgraduate programme;

Ethics Review Board: This study has been approved by the ERB of University of Nairobi/Kenyatta National Hospital. Contact ERB if you have questions or concerns regarding your child's right as a participant,

Contact ERB using the address; The Chairman ERB, Box 20723, Nairobi

Voluntary Participation: It is up to you to decide whether your child takes part in this study. Refusal to participate research has no penalty or loss of benefits to which your child is otherwise entitled. This will not affect your relationship with the investigators.

Right of investigator to withdraw

The investigator can withdraw your child from the research without your approval.

Costs and Compensation: There is no cost to you, and there is no compensation to subjects

Number of Participants: 100 diabetic and 100 non diabetic children aged 2 – 18 years. For all participants parent proxy report shall be obtained.

Authorization for use of your protected health information

This study does not entail the use of your child's protected health information. Thank you for your child's participation in this research and we truly appreciate your help.

APPENDIX 9:1 CONSENTFORM

CONSENT TO PARTICIPATE IN THE STUDY

TITLE: QUALITY OF LIFE IN DIABETIC CHILDREN AT KENYATTA NATIONAL HOSPITAL

SERIAL NUMBER

DATE.....

By signing this consent form, I confirm I have read the information in this consent form and have had the opportunity to ask questions. I voluntarily agree to take part in this study.

Name of Caregiver / Parent.....Signature/Mark..... Date.....

Name of InvestigatorSignature..... Date.....

(Kwa kuweka sahihi hapa, naidhinisha ya kwamba nimesoma au kuelezwa kuhusu uhunguzi unaofanywa ni nimepata nafasi ya kuuliza maswali. Nimefanya uamuzi wangu kuhojiwa.

Jina la mhojiwa.....Sahihi/alama.....Tarehe.....

Jina la mwenye kuhoji.....Sahihi.....Tarehe.....)

2. ASSENT

Your parent has agreed that you take part in our study where we are looking at the quality of life of diabetic children. By signing this form, you agree to voluntarily participate in this study.

Name of child.....Alama.....Tarehe.....

Name of investigator.....Sahihi.....Tarehe.....

(Mzazi wako amekubali ya kwamba uhojiwe kwenye utafiti ambao tungependa kujua hali ya maisha ya watoto walio na ugojwa wa sukari. Kwa kuweka alama kwenye hii fomu ni kutoa idhini ya kuhojiwa.

Jina ya mtoto.....Alama.....Tarehe.....

Jina ya mwenye kuhoji.....Sahihi.....Tarehe.....)

APPENDIX 10 : PHONE CALL INTERVIEW FOR CONTROL

Hello Mr/Ms/Mrs _____parent to_____ I am MR/Mrs/Dr_____ from the University of Nairobi / Kenyatta National hospital and we are doing a study on the Quality of life of children comparing those with diabetes and those without. We got your contact from one of our clients attending the diabetic clinic who participated in the study and nominated your child as their best friend. It takes about 5 -10 minutes to respond to the question and it's your right to participate or not. I shall also interview your child. The information provided will be handled with confidentiality as your responses will be anonymous with no names. The lead investigator is Dr.Melab Musabi from the University of Nairobi and in case of any questions; she can be reached on 0724846944. May I know if you are ready to be interviewed now or if not, kindly give me the appropriate time I can call back so that I can interview you and the child?

Time to call back.....Date.....

(When ready, the interviewer administers the questionnaire and ticks the responses appropriately.

Once finished, the interviewer asks the respondent if he/she has any questions and thanks the respondent for their time and agreeing to take part in the study).

(Habari yako Bw/Bimzazi wa mimi ni Bw/Bi kutoka Chuo Kikuu Cha Nairobi/ Hospitali Kuu Ya Kenyatta. Tunafanya uchunguzi kuhusu hali ya maisha ya watoto tukiwalingalisha na wale walio na ugonjwa wa sukari. Tulipata nambari zako za simu kutoka kwa mmoja ya wale watoto wanaohudhuria Kliniki yetu ya ugonjwa wa sukari na wanaenda shule moja na mototo wako.Maswali haya yatachukua kardi dakika 1kumi na tano hadi ishirini.Ningependa kukuhakikishia ya kwamba majibu ambayo unatoa ni siri kwani hatuandiki majina ya waliohojiwa hayataandikwa.Mtafiti mkuu anaitwa Dr.Melab Musabi kutoka chuo Kikuu Cha Nairobi nambari yake ya simu ikwa 0724846944.Nigependa kujua ikiwa uko tayari kuhojiwa

pamoja na motto wako na kiwa hauko tayari, unaweza kunipatia wakati ambao utakuwa tayari
kuhojiwa. Wakati wa kuhojiwa..... Tarehe.....

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