MICROALBUMINURIA AMONG CHILDREN WITH DIABETES MELLITUS ATTENDING OUTPATIENT CLINIC AT MOI TEACHING AND REFERRAL HOSPITAL, ELDORET, KENYA

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DECLARATION

Student's declaration

This research thesis is my original work done during the course of Masters of Medicine in Child Health and Pediatrics degree course of Moi University.

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DEDICATON

I dedicate this work to my family and especially my wife Zainab who embodies my inspiration.

ACKNOWLEDGEMENT

I wish to thank my supervisors Dr Bonface Ganda and Dr. Esther Nabakwe for their guidance and support; and Mr Alfred Keter for his immense help in analyzing the data.

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Lastly I thank my family for their patience and prayers during the study.

ABBREVIATIONS AND ACRONYMS

ACE Angiotensin Converting Enzyme

ACR	Albumin to creatinine ratio
AGE	advanced glycated proteins
ARBs	Angiotensin Receptor Blockers
DCCT	Diabetes Control and Complications Trial
DKA	Diabetic ketoacidosis
DM	Diabetes Mellitus
DN	Diabetic nephropathy
DOPC	Diabetic outpatient clinic
ESRD	End stage renal disease
GFR	Glomerular Filtration Rate
HbA1c	Glycated Hemoglobin
IREC	Institutional Research and Ethics Committee
KDOQI	Kidney Disease Outcomes Quality Initiative
MA	microalbuminuria
MTRH	Moi Teaching and Referral Hospital
NKF	The National Kidney Foundation
UAE	Urine Albumin Excretion

OPERATIONAL DEFINITION

Child – person of 17 years of age and below

Hypertension – blood pressure > 95^{th} percentile according to age, sex and height

Microalbuminuria - urinary albumin to creatinine ratio between 30 - 299mg/g

Macroalbuminuria - urinary albumin to creatinine ratio >300mg/g

Duration of Diabetes mellitus - duration of disease from the time of diagnosis to the time data was collected

MICROALBUMINURIA AMONG CHILDREN WITH DIABETES MELLITUS ATTENDING OUTPATIENT CLINIC AT MOI TEACHING AND REFERRAL HOSPITAL, ELDORET, KENYA.

ABSTRACT

Background: Type1 Diabetes Mellitus (DM), is caused by insulin deficiency. Microalbuminuria is a serious complication of diabetes. Sustained hyperglycemia and hypertension are known causes of microalbuminuria. In Tanzania, the prevalence of microalbuminuria was 12% in type 1 DM. Recommended time for screening for microalbuminuria in children with diabetes is 5 years after diagnosis.Microalbuminuria has been mistaken to be a condition of adults.Screening needs to be done early enough to prevent rapid progression of the disease.

Objective: To determine the prevalence of microalbuminuria among children with diabetes mellitus seen at the outpatient clinic at Moi Teaching and Referral Hospital(MTRH), Eldoret-Kenya.

Methods: A cross sectional study design was used. Data was collected from 80 participants attending the diabetic outpatient clinic at MTRH using a questionnaire. Blood pressure, height and weightwere measured and spot urine sample were collected to measure urinary albumin to creatinine ratio. The most recent HbA1c level and other clinical information were recorded from the file. Data was analyzed using SAS version 9.3 at 95% confidence level. The demographic and clinical characteristics were summarized using descriptive statistics. Categorical variables were summarized using frequencies with respective percentages and their associations were assessed using Fisher's exact test. Mean with standard deviation (SD) were used for continuous variables.

Results: Out of the 80 participants, 48% were female, 52% were aged 10-15 years. The median age at diagnosis of diabetes was 6.5 years (IQR 4-10) while the median duration with diabetes was 4 years (IQR 2-6).Eighty percent of the children were underweight and younger participants are more likely to be underweight (p=0.015)

The prevalence of microalbuminuria was (n=6) 7.5% while that of macroalbuminuria was 1% (n=1). The prevalence of hypertension was 6% (n=5) and none of those with hypertension had microalbuminuria. The mean age of duration of diabetes for children with microalbuminuria was 4.3 years (95% CI 3.5-4.9)as compared to 4.2 years for those with normolbuminuria (SD 3.0, p value= 0.929).The relative risk of developing microalbuminuria at less than 5 years of duration of DM is 1.56 but is not statistically significant.Children with diabetes residing in an urban area is associated with developing microalbuminuria(p=0.04). Almost all children had poor glycemic control in the past with a mean glycated heamoglobin of 11.3%. Children with an older age at diagnosis of DM was associated with developing microalbuminuria(p=0.042)

Conclusion: The prevalence of microalbuminuria in children with diabetes at MTRH is 7.5%. Older age at diagnosis and urban residence is associated with developing microalbuminuria.

Recommendation:Further longitudinal studies of a larger sample size needs to be done to assess risk factors for developing microalbuminuria in this population.

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CHAPTER ONE: INTRODUCTION

Type 1 diabetes mellitus, one of the most common chronic diseases in childhood, is caused by insulin deficiency following destruction of the insulin-producing pancreatic beta cells.

The incidence of Type 1 Diabetes varies worldwide. The highest reported incidence occurs in Finland and Sardinia with 37 to 45 per 100000 children. On the other end China and Venezuela report the lowest incidence with 0.1 to 0.5 per 100000 children (Silink, 2002; Yang, 1998; De Beaufort, 2006). Studies done in the African continent show a prevalence of 4 per 100000 children in Mozambique to 12 per 100000 children in Zambia (Hall et al., 2011), while another study done in Nigeria revealed a prevalence of 33/100000 (Afoke, 1993).

Microalbuminuria, a complication of type 1 and type 2 diabetes, progresses to macroalbuminuria and is the leading cause of kidney disease in patients starting renal replacement therapy in the United States of America (Collins & Foley 2012) and is associated with increased cardiovascular mortality(Valmadrid et al., 2000).

Small amounts of albumin in the urine not usually detected by conventional methods, is termed as microalbuminuria or incipient nephropathy. Microalbuminuria is defined as urinary albumin excretion between 30 and 299 mg/g of creatinine and macroalbuminuria is defined as urinary albumin excretion above 300 mg/gof creatinine.The main potentially modifiable microalbuminuria initiation and progression factors in susceptible individuals are sustained hyperglycemia and hypertension (Stratton, 2000; Nelson, 1998).

Diabetes causes unique changes in kidney structure. Classic glomerulosclerosis is characterized by increased glomerular basement membrane width, diffuse mesangial sclerosis, hyalinosis, microaneurysm and hyaline arteriosclerosis.

The basis for the prevention of microalbuminuria is the treatment of its known risk factors: hypertension, hyperglycemia, smoking and dyslipidemia. In the Diabetes Control and Complications Trial, carried out in the United States of America in 1991, intensive treatment of diabetes reduced the incidence of microalbuminuria by 39% (Diabetes Control and Complications Trial Research Group, 1993). In the HOT (Hypertension Optimal Treatment) randomized multicentre study completed in 1998, a reduction of diastolic blood pressure from 85 to 81mmHg resulted in a 50% reduction in the risk of cardiovascular events in diabetic but not in nondiabetic patients (Hanssonet al., 1998).

Early detection of microalbuminuria, adoption of multifactorial interventions targeting the main risk factors (hyperglycemia, hypertension, dyslipidemia and smoking), and use of agents with a renoprotective effect (Angiotensin Converting Enzyme inhibitors and/or Angiotensin receptor blockers) do indeed reduce the progression of renal disease.

The Finnish Diabetic Nephropathy study showed that in 4201 type 1 DM adults followed over a median of 7 years, those who were normoalbuminuric had a similarmortality risk as the general population (Ngwiri, Were, Predieri, Ngugi, & Iughetti, 2015). However, compared to normoalbuminuria, those with microalbuminuria (moderatealbuminuria), macroalbuminuria (severe albuminuria) and ESRD had increased standardized mortality hazard ratios (HR) of 2.8, 9.2 and18.3, respectively.

According to National Kidney Foundation Kidney Disease Outcomes Quality Initiative (NKF KDOQI) guidelines (2012), Patients with diabetes should be screened annually for Diabetic Kidney Disease. Initial screening should commence:

- 5 years after the diagnosis of type 1 diabetes; or
- From diagnosis of type 2 diabetes.

Screening should include:

  - Measurements of urinary Albumin to Creatinine Ratio in a spot urine sample;
  - Measurement of serum creatinine and estimation of glomerular filtration rate.

In diabetic patients with microalbuminuria and retinopathy, the diagnosis of diabetic nephropathy (DN) is highly likely, including in patients with type 1 diabetes of 10 years' duration and microalbuminuria.

An update from the same recommends a target hemoglobin A1c (HbA1c) of 7.0% to prevent or delay progression of the microvascular complications of diabetes, including diabetic nephropathy (Rocco, & Berns, 2012).

A follow up study done after The Diabetes Control and Complications Trial in which one cohort was given intensive therapy while the other conventional therapy for 6.5 years, the Epidemiology of Diabetes Interventions and Complications showed that the reduction in the risk of progressive retinopathy and nephropathy resulting from intensive therapy in patients with type 1 diabetes persists for at least four years, despite increasing hyperglycemia (Epidemiology of Diabetes Interventions and Complications Research Group, 2000).

1.2 Problem Statement

Microalbuminuria is a common and serious complication of type 1 diabetes (10 -21%) (Hall et al., 2011), It can be prevented and its progression delayed (Rocco & Berns, 2012).

Most studies done on microalbuminuria and have subjects with type 2 DM and limited studies have only children with DM and microalbuminuria is usually mistaken to be a condition of the adults.

The progression of microalbuminuria including chronic kidney disease and end stage renal disease have a huge cost implication on the patient management.

It is estimated that up to a third of patients undergoing chronic dialysis at MTRH have diabetes mellitus. It is known that in resource limited-settings, the cost and access of dialysis and renal transplantation is restrictive and expensive. This has contributed to increased morbidity and mortality, and likely a reduction in economic productivity among the affected patients

1.3 Justification

Diabetes prevalence is increasing globally, and Sub-Saharan Africa is no exception like Nigeria having a prevalence of type 1 DM as high as 33/100000 person. With diverse health challenges, health authorities in Sub-Saharan Africa and international donors need robust data on the epidemiology and impact of diabetes in order to plan and prioritize their health programmes.

With diverse health challenges in Kenya, data on the impact of diabetes is required in order to plan and prioritize health programmes. . However, among children with diabetes, there is no routine screening for microalbuminuria in most health care

facilities in Kenya including MTRH, hence, the prevalence of microalbuminuria is not known.

1.4 Research Question

What is the prevalence of microalbuminuria among children attending the Diabetic Outpatient clinic at MTRH?

1.5 Research Objectives

1.5.1 Broad Objective

To determine the prevalence of microalbuminuria among children attending diabetic outpatient clinic at MTRH

1.5.2 Specific Objectives

1. To determine the prevalence of microalbuminuria among children with diabetes seen at MTRH
2. To determine the factors associated with microalbuminuria in children attending the diabetic outpatient clinic at MTRH.

CHAPTER TWO:LITERATURE REVIEW

2.1 Definition

Microalbuminuria refers to an abnormally increased excretion rate of albumin in the urine in the range of 30-299 mg/g creatinine. It is a marker of endothelial dysfunction and increased risk for cardiovascular morbidity and mortality especially, but not exclusively, in high-risk populations such as diabetics and hypertensives.

Diabetic nephropathy (DN) is typically defined by macroalbuminuria—that is, a urinary albumin excretion of more than 300 mg in a 24-hour collection—or macroalbuminuria and abnormal renal function as represented by an abnormality in serum creatinine, calculated creatinine clearance, or glomerular filtration rate (GFR). Clinically, diabetic nephropathy is characterized by a progressive increase in proteinuria and decline in GFR, hypertension, and a high risk of cardiovascular morbidity and mortality

2.2 Epidemiology

The cumulative incidence of microalbuminuria in patients with type 1 DM was 12.6% over 7.3 years according to the European Diabetes (EURODIAB) Prospective Complications Study Group (Chaturvedi, 2001).

The prevalence of diabetic nephropathy at a diabetic clinic in United Kingdom was 9.5% Craig et al., (2003) while the prevalence in an Urban South Indian Population was 2.2% for overt nephropathy and 26.9% for incipient nephropathy (Unnikrishnanet al., 2007).

In a recent study by Lutale et al on microalbuminuria among type 1 and type 2 diabetic patients of African origin in Dar es Salaam, the overall prevalence of microalbuminuria was 11% and macroalbuminuria 5%. In type 1 patients,

microalbuminuria was present in 12% and macroalbuminuria in 1% (Lutale et al., 2007).

According to Ngugi et al, the prevalence of diabetic nephropathy was 15.8% for both type 1and type 2 diabetes at Kenyatta National Hospital. The prevalence of diabetic nephropathy increased with duration of diabetes in the insulin dependent diabetics the lowest prevalence being 3.2% at upto 5 yearsof diabetes mellitus and the highest 60% at 16 to 20 years (Githaiga, 2002).

2.3 Pathogenesis

Microalbuminuria involves pathological changes, the hallmark being extra cellular matrix accumulation. Transforming Growth Factor (TGF)-B, which is stimulated by glucose, advanced gylcated proteins (AGE), vasoactive hormones such as angiotensin II and endothelin play an important part in mediating the interaction between metabolic and hemodynamic factors leading to extra cellular matrix accumulation in the diabetic kidney (Cooper, 1998).

Microalbuminuria in type 1 diabetes is preceded by markers of endothelial dysfunction, including elevated serum von Willebrand factor (vWF) and increased transcapillary albumin escape rate. Diabetes is a state of chronic hyperglycaemia, therefore it is probable that glucose- dependent processes are involved in microalbuminuria. For example, the chronic effects of glucose in inducing tissue injury may occur via the generation of advanced glycated proteins (AGE). AGE accumulate in the kidney, particularly in people with diabetes or declining renal function or both.Glomerular endothelial cells are highly specialised cells with regions of attenuated cytoplasm punctuated by numerous fenestrae, circular transcellular pores 60–80 nm in diameter. The glycocalyx covers both fenestral and inter-fenestral

domains of the glomerular endothelial cell luminal surface. The glycocalyx is a dynamic, hydrated layer largely composed of glycoproteins and proteoglycans with adsorbed plasma proteins. Heparan sulphate proteoglycans (HSPGs) are largely responsible for the negative charge characteristics of the glycocalyx. Removal of the glycocalyx increases vascular protein permeability(Satchell, & Tooke, 2008).

Risk factors for microalbuminuria include long duration of diabetes. In a study done by Claire Levy- Marchal et al, duration of diabetes was an independant risk factor for microalbuminuria (Odds Ratio 1.04-1.32)(Afoke, 1993). Patrecia Gallego et al in Australia, found out that onset of puberty, diabetes duration and metabolic control are major factors predisposing the development of microalbuminuria (Gallego et al., 2006). In a longitudinal cohort study by Monique. L. Stone et al, the predictors for microalbuminuria in children and adolescents using Cox regression were HbA1c (hazardratio 1.4 [95% CI 1.1–1.7]), age at diagnosis (1.2 [1.1–1.3]), obesity (3.6 [0.8 –15.5]), and insulin dose (2.7 [1.0 –7.5])(Stone et al., 2006).

2.4 Clinical Features

Patients with type 1 diabetes often have an initial elevation in their glomerular filtration rate (GFR), accompanied by enlarged kidneys. The earliest laboratory evidence of nephropathy is microalbuminuria (incipient nephropathy)

Without specific interventions, 80% of patients with type 1 diabetes and persistent microalbuminuria will progress to clinical albuminuria (overt nephropathy) within 10-15 years. Hypertension will also develop during this time

Hypertension is seen in 12-25% of patients with microalbuminuria and 75-85% with overt nephropathy, and contributes to the further progression of nephropathy

Patients with overt nephropathy who do not receive specific treatment will have a gradual decline in their GFR over several years. The rate of decline is highly variable between individual patients (2-20mL/min/year). 50% of patients will progress to ESRD within 10 years; more than 75% will develop ESRD within 20 years

Table 1: Urine Albumin levels in relation to time

Category	Spot Collection mg/g creatinine	24 – hour collection mg/24hrs	Timed collection ug/min
Normoalbuminuria	< 30	<30	<20
Microalbuminuria	30 – 300	30 – 300	20 – 200
Macroalbuminuria	>300	>300	>200

2.5 Screening and Diagnosis

For patients with type 1 diabetes, the first screening has been recommended at 5 years after diagnosis (but not before puberty) (Gross et al., 2005). However, the prevalence of microalbuminuria before 5 years in this group can reach 18%, especially in patients with poor glycemic and lipid control and high normal blood pressure levels (Stephenson et al., 1994). Furthermore, puberty is an independent risk factor for microalbuminuria (Schultz et al., 1999). Therefore, in type 1 diabetes, screening for microalbuminuria might be performed 1 year after diabetes diagnosis, especially in patients with poor metabolic control and after the onset of puberty. If microalbuminuria is absent, the screening must be repeated annually for both type 1 and 2 diabetic patients (Gross et al., 2005).

The first step in the screening and diagnosis of microalbuminuria is to measure albumin in a spot urine sample, collected either as the first urine in the morning or at random, for example, at the medical visit. This method is accurate, easy to perform, and recommended by American Diabetes Association guidelines (Gross et al., 2005).

2.6 Prevention

The basis for the prevention of microalbuminuria is the treatment of its known risk factors: hypertension, hyperglycemia and dyslipidemia.

2.6.1 Intensive blood glucose control

Clinical trials have consistently demonstrated that HbA1c levels <7% are associated with decreased risk for clinical and structural manifestations of microalbuminuria in type 1 and type 2 diabetic patients. In the Diabetes Control and Complications Trial (DCCT), intensive treatment of diabetes reduced the incidence of microalbuminuria by 39% (Diabetes Control and Complications Trial Research Group, 1993). It is interesting to note that patients randomized to strict glycemic control had a long lasting reduction of around 40% in the risk for development of microalbuminuria and hypertension 7 – 8 years after the end of DCCT (Epidemiology of Diabetes Interventions and Complications Research Group, 2000).

2.6.2 Intensive blood pressure control

Treatment of hypertension dramatically reduces the risk cardiovascular and microvascular events in patients with diabetes. Hypertension is common in diabetic patients, even when renal involvement is not present. About 40% of type 1 diabetic patients with normoalbuminuria have blood pressure levels >140/90mmHg (Nielsen et al., 1995). In the UKPDS, a reduction from 154 to 144mmHg on systolic blood pressure reduced the risk for the development of microalbuminuria by 29% (UK

Prospective Diabetes Study Group, 1998) .A large European study in children with type 1 diabetes (*n* = 2,105, aged 5–18 years) evaluated risk factors that led to hypertension and microalbuminuria. A clear link was found between the quality of metabolic control and altered blood pressure regulation and showed that age, diabetes duration, sex, BMI, A1C, and insulin dose were related to altered blood pressure profiles (Dost et al., 2008).

2.6.3 Renin – angiotensin system blockade

Angiotensin-converting enzyme (ACE) inhibitors and Angiotensin II receptor blockers decrease urinary albumin excretion and the rate of progression from microalbuminuria to more advanced stages of diabetic nephropathy. A meta-analysis of 12 trials evaluating 698 non-hypertensive microalbuminuric type 1 diabetic patients showed that treatment with ACE inhibitors decreased the risk of progression to macroalbuminuria by 60%and increased the chance of regression to normoalbuminuria (Strippoli et al., 2004).

CHAPTER THREE:METHODOLOGY

3.0Study Design

Cross sectional study design

3.1 Study Site

The study was conducted at the Diabetic Outpatient Clinic of MTRH which is located in Eldoret town, about 300km from Nairobi, in Uasin Gishu County, Kenya. This is mainly an agricultural region with both large scale and small scale farming.

The hospital is an 800 bed capacity tertiary hospital that also serves institutions around Eldoret. It also serves as a referral hospital for the western part of Kenya, with a catchment population of about 13 million people - 33% of Kenyan population. The hospital provides various services ranging from primary to specialized care and serves urban, peri-urban and rural populations from near and far counties.The hospital also serves patients from neighboring countries; Uganda, Sudan, South Sudan and Rwanda.

The DOPC(at the time the study was conducted) was located in the administration building ground floor room no 49 and room no 52for adult and paediatric clients respectively. Glycated Hemoglobin levels are done on a 3 monthly basis at the DOPC while random blood sugar is done at every visit. Other tests are done as requested by the clinician.

3.2 Study Population

Children with diabetes mellitus of age 17 years and below

3.2. Eligibility criteria

3.2. Inclusion Criteria

Children with diabetes on follow up at MTRH diabetic outpatient clinic who had at least one HbA1c reading in the last 3 months.

3.2.2 Exclusion criteria

Children who had been diagnosed with other renal disease prior to sample collection

3.3 Sample Size Calculation

3.3.1 Sample Size and Sampling Technique

Sample size was computed using the Fishers formula. According to a study done in Tanzania, the prevalence of microalbuminuria was 12% in diabetic children. The prevalence of microalbuminuria in a Kenyan study was 15.8%, however, this was for both type 1 and type 2 diabetes patients. Since our study will focus on children with diabetes, we will use the 12% prevalence from Tanzania to estimate our sample size. There is a total of 148 type 1 diabetes patients seen at the DOPC at MTRH up to the age of 17 years. To estimate our sample size, we use the Fisher formula as follows;

$$n = \frac{NZ_{\alpha/2}^2 \times p \times (1-p)}{d^2(N-1) + Z_{\alpha/2}^2(p(1-p))}$$

Where;

$n =$ Is the anticipated sample size with finite population correction

$N =$ Is the population size (148 – the number of patients seen at MTRH clinic)

$Z_{\alpha/2} = 1.96$, standard normal variation

$p =$ Estimated prevalence of microalbuminuria in the population at 12%

$d =$ Margin of error at 5%

Calculating sample size yields the following figure;

$$n = \frac{(148 \times 1.96^2) \times (0.12 \times 0.88)}{(0.05^2 \times 140) + (1.96^2 \times 0.12 \times 0.88)}$$

$$n = \frac{60.0396}{0.7556}$$

$n = 80, subjects$

k^{th}number 148/80 = 1.85

On calculating the k^{th} number to determine the sampling frame it was 1.85, thus consecutive sampling was done.

A sample size of 80 subjects were needed for the study. The significance level is 0.05. Patients in the MTRH DOPC who met the inclusion criteria and parents/guardians consented were sampled consecutively until the desired sample size was achieved.

3.4 Study Procedure

3.4.1 Data Collection

Data collection was done by the principal investigator and a trained research assistant (Clinical Officer). The personnel and the clinicians in the clinic were briefed about the study. Those patients who met the inclusion criteria were recruited in the study and data was collected and urine sample taken. Socio-demographic information was collected and the data recorded in a data collection form. Clinical features like height, weight and blood pressure was measured on the day of visit using a calibrated stadiometer, weighing scale and a diamond brand mercury sphygmomanometer with the correct cuff for age (covering two thirds of the left upper arm) and the elbow held at the level of the heart respectively. If the child was found hypertensive, a repeat blood pressure measurement was taken in the same visit at least 30 minutes apart. The United States Of America National Heart Lung and Blood Institute guidelines were used to diagnose hypertension (see appendix III). The most recent HbA1c reading in the last 3 months was recorded from the file. Children found to have microalbuminuria or hypertension were referred to the clinician at the clinic for further management.

3.4.2 Sample Collection

A spot sample of urine was taken in a standard urine collection bottle and then assayed for albumin levels and albumin to creatinine ratio at the cost of the study. The assay was done using the Siemens DCA vantage analyzer using the enzyme immunoassay (EIA) method. Control samples for the same were run on each day the tests were run for quality purposes. The results were then recorded in the data collection form. If significant albuminuria was found, urinalysis was done on the same sample for nitrites and leukocytes to rule out urinary tract infection.

3.5 Statistical Analysis

Data analysis was done using R: A language and environment for statistical computing (Team, 2017). Categorical variables were summarized using frequencies and corresponding percentages. Continuous variables were assessed for Gaussian assumptions using histograms and normal probability plots. Violation of the Gaussian assumptions was not severe so they were summarized using mean and the corresponding standard deviations (SD). Association between categorical variables was assessed using Fisher's exact test, and continuous variables were compared using independent samples t-test, and p-value of less than 0.05 was used to define statistical significance.

Body mass index (BMI) was computed for the participants aged above five years, and weight-for-height z-scores (WHZ) were computed for the participants aged 5 years and below. We defined underweight as participants with BMI < 18.5 Kg/m^2 or WHZ <-2 Z-scores, normal weight as BMI ≥ 18.5Kg/m^2 and BMI < 25.0Kg/m^2 or WHZ ≥ -2 Z-scores and WHZ < 2 Z-scores, overweight as BMI ≥ 25.0Kg/m^2 and BMI < 30.0Kg/m^2 or WHZ ≥ 2 Z-scores and WHZ < 3 Z-scores, and obese as BMI ≥ 30.0Kg/m^2 or WHZ ≥ 3 Z-scores.

3.6 Limitations of the Study

We were not able to measure serum creatinine and further measure glomerular filtration rate which is one of the tools used for screening diabetic kidney disease as per the NKF KDOQI guidelines.

This study was not powered to assess risk factors for developing microalbuminuria since the "P" to calculate the sample size, was from a prevalence study and not associations or risk factors.

3.7Ethical Considerations

- This study started after approval by the Institutional Research and Ethics Committee (IREC) of MTRH and Moi University School of Medicine.
- Informed consent was obtained from patients/ guardians included in this study. Those who declined to participate in the study were not discriminated against.
- Informed consent and assent was taken from children above 7 years of age
- Confidentiality was maintained throughout the study.
- All patients received standard care of management.
- No form of coercion or inducement was applied in selecting participants.

There were no anticipated risks to the participants attributable to this study.

CHAPTER FOUR: RESULTS

The study was carried out between February 2015 to July 2015. A total of 85 participants were recruited but 5 did not meet the inclusion criteria.

Baseline Characteristics

There were a total of 80 participants (diabetic children) interviewed for the study. The average age at inclusion in the study was 11.1 (SD: 4.1) years with a range of 2 to 17 years.

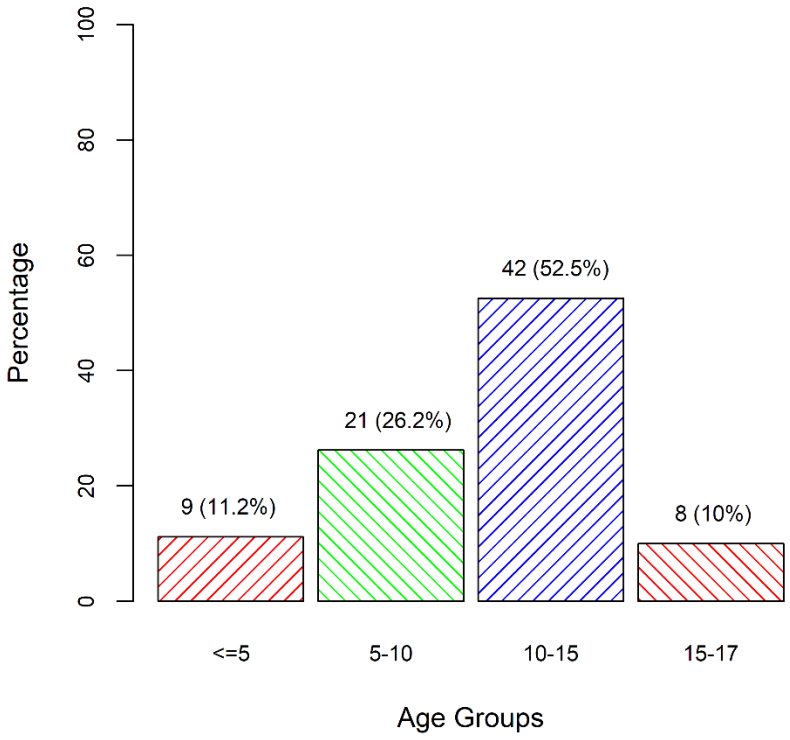

Figure 1: Distribution of participants by age

Half of the participants (52.5%) were aged 10 – 15 years.

Table 2: Demographic characteristics

Variable	Mean (SD) or n (%)
Age (Years)	11.1 (4.1)
Female	38 (47.5%)
Male	42 (52.5%)
Location	
Rural	67 (83.8%)
Urban	13 (16.2%)

Thirty eight (47.5%) were female, and 67 (83.8%) from rural areas. Majority of the participants were from Uasin Gishu County, 46 (57.5%).

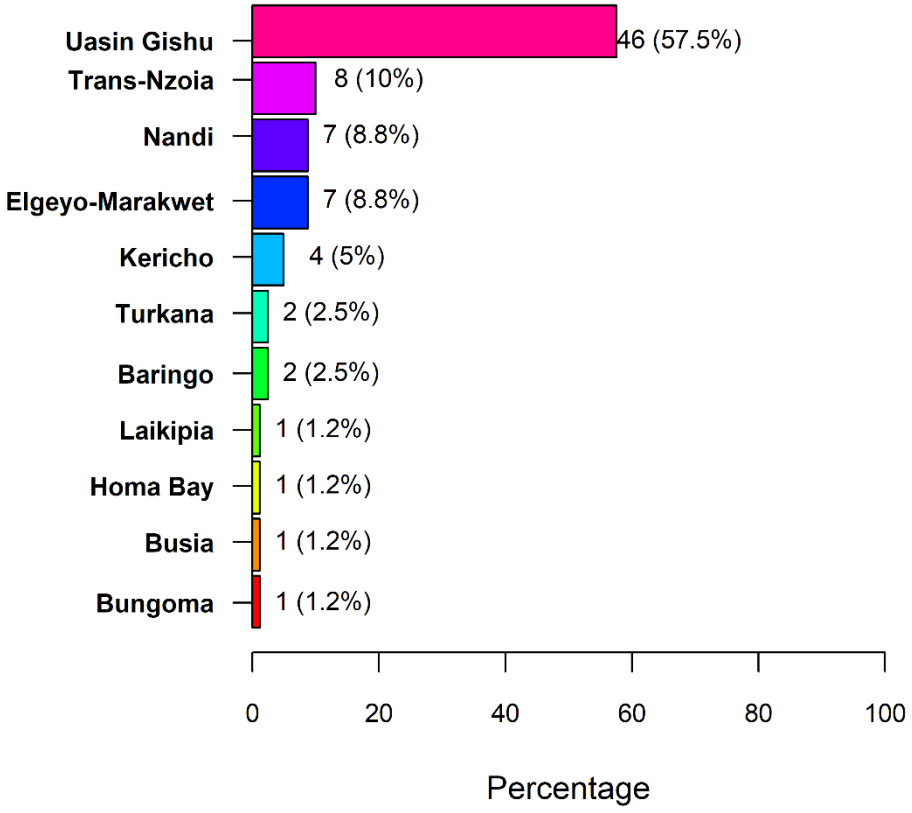

Figure 2: Distribution according to county of residence

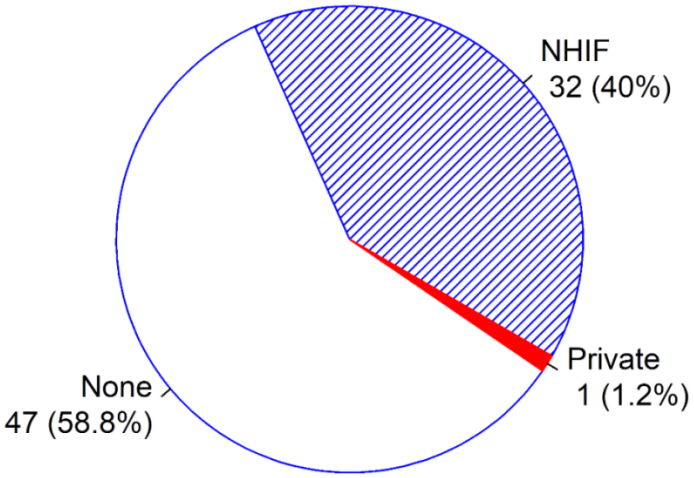

Figure 3: Insurance cover among children with diabetes

Up to 33 (41.2%) of the participants had an insurance cover, 32 (40.0%) National Insurance Fund (NHIF), and 1 (1.2%) private insurance.

Table 3: Clinical characteristics

Variable	Mean (SD)or n (%)	Range (Min - Max)
Age at diagnosis (Years)	6.9 (3.6)	2.0 - 15
Duration with diabetes mellitus (Years)	4.2 (3.0)	1.0 - 12.0
Family history of diabetes mellitus	20 (25.0%)	
Hypertensive	5 (6.2%)	
HBA1c (%)	11.3 (2.2)	6.4 - 14.0
Diabetes ketoacidosis in 12 months	26 (32.5%)	
Admission		
None	30 (37.5%)	
Once	37 (46.2%)	
Twice	11 (13.8%)	
Thrice	2 (2.5%)	
Have received nutritional counselling	77 (96.2%)	
Weight		
Underweight	64 (80.0%)	
Normal	15 (18.8%)	
Overweight	1 (1.2%)	

The mean age at diagnosis of diabetes was 6.9 (SD: 3.6) years (Range: 2.0 – 15.0) and the mean duration with diabetes was 4.2 (SD: 3.0) years (Range: 1.0 – 12.0).One

quarter, 20 (25.0%) had family history of diabetes mellitus, and 5 (6.2%) were hypertensive. The overall mean HbA1c among the participants was 11.3% (SD: 2.2).

All participants were using insulin and majority of the participants were using Biphasic Isophane Insulin Injection (pre-mixed 70/30 insulin), which is a mixture of fast(30) and longer-acting(70) insulin (88.8%) and had received nutritional counseling (96.2%) at one point in time.

Up to 64 (80.0%) of the participants were underweight, 15 (18.8%) were of normal weight, and 1 (1.2%) who was aged 17 years and weighed 65 kilograms was overweight (BMI: 25.7 Kg/m^2).

Sixty three percent of all participants had been admitted at least once in the past one year of which a small proportion (17%) had been admitted more than once. Most of them were diagnosed with diabetic ketoacidosis (52%) and hyperglycemia (60%)(Figure 5).

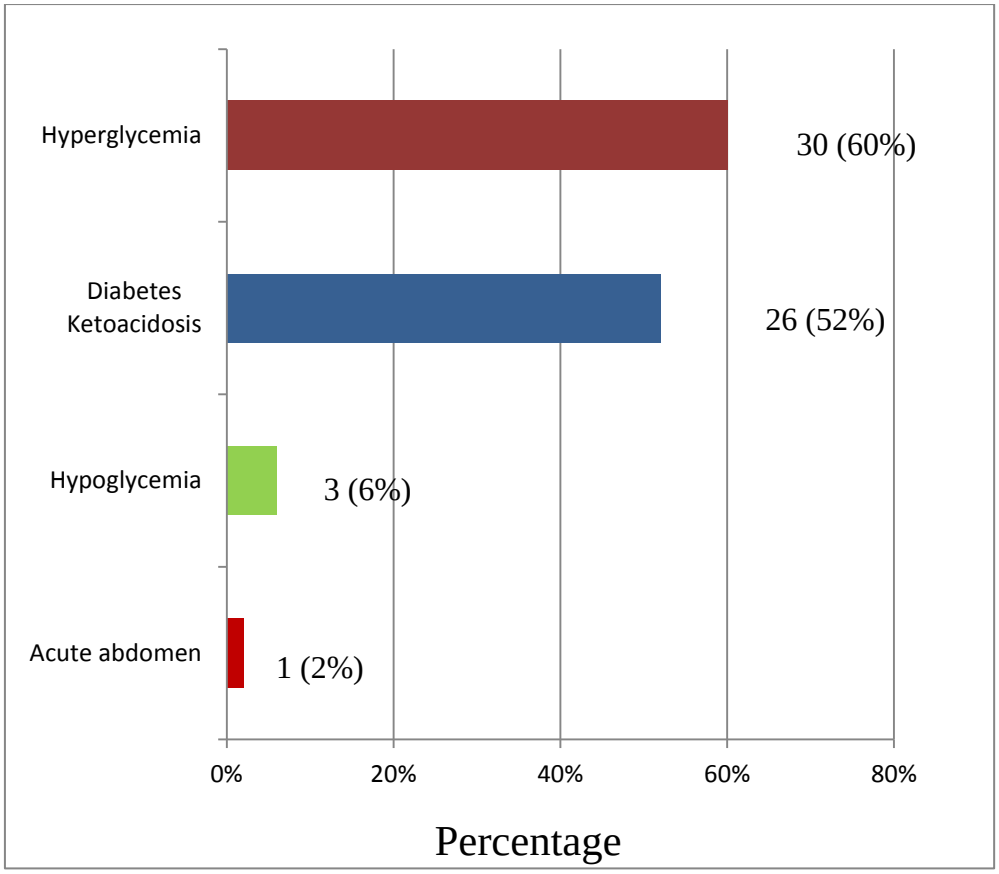

Figure 4: Diagnosis during admission in the past one year

Microalbuminuria

The prevalence of microalbuminuria was 7.5% (95% CI: 2.8, 15.6) (n=6) and macroalbuminuria was observed in one child (1.3%). Seventy two percent of all participants had undetected albumin levels (<5 micromoles per litre).

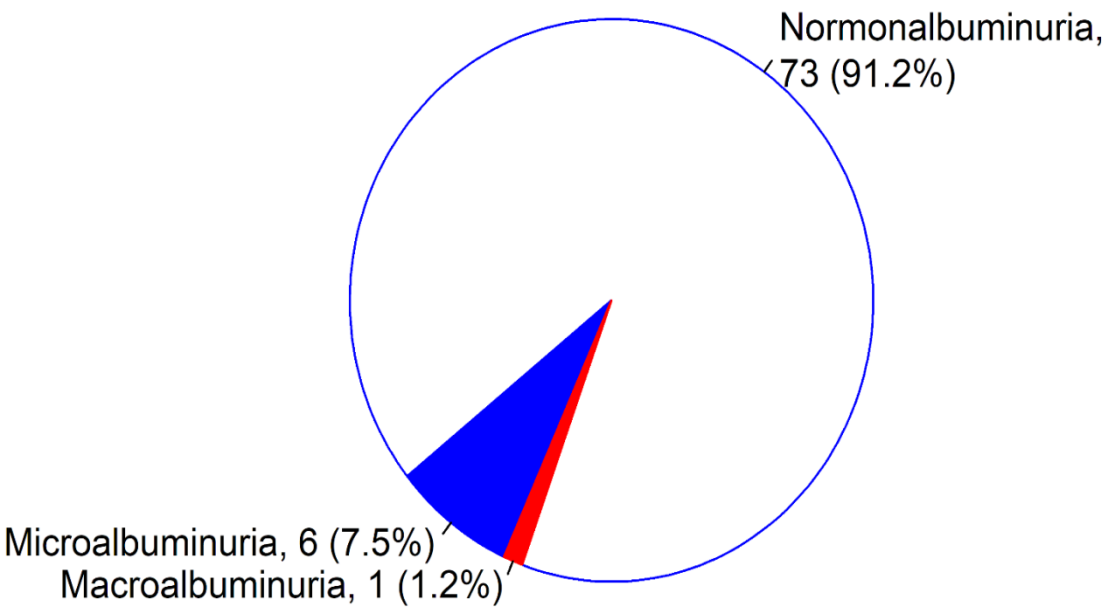

Figure 5 : Urine albumin levels

On urinalysis, none of them had nitrites or leukocytes suggesting a urinary tract infection or proteinuria levels suggesting nephrotic syndrome.

We compared the demographic and clinical characteristics of the participants who had microalbuminuria to those who had normoalbuminuria excluding the participant who had macroalbuminuria (Table 4).

Table 4: Comparison of clinical and demographic characteristicsofchildren with normoalbuminuria and microalbuminuria

	Normoalbuminuria (N=73)	Microalbuminuria (N=6)	P-value
Age (Years)	10.9 (4.1)	13.7 (3.7)	0.127[t]
Aged ≤ 5 Years	9 (12.3%)	0 (0.0%)	
Aged > 5 Years	64 (87.7%)	6 (100.0%)	
Female	33 (45.2%)	4 (66.7%)	0.411[f]
Residence			
Rural	64 (87.7%)	3 (50.0%)	0.042[f]
Urban	9 (12.0%)	3 (50.0%)	
Age at diagnosis (Years)	6.7 (3.6)	9.8 (2.9)	0.042[t]
Range (Min. – Max.)	2.0 – 16.0	6.0 – 14.0	
Duration of Diabetes (Years)	4.2 (3.0)	3.8 (3.3)	0.814[t]
Range (Min. – Max.)	0.0 – 12.0	1.0 – 8.0	
HbA1c (%)	11.4 (2.3)	11.4 (1.6)	0.894[t]
Range (Min. – Max.)	6.4 – 14.0	8.9 – 13.1	
Admitted in the past year	45 (61.6%)	5 (83.3%)	0.406[f]
[†]Weight: Underweight	60 (82.2%)	4 (66.7%)	0.319[f]
Normal Weight	13 (17.8%)	2 (33.3%)	
Hypertensive	5 (6.8%)	0 (0.0%)	

[f]Fisher's Exact test, [t]Independent samples t-test; [†]Overweight participant with BMI of 25.7 kg/m^2 was combined with participants with normal weight (BMI: 18.5 – 24.9 Kg/m^2)

The mean age of children with microalbuminuria was 13.7 years (SD 3.7). Compared to the age of those with normoalbuminuria, the difference was not statistically significant($p = 0.127$). All of the participants with microalbuminuria were aged > 5 years. Two thirds of the children with microalbuminuria (n=4) were female. However, this proportion was not statistically significant ($p = 0.411$). A significantly higher proportion of the participants with albuminuria were from the urban location compared to those who had nornoalbuminuria (50.0% vs. 12.0%, $p = 0.042$). Compared to normoalbuminuric participants, those who had microalbuminuria were more likely to be diagnosed with diabetes mellitus at older age, mean age: 9.8 (SD: 2.9) years vs. 6.7 (SD: 3.6) years, $p = 0.042$. Two thirds of the participants with microalbuminuria were underweight, and none was hypertensive.

The mean duration of living with diabetes among the participants with microalbuminuria was 3.8 (SD: 3.3) years. This was not statistically significantly different compared to those with normoalbuminuria4.2 (SD: 3.0) years (p =0.814).The mean HbA1c of those participants with microalbuminuria was 11.4% (SD: 2.3) versus 11.4% (SD: 1.6) of those having normoalbuminuria, however this was not statistically significant (p-value=0.894).

The relative risk of developing microalbuminuria at less than 5 years of duration of living with diabetes mellitus is 1.56 (95% CI: 0.30, 8.01). However, there was no sufficient evidence to link less than 5 year duration of living with diabetes mellitus to development of microalbuminuria.

Table 5: Association between duration of living with diabetes and development of microalbuminuria

		Duration with Diabetes		
		<5 years	≥ 5 years	RR (95% CI)
Microalbuminuria	Yes	4 (8.9%)	2 (5.7%)	1.56 (0.30, 8.01)
	No	2 (91.1%)	33 (94.3%)	
	Total	6	35	

CI: Confidence Interval, RR – Relative Risk

Hypertension

The overall prevalence of hypertension among the participants was 6% (n=5) of which one participant was a known hypertensive on antihypertensive. All these hypertensive participants had no microalbuminuria or macroalbuminuria. Consequently, there was no significant difference in prevalence of hypertension among participants with compared to those without microalbuminuria (p-value > 0.999).

All hypertensive children were male with a mean age of 11.4 years (range 9 to 15 years) and had a mean HbA1c of 11.4%. Up to 80.0% (n=4) were underweight.

All newly diagnosed hypertensive children had stage one hypertension according to the United States National Heart, Blood and Lung Institute guidelines. The child on follow up for hypertension had a normal blood pressure.

Table 6: Comparison of characteristics of hypertensive to non-hypertensive children

	Non-hypertensive (N=75)	Hypertensive (N=5)	P-value
Age (Years)	11.1 (4.2)	11.4 (2.5)	0.905[t]
Range (Min. – Max.)	2.0 – 17.0	9.0 – 15.0	
Aged ≤ 5 Years	9 (12.0%)	0 (0.0%)	
Aged > 5 Years	66 (88.0%)	5 (100.0%)	
Female	38 (50.7%)	0 (0.0%)	0.056[f]
Location			
Rural	62 (82.7%)	5 (100.0%)	0.586[f]
Urban	13 (17.3%)	0 (0.0%)	
Age at diagnosis (Years)	7.0 (3.6)	6.0 (4.2)	0.530[t]
Range (Min. – Max.)	2.0 – 16.0	2.0 – 13.0	
Duration of Diabetes (Years)	4.1 (3.1)	5.4 (2.4)	0.259[t]
Range (Min. – Max.)	0.0 – 12.0	2.0 – 8.0	
HbA1c (%)	11.3 (2.2)	11.5 (2.6)	0.832[t]
Range (Min. – Max.)	6.4 – 14.0	7.0 – 13.0	
Admitted in the past year	47 (62.7%)	3 (60.0%)	>0.999[f]
[†]Weight: Underweight	60 (80.0%)	4 (80.0%)	>0.999[f]
Normal Weight	15 (20.0%)	1 (20.0%)	
Microalbuminuria	6 (8.0%)	0 (0.0%)	

[f]Fisher's Exact test, [t]Independent samples t-test;[†]Overweight participant with BMI of 25.7 kg/m^2 was combined with participants with normal weight (BMI: 18.5 – 24.9 Kg/m^2)

The average HBA1c was 11.3% (SD: 2.2) among those who were hypertensive, and 11.5% (SD: 2.6) among those who were non-hypertensive. However, the difference was not statistically significant, p = 0.832.

CHAPTER FIVE : DISCUSSION

The mean age at diagnosis was approaching 7 years while another study done in Nairobi by (Ngiri et al., 2015) looking at 82 participants, a similar sample size as ours, had a mean age at diagnosis of 10 years. This is probably due to a different subset of population in Nairobi. However, the mean duration of diagnosis was similar in both studies at 4 years. Majority of children attending the diabetic outpatient clinic were residing in a rural area. This is comparable to a study done in Finland by Rytkonen et al, where the incidence of diabetic children was highest in rural heartland areas (Rytkonen et al., 2003). More than half of children with diabetes resided in Uasin Gishu county. This can be explained by the fact that MTRH is located in Uasin Gishu county.

One third of all participants were admitted with a diagnosis of diabetic ketoacidosis which is quite high. A study done in Kenyatta National Hospital by Mbugua et al. (2005), found that 8% of all diabetes related admission had a diagnosis of diabetic ketoacidosis. However the KNH study was done for both type 1 and type 2 diabetes mellitus, while DKA is a common complication for patients with type 1 diabetes mellitus. Majority of children with diabetes having a high HbA1c could explain the finding that more than half of all recruits were admitted with a diagnosis of either DKA or hyperglycemia.

Most of the children with diabetes were underweight which can be explained by the pathophysiology of diabetes. In children with diabetes, insufficient insulin prevents the body from getting glucose from the blood into the body's cells to use as energy. When this occurs the body starts burning fatand muscle energy, causing a reduction in overall body weight. This was in contrast to a study done by N Holman et al who

assessed BMI of diabetic children in England and Wales, where only around two percent were underweight (Holman et al., 2015).

The prevalence of microalbuminuria in this study was 7.5% which is lower than in patients with type 1 diabetes mellitus in a study done by Lutale et al in Tanzania which was 12% (Lutale et al., 2007). The difference could probably due to difference in sample collection. Two overnight urine samples were analyzed in the Lutale et al study. The unique finding in this study is that, the females were the dominating gender in participants with microalbuminuria, while in most studies including the Tanzania study and DCCT, males were the predominant gender.

The overall median HbA1c among the participants in our study was 11.7 (IQR 9.0-13.0), while in a study done by Ngiri et al (2015) in Nairobi revealed that their range was 6.4–19%, median HbA1c was 12.1% which show minimal differences in the glycemic control ofdiabetic children, while participants in the Ngiri et al study done in Nairobi had a third of them with normal HbA1c levels. Their cut off for normal was 8% while we used 7% similar to the DCCT. In our study, there was no significant difference in the HbA1c of children with and without microalbuminuria which is similar to the Tanzania study but in contrast to the DCCT. The difference could be explained by the difference in the study design. The DCCT was a prospective study.

In children with microalbuminuria, the mean duration of diabetes was 4.3 years, which was similar to the study done by Lutale et al (2007) in Dar es salam. This was in contrast to a study done in Brazil, where Roberta A.C et al did a longitudinal study. They documented that microalbuminuria developed 11 years after diagnosis of type 1 DM (Cobas et al., 2011).The relative risk of getting microalbuminuria with duration of diabetes of less than 5 years was 1.5. This means that the subset of children and

adolescents from around Eldoret are at risk of getting microalbuminuria at a lower age. This however not statistically significant probably due to a small sample size. A study done in Australia by (Stone, 2006) showed that the prevalence of microalbuminuria increased with duration of diabetes in the insulin dependent diabetics with the lowest prevalence being 3.2% at 0 to 5 years of diabetes mellitus and the highest 60% at 16 to 20 years. A study done in Nigeria by Alebiosu, (2003) revealed mean duration of 6.5 years for participants with microalbuminuria in type 1 diabetes mellitus. The latter 2 studies had a larger sample size and also included adult participants.

Half of the children with microalbuminuria were from an urban area. This was statistically significant. This could probably due to the fact that families in these setting can afford a sedentary lifestyle. However, there are no studies comparing children with microalbuminuria from an urban area versus rural area.

In our study, microalbuminuria was present in children with an older age at diagnosis compared to those with normoalbuminuria and this was statistically significant. This was comparable to a longitudinal cohort study done by Monique Stone et al, who found that older age at diagnosis was predictive of developing persistent microalbuminuria (Stone et al., 2006). Similarly, a prospective inter ethnic study done by Kalk et al in South Africa, comparing risk factors for microalbuminuria revealed that Africans with microalbuminuria had a higher age at diagnosis compared to whites ($p=<0.0001$).

The prevalence of hypertension in diabetic children was 6% and none of them had microalbuminuria. This was comparable to a study done by Rohani et al., (2014) where the prevalence for stage 1 hypertension was around 5% and was not associated

with microalbuminuria and HbA1c levels. However, this was in contrast when compared to a study done by Mohamed S, hypertension was greater and significant in microalbuminuric diabetic patients and significantly related glycated heamoglobin and body mass index (Shalaby, 2015). It is possible that hypertension in children in this study is secondary to other causes than diabetes or microalbuminuria.

CHAPTER SIX: CONCLUSION AND RECOMENDATION

6.1 Conclusion

The prevalence of microalbuminuria in children with diabetes mellitus at MTRH is 7.5%.

6.2Recommendation

There is need to screen for microalbuminuria earlier than the recommended 5 years.

Further longitudinal studies of a larger population need to be done to assess risk factors for developing microalbuminuria in this population.

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APPENDIX

Appendix 1: Data Collection Form

Serial No._____

Date_____

Thank you for agreeing to take part in this study. We will interview you/ your child briefly and measure blood pressure and take a urine sample for our study. Information given by you or your child shall remain confidential.

PART ONE: CHILD'S PARTICULARS

1. Initials _____
2. Gender: Male ☐ Female ☐
3. Age in years _____
4. Residence (County) _____
5. Ethnicity _____
6. Religion _____
7. Insurance Cover: None ☐ NHIF ☐ Others ☐
8. Year of Diagnosis of DM _____
9. Family History of DM in the family? Yes ☐ No ☐
10. If Yes to above, indicate the family member _____
11. What medication is the child on and their dosage?_____
12. Has the child received nutritional counseling?_____
13. Is he/she hypertensive? Yes ☐ No ☐
14. If Yes to question No 5., which medication is the child on?

    _____

    _____

    _____
15. Episodes of Diabetic Ketoacidosis in the past 12 months? _____
16. Number of admissions related to diabetes mellitus in the past 12 months?_____
    I. Diagnosis of admission _____

       _____

       _____

PART TWO: CLINICAL AND LAB FEATURES

1. Height (centimetres) _____Weight _____ BMI _____
2. Blood Pressure : Systolic_____ Diastolic _____
3. If Newly diagnosed (check Chart) Blood pressure 1 systolic_____ diastolic _____

Blood Pressure 2 systolic _____ diastolic _____

4. Random Blood Sugar _____
5. HbA1c (most recent)
   i. _____
6. Urinary Albumin levels _____
7. Urinary albumin to creatinine ratio _____
8. Urinalysis results (if significant albuminuria)

   Proteins _____

   Leukocytes_____

   Nitrites _____

   Glucose _____

Appendix 11: Consent Form
CONSENT TO PARTICIPATE IN THE STUDY SERIAL NUMBER ……

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 to take part in this study

The purpose of this study is to determine the prevalence of diabetic nephropathy that is, a complication of the kidney in relation to diabetes. We are also going to relate the diabetic nephropathy with their blood pressure and glucose control. Our study is for research purposes but we hope that the information obtained will be used to help the hospital and clinicians manage Diabetes mellitus better and prevent complications which will result in improved healthcare service delivery.

Study Procedure

A urine sample will be collected to measure the proteins in urine. Blood pressure will also be measured and previous HBA1C recorded into a form. The findings during subsequent assessments cannot be linked to your child and are completely anonymous and confidential since we shall be using serial numbers.

Risks

There are no risks involved in this study. This study will be anonymous. The child will receive treatment as per the diagnosis made based on the hospital protocols.

Benefits

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 based on the recommendations of this study.

Alternative Procedures

You may choose your child not to participate in this study

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 baby. 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 investigator from Moi University, School of Medicine, department of Child Health and Paediatrics, Postgraduate programme; Dr. Adnaan Mustafa +254722273729 email:adnaanezzi@gmail.com

Institutional Review Board

This study has been approved by the Institutional Research and Ethics Committee (IREC) of Moi University/Moi Teaching and Referral Hospital. Contact IREC if you have questions regarding your child's right as a participant, and also if you have complaints or concerns which you do not feel you can discuss with the investigator. Contact IREC using the address; The Chairman IREC, Moi Teaching and Referral Hospital, PO BOX 3, Eldoret, Kenya. Tel. 33471/2/3

Voluntary Participation

It is up to you to decide whether your child takes part in this study. Refusal to participate or the decision to withdraw from this research will involve 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 to participants There is no cost to you, and there is no compensation to subjects for participation in this study.

Authorization for use of your protected health information

This study that 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.

CONSENT

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 will be given a signed copy of this consent form. I voluntarily agree to take part in this study.

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

Name of Investigator ……Signature…… Date……..

Pediatric Assent Form

INTRODUCTION

- In order to learn more about your illness, which is called diabetes mellitus, Dr. Adnaan with other doctors are doing a "project" (some people call it a study). I am here to give you more information about this project and to ask you if you would like to be a part of it.

PURPOSE OF THE PROJECT

- The purpose of the project is to find out problems affecting the kidneys related to your condition – diabetes mellitus
- Your urine will be taken in a bottle and will be tested in a machine.

BENEFITS

- Being a part of the project may or may not help you and other children which have your same illness.
- Being a part of the project may help doctors learn more about your illness and its treatment.

ASSENT

- I understand that my Mom or Dad has said that it is okay for me to take part in this project (study) about my illness called: Diabetes Mellitus
- I understand what this project (study) is about.
- I am going to be in this project (study) because I want to.
- I have been told that I can stop being a part of this project (study) anytime I want to. Nothing will happen to me if I want to stop. I will still be able to get treatment for my illness.

_____ _____

Signature of Child Date

_____ _____

Signature of Presenter Date

FOMU IDHINISHO

IDHINI YA KUSHIRIKI KATIKA UTAFITI NAMBARI……

UTANGULIZI

Unaombwa kushiriki katika utafiti huu. Kabla ya kutoa uamuzi ni muhimu kuelewa lengo la utafiti na yatakayo jumulishwa. Soma habari ifuatayo kwa uangalifu na uulize iwapo kuna chochote huelewi au unahitaji ufafanuzi zaidi. Tafadhali tafakari zaidi kabla ya kutoa uamuzi iwapo wataka kuhusika katika utafiti.

Lengo la utafiti huu ni kuangazia kiwango cha ugonjwa wa figo kwa watoto ambao wana ugonjwa ya sukari ambao unaitwa Diabetes Mellitus katika hospitali ya rufaa ya Eldoret, Uchunguzi wetu ni wa utafiti japo tunadhamiria kuwa habari tutakayoipata itasaidia kujulisha hospitali na watungaji wa sera kwa madhumuni ya kuangaza kiwango cha uenezaji wa afya bora

NAMNA YA KUFANYA UTAFITI

Sampuli ya mkojo itachukuliwa na protini katika mkojo ya mwanao itapimwa. Mtoto atapimwa shinikizo la damu (blood pressure) na kiwango ya sukari itasomwa kutoka faili ya hospitali. Rekodi itahifadhiwa kuhusu vipimo na maradhi yaliyosababisha motto kulazwa hospitalini. Yatakayojiri katika utafiti unaofutuata hayatahusishwa na mwanao na yatahifadhiwa kw siri kwa vile tutatumia nambari wala si majina halisi.

MADHARA

Hakuna madhara yoyote yatakayohusishwa katika utafiti huu. Utafiti utakuwa wa kisiri. Mtoto atapata matibabu ya ugonjwa kulingana na matokeo au sera zinazokubaliwa na hospitali hii pamoja na utaratibu wa wizara ya Afya.

FAIDA

Hakutakuwepo na faida ya moja kwa moja ya kimatibabu itakayomfahidi mwanao kwa kuhusika katika utafiti huu. Faida inayotarajiwa ni kuhimarisha viwango vya afya ya watoto kutokana na mapendekezo ya utafiti huu.

NJIA MBADALA

Una uhuru wa kuamua mwanao asihusike katika utafiti huu.

USIRI

Utafiti huu utatekelezwa kulingana na sheris za nchi ya Kenya na utaratibu unaohifadhi haki za binadamu katika maswala ya utafiti.Rabari kuhusu afya ya mwanaaekodi zote na habari zote zitakazopatikana zitahifadhiwa kisiri na habari kuhusu afya ya mwanao haitatumiwa bila idhini.Njia zote za kupata habari zitatambuliwa kwa nambari au kuficha uhalisia ili kuhifadhi habari inayoweza kutumiwa kumtambulisha mwanao. Matokeo ya utafiti huu yanaweza kuchapishwa hakuna majina au habari za kukutambulisha zitakazotolewa.

MAWASILIANO

Iwapo una swali lolote, malalamishi au jambo lisilokuridhisha kuhusiana na utafiti huu, mjulishe mtafiti mkuu kutoka Chuo kikuu cha Moi, Kitivo cha utabibu, idara ya Afya ya watoto:

Daktari Adnaan Mustafa

Nambari ya simu 0722273729

Barua pepe adnaanezzi@gmail.com

IDHINISHO KUTOKA KWA BODI

Utafiti huu umekubaliwa na kamati ya chuo ya utafiti na maadili (IREC) ya chuo kikuu cha Moi na hospitati ya mafunzo na Rufaa ya Moi Eldoret.

Julisha idara hii ukiwa na swali kuhusu haki ya motto wako kuhusishwa katika utafiti au kama una malalamishi au ujembe unaonelea huwezi kujadiliana na mtafiti kupitia kwa anwani hii:

Mwenyekiti kamati ya chuo ya utafiti na maadili (IREC) ya chuo kikuu cha Moi na hospitali ya mafunzo na Rufaa ya Moi Eldoret,

S.L.P. 3, ELDORET, Kenya

Nambari ya simu: 3371/2/3

HIARI YA KUHUSIKA

Ni uamuzi wako iwapo mwanao atashiriki katika utafiti huu.Kukataa kuhusika au kuamua kujiondoa katika utafiti huu hautahusisha adhabu yoyote au kukosa manufaa yoyote ambayo mwanao anastahili. Haya hataadhiri uhusiano wako na mtafiti.

HAKI YA MTAFITI KUMWONDOA MHUSIKA

Mtafiti anaweza kumwondoa mwanao katika utafiti bila idhini yako.

MALIPO NA RIDHAA KWA WAHUSIKA

Hakuna malipo yoyote kwako na ridhaa kwa yeyote anayehusika katika utafiti huu.

IDADI YA WAHUSIKA

Watoto wachanga waliolazwa katika wadi ya watoto wachanga walio chini ya mwezi mmoja.

MAMLAKA YA KUTUMIA HABARI ZA AFYA ZILIZOLINDWA

Utafiti huu hautahusu kutumia habari za afya za mwanao zilizolindwa.

Asante sana kw kuruhusu mwanao kushiriki katika utafiti huu na tunatambua usaidizi wako.

IDHINI:

Kwa kutia sahihi fomu hii, ninadhibitisha kwamba nimesoma habari iliyomo na nimekuwa na fursa ya kuuliza maswali. Nitapewa nakala iliyotiwa sahihi ya fomu hii.Nina hiari kukubali kuhusika katika utafiti huu.

MAJINA YA MZAZI…….Sahihi/Alama……..Tarehe……...

MAJINAYA
MTAFITI……..Sahihi/Alama……..Tarehe……...

Fomu ya kuidhinisha (Ya Mtoto)

Utangulizi

Ilikujua zaidi kuhusu ugonjwa wako ambao unaitwa diabetes mellitus, Daktari Adnaan na wengine wanafanya utafiti. Niko hapa ili niweze kukuelezea zaidi kuhusu utafiti na kukuulizia kama unaweza kuwa kwa utafiti huu.

Namma Ya utafiti

- Sababu ya kufaya utafiti huu ni kujua madhara ya figo ambao unahusiana na ugonjwa wa sukari
- Mkojo wako itachukuliwa kwa chupa na itapimwa kwa mashini.

Faida

- Kuwa pamoja kwa utafiti haitakufaidika wala watoto wengine lakini itasaidia madaktari kujua zaidi kuhusu ugonjwa na matibabu.

Kusaini na Mzazi

- Ninaelewa kwamba mzazi/mlezi wangu wamekubali niwe kwa utafiti yenu
- Ninaelewa kuhusu utafiti wenu
- Niko katika utafiti kwa sababu ninataka kuwa katika utafiti
- Ninajua ya kwamba kama ninitaka kuwacha kuwa kwa utafiti, nitaweza kufanya hivyo bila mimi kukosa matibabu ya aina yeyote.

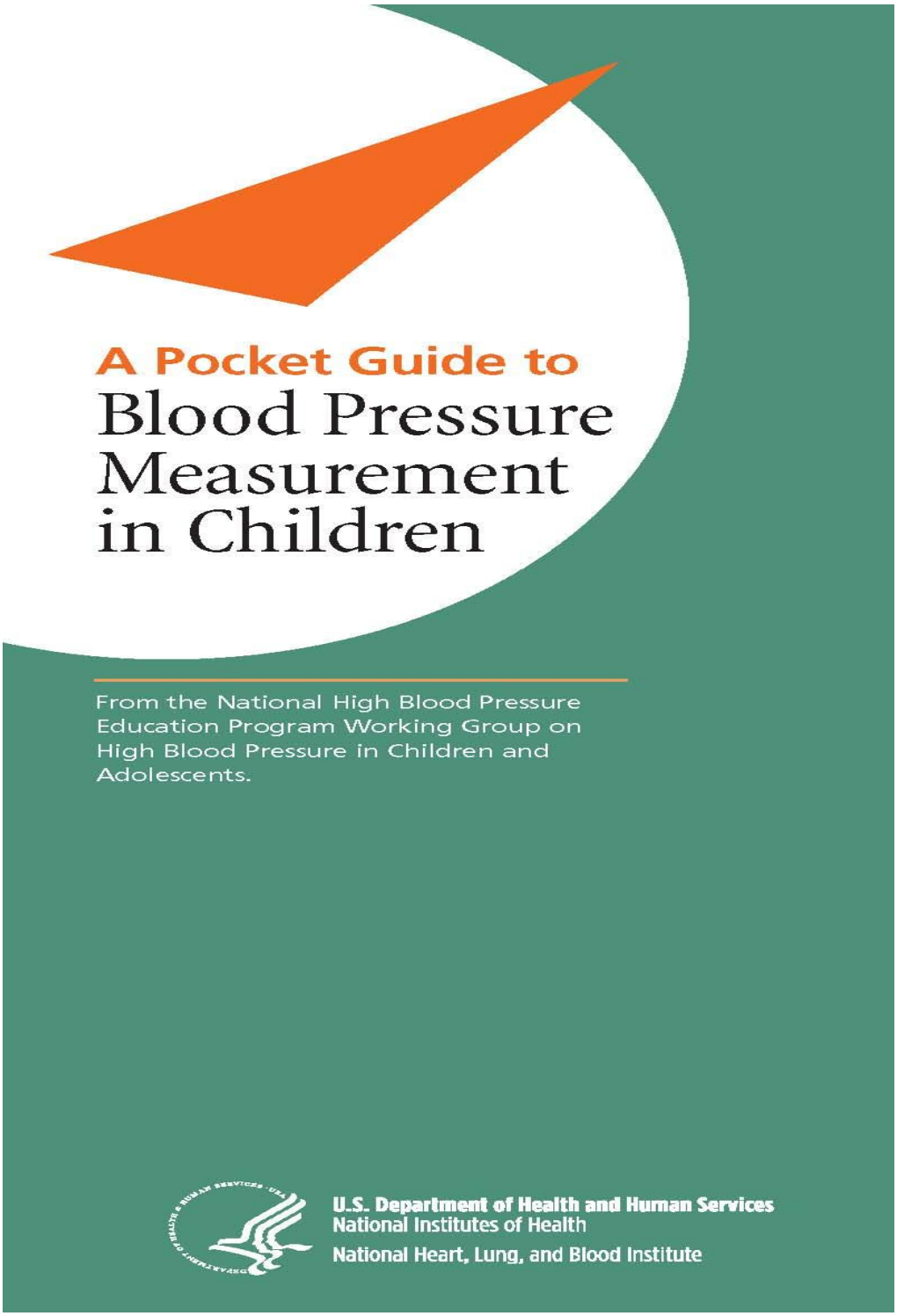
_____ _____

Saini Ya mtoto Tarehe

_____ _____

Saini ya mtafiti Tarehe

Appendix III: Blood Pressure Chart



Measurement

- Begin routine blood pressure (BP) measurement at 3 years of age.
- Correct cuff size depends on arm size. Practically speaking, correct cuff size equals largest cuff that will fit on the upper arm with room below for the stethoscope head.
- BP should be measured in the right arm of a relaxed, seated child.
- BP measurement by auscultation is the Gold Standard.
- BP by automated device correlates reasonably well with auscultation, with practical advantages of rapid measurement remote from child and elimination of reader error.
- If BP is high by automated device, repeat by auscultation.

BP Classification/Interpretation

BP is classified by systolic BP (SBP) and diastolic BP (DBP) percentiles for age/sex/height. If SBP or DBP >90th percentile, repeat twice at same office visit before interpreting result.

Normal BP: SBP and DBP <90th percentile
→ Recheck in 1 year.
Prehypertension: SBP or DBP ≥ 90th percentile to <95th percentile or BP >120/80 mmHg to <95th percentile
→ Recheck in 6 months.
→ Begin weight management (as appropriate).
Stage 1 Hypertension (HTN): SBP and/or DBP ≥95th percentile to ≤ 99th percentile plus 5 mmHg
→ Recheck in 1 to 2 weeks.
→ If BP remains at this level on recheck, begin evaluation and treatment including weight management if appropriate.
Stage 2 HTN: SBP and/or DBP >99th percentile plus 5 mmHg
→ Begin evaluation and treatment within 1 week, immediately if symptomatic.

Systolic BP Percentile Tables

Since diastolic HTN rarely occurs without systolic HTN in children, the SBP percentile tables on the next page can be used for HTN screening. If a child's SBP on screening is classified as prehypertension or HTN, then both SBP and DBP percentiles should be determined using the tables in the complete report: The Fourth Report on the Diagnosis, Evaluation, and Treatment of High Blood Pressure in Children and Adolescents. *Pediatrics 2004 Aug;114(Suppl 2:)555-76*; or http://www.nhlbi.nih.gov/health/prof/heart/hbp/hbp_ped.htm.

Directions for Use of Tables

1. Heights in the table are given for age at midyear. Use closest height to interpret BP.
2. Prehypertension SBP ≥ value from table (90th percentile) to < Stage 1 HTN value; or SBP >120 mmHg to < Stage 1 HTN value.
   Stage 1 HTN SBP ≥ value from the table (95th percentile) to ≤ Stage 2 HTN.
   Stage 2 HTN SBP >value from table (99th percentile plus 5 mmHg).

For more information go to: www.nhlbi.nih.gov.

Girls SBP by Age and Height
(Normal SBP is less than the prehypertensive result.)

Age	BP Classification	Systolic BP (mmHg)						
3	***Height (cm)***	***91***	***92***	***95***	***98***	***100***	***103***	***105***
	Prehypertension	100	100	102	103	104	106	106
	Stage 1 HTN	104	104	105	107	108	109	110
	Stage 2 HTN	116	116	118	119	120	121	122
4	***Height (cm)***	***97***	***99***	***101***	***104***	***108***	***110***	***112***
	Prehypertension	101	102	103	104	106	107	108
	Stage 1 HTN	105	106	107	108	110	111	112
	Stage 2 HTN	117	118	119	120	122	123	124
5	***Height (cm)***	***104***	***105***	***108***	***111***	***115***	***118***	***120***
	Prehypertension	103	103	105	106	107	109	109
	Stage 1 HTN	107	107	108	110	111	112	113
	Stage 2 HTN	119	119	121	122	123	125	125
6	***Height (cm)***	***110***	***112***	***115***	***118***	***122***	***126***	***128***
	Prehypertension	104	105	106	108	109	110	111
	Stage 1 HTN	108	109	110	111	113	114	115
	Stage 2 HTN	120	121	122	124	125	126	127
7	***Height (cm)***	***116***	***118***	***121***	***125***	***129***	***132***	***135***
	Prehypertension	106	107	108	109	111	112	113
	Stage 1 HTN	110	111	112	113	115	116	116
	Stage 2 HTN	122	123	124	125	127	128	129
8	***Height (cm)***	***121***	***123***	***127***	***131***	***135***	***139***	***141***
	Prehypertension	108	109	110	111	113	114	114
	Stage 1 HTN	112	112	114	115	116	118	118
	Stage 2 HTN	124	125	126	127	128	130	130
9	***Height (cm)***	***125***	***128***	***131***	***136***	***140***	***144***	***147***
	Prehypertension	110	110	112	113	114	116	116
	Stage 1 HTN	114	114	115	117	118	119	120
	Stage 2 HTN	126	126	128	129	130	132	132
10	***Height (cm)***	***130***	***132***	***136***	***141***	***146***	***150***	***153***
	Prehypertension	112	112	114	115	116	118	118
	Stage 1 HTN	116	116	117	119	120	121	122
	Stage 2 HTN	128	128	130	131	132	134	134
11	***Height (cm)***	***136***	***138***	***143***	***148***	***153***	***157***	***160***
	Prehypertension	114	114	116	117	118	119	120
	Stage 1 HTN	118	118	119	121	122	123	124
	Stage 2 HTN	130	130	131	133	134	135	136
12	***Height (cm)***	***143***	***146***	***150***	***155***	***160***	***164***	***166***
	Prehypertension	116	116	117	119	120	120	120
	Stage 1 HTN	119	120	121	123	124	125	126
	Stage 2 HTN	132	132	133	135	136	137	138
13	***Height (cm)***	***148***	***151***	***155***	***159***	***164***	***168***	***170***
	Prehypertension	117	118	119	120	120	120	120
	Stage 1 HTN	121	122	123	124	126	127	128
	Stage 2 HTN	133	134	135	137	138	139	140
14	***Height (cm)***	***151***	***153***	***157***	***161***	***166***	***170***	***172***
	Prehypertension	119	120	120	120	120	120	120
	Stage 1 HTN	123	123	125	126	127	129	129
	Stage 2 HTN	135	136	137	138	140	141	141
15	***Height (cm)***	***152***	***154***	***158***	***162***	***167***	***171***	***173***
	Prehypertension	120	120	120	120	120	120	120
	Stage 1 HTN	124	125	126	127	129	130	131
	Stage 2 HTN	136	137	138	139	141	142	143
16	***Height (cm)***	***152***	***154***	***158***	***163***	***167***	***171***	***173***
	Prehypertension	120	120	120	120	120	120	120
	Stage 1 HTN	125	126	127	128	130	131	132
	Stage 2 HTN	137	138	139	140	142	143	144
17	***Height (cm)***	***152***	***155***	***159***	***163***	***167***	***171***	***174***
	Prehypertension	120	120	120	120	120	120	120
	Stage 1 HTN	125	126	127	129	130	131	132
	Stage 2 HTN	138	138	139	141	142	143	144

Boys SBP by Age and Height
(Normal SBP is less than the prehypertensive result.)

Age	BP Classification	Systolic BP (mm Hg)						
3	*Height (cm)*	*92*	*94*	*96*	*99*	*102*	*104*	*106*
	Prehypertension	100	101	103	105	107	108	109
	Stage 1 HTN	104	105	107	109	110	112	113
	Stage 2 HTN	116	117	119	121	123	124	125
4	*Height (cm)*	*99*	*100*	*103*	*106*	*109*	*112*	*113*
	Prehypertension	102	103	105	107	109	110	111
	Stage 1 HTN	106	107	109	111	112	114	115
	Stage 2 HTN	118	119	121	123	125	126	127
5	*Height (cm)*	*104*	*106*	*109*	*112*	*116*	*119*	*120*
	Prehypertension	104	105	106	108	110	111	112
	Stage 1 HTN	108	109	110	112	114	115	116
	Stage 2 HTN	120	121	123	125	126	128	128
6	*Height (cm)*	*110*	*112*	*115*	*119*	*122*	*126*	*127*
	Prehypertension	105	106	108	110	111	113	113
	Stage 1 HTN	109	110	112	114	115	117	117
	Stage 2 HTN	121	122	124	126	128	129	130
7	*Height (cm)*	*116*	*118*	*121*	*125*	*129*	*132*	*134*
	Prehypertension	106	107	109	111	113	114	115
	Stage 1 HTN	110	111	113	115	117	118	119
	Stage 2 HTN	122	123	125	127	129	130	131
8	*Height (cm)*	*121*	*123*	*127*	*131*	*135*	*139*	*141*
	Prehypertension	107	109	110	112	114	115	116
	Stage 1 HTN	111	112	114	116	118	119	120
	Stage 2 HTN	124	125	127	128	130	132	132
9	*Height (cm)*	*126*	*128*	*132*	*136*	*141*	*145*	*147*
	Prehypertension	109	110	112	114	115	117	118
	Stage 1 HTN	113	114	116	118	119	121	121
	Stage 2 HTN	125	126	128	130	132	133	134
10	*Height (cm)*	*130*	*133*	*137*	*141*	*146*	*150*	*153*
	Prehypertension	111	112	114	115	117	119	119
	Stage 1 HTN	115	116	117	119	121	122	123
	Stage 2 HTN	127	128	130	132	133	135	135
11	*Height (cm)*	*135*	*137*	*142*	*146*	*151*	*156*	*159*
	Prehypertension	113	114	115	117	119	120	120
	Stage 1 HTN	117	118	119	121	123	124	125
	Stage 2 HTN	129	130	132	134	135	137	137
12	*Height (cm)*	*140*	*143*	*148*	*153*	*158*	*163*	*166*
	Prehypertension	115	116	118	120	120	120	120
	Stage 1 HTN	119	120	122	123	125	127	127
	Stage 2 HTN	131	132	134	136	138	139	140
13	*Height (cm)*	*147*	*150*	*155*	*160*	*166*	*171*	*173*
	Prehypertension	117	118	120	120	120	120	120
	Stage 1 HTN	121	122	124	126	128	129	130
	Stage 2 HTN	133	135	136	138	140	141	142
14	*Height (cm)*	*154*	*157*	*162*	*167*	*173*	*177*	*180*
	Prehypertension	120	120	120	120	120	120	120
	Stage 1 HTN	124	125	127	128	130	132	132
	Stage 2 HTN	136	137	139	141	143	144	145
15	*Height (cm)*	*159*	*162*	*167*	*172*	*177*	*182*	*184*
	Prehypertension	120	120	120	120	120	120	120
	Stage 1 HTN	126	127	129	131	133	134	135
	Stage 2 HTN	139	140	141	143	145	147	147
16	*Height (cm)*	*162*	*165*	*170*	*175*	*180*	*184*	*186*
	Prehypertension	120	120	120	120	120	120	120
	Stage 1 HTN	129	130	132	134	135	137	137
	Stage 2 HTN	141	142	144	146	148	149	150
17	*Height (cm)*	*164*	*166*	*171*	*176*	*181*	*185*	*187*
	Prehypertension	120	120	120	120	120	120	120
	Stage 1 HTN	131	132	134	136	138	139	140
	Stage 2 HTN	144	145	146	148	150	151	152

U.S. Department of Health and Human Services
National Institutes of Health

National Heart Lung and Blood Institute
People Science Health

NIH Publication 07-5268
May 2007

Appendix IV: IREC Approval

APPENDIX IV: IREC APPROVAL

INSTITUTIONAL RESEARCH AND ETHICS COMMITTEE (IREC)

MOI TEACHING AND REFERRAL HOSPITAL
P.O. BOX 3
ELDORET
Tel: 33471//2/3

MOI UNIVERSITY
SCHOOL OF MEDICINE
P.O. BOX 4606
ELDORET

Reference: IREC/2014/154
Approval Number: 0001294

23rd October, 2014

Dr. Adnaan Mustafa,
Moi University,
School of Medicine,
P.O. Box 4606-30100,
ELDORET-KENYA.

INSTITUTIONAL RESEARCH & ETHICS COMMITTEE
23 OCT 2014
APPROVED
P. O. Box 4606-30100 ELDORET

Dear Dr. Mustafa,

RE: FORMAL APPROVAL

The Institutional Research and Ethics Committee has reviewed your research proposal titled:-

"The Prevalence of Diabetic Nephropathy in Children at Moi Teaching and Referral Hospital, Eldoret."

Your proposal has been granted a Formal Approval Number: ***FAN: IREC 1294*** on 23rd October, 2014. You are therefore permitted to begin your investigations.

Note that this approval is for 1 year; it will thus expire on 22nd October, 2015. If it is necessary to continue with this research beyond the expiry date, a request for continuation should be made in writing to IREC Secretariat two months prior to the expiry date.

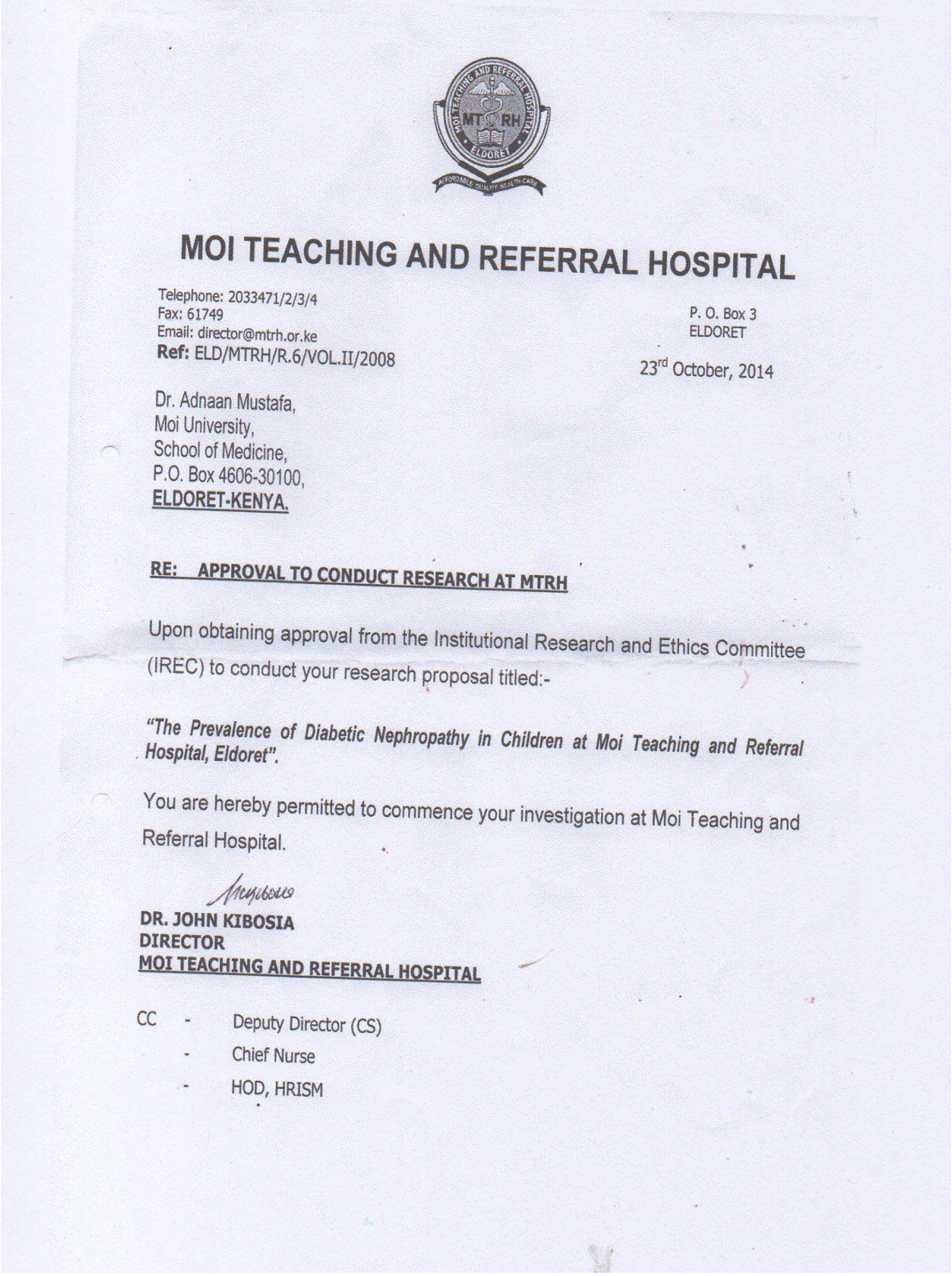
You are required to submit progress report(s) regularly as dictated by your proposal. Furthermore, you must notify the Committee of any proposal change (s) or amendment (s), serious or unexpected outcomes related to the conduct of the study, or study termination for any reason. The Committee expects to receive a final report at the end of the study.

Sincerely,

PROF. E. WERE
CHAIRMAN
INSTITUTIONAL RESEARCH AND ETHICS COMMITTEE

cc Director - MTRH Dean - SOP Dean - SOM
Principal - CHS Dean - SON Dean - SOD

Appendix V: MTRH Approval



MOI TEACHING AND REFERRAL HOSPITAL

Telephone: 2033471/2/3/4
Fax: 61749
Email: director@mtrh.or.ke
Ref: ELD/MTRH/R.6/VOL.II/2008

P. O. Box 3
ELDORET

23rd October, 2014

Dr. Adnaan Mustafa,
Moi University,
School of Medicine,
P.O. Box 4606-30100,
ELDORET-KENYA.

RE: APPROVAL TO CONDUCT RESEARCH AT MTRH

Upon obtaining approval from the Institutional Research and Ethics Committee (IREC) to conduct your research proposal titled:-

"The Prevalence of Diabetic Nephropathy in Children at Moi Teaching and Referral Hospital, Eldoret".

You are hereby permitted to commence your investigation at Moi Teaching and Referral Hospital.

DR. JOHN KIBOSIA
DIRECTOR
MOI TEACHING AND REFERRAL HOSPITAL

CC - Deputy Director (CS)
- Chief Nurse
- HOD, HRISM