PREVALENCE OF DIABETES MELLITUS AND OTHER CARDIOVASCULAR RISK FACTORS IN KIBERA SLUM

A DISSERTATION SUBMITTED IN PART FULFILLMENT OF THE REQUIREMENTS FOR THE AWARD OF THE MASTER OF MEDICINE IN INTERNAL MEDICINE OF THE UNIVERSITY OF NAIROBI.

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DECLARATION

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ABBREVIATIONS

- ADA- American Diabetes Association
- AMI- Acute Myocardial Infarction
- BMI- Body Mass Index
- CAD- Coronary Artery Disease
- **CRP-** C Reactive Protein
- CVD- Cardiovascular Disease
- DM- Diabetes Mellitus
- ECG- Electrocardiogram
- FBG- Fasting Blood Glucose
- HbA1C- Glycated Haemoglobin
- HDL- High Density Lipoprotein
- HIV/AIDS- Human Immunodeficiency Virus/ Acquired Immunodeficiency Syndrome
- hsCRP- Highly sensitive C Reactive Protein
- IFG- Impaired Fasting Glucose
- IGT- Impaired Glucose Tolerance
- **IOTF-** International Obesity Task Force
- JNC V11- Joint National Committee on the prevention and management of hypertension 7
- KNH- Kenyatta National Hospital

LDL- Low density Lipoprotein

NCD- Non Communicable Disease

OGTT- Oral Glucose Tolerance Test

PAR- Population Attributable Risk

RBS- Random Blood Sugar

SHIELD- Study to Help Improve Early evaluation and management of risk factors Leading to Diabetes

STEPS- Stepwise approach to surveillance of non communicable diseases.

UK- United Kingdom

UON- University of Nairobi

US- United States of America

WC-Waist Circumference

WHO-World Health Organization

WHR- Waist Hip Ratio

ABSTRACT

Background

Diabetes is a global health problem affecting 197 million people worldwide and over 10 million in Sub Saharan Africa. According to the World Health Organization (WHO), it has been postulated that prevalence of non-communicable diseases will outstrip that of communicable diseases by 2020. The developing countries are however, experiencing a double burden of disease as they still have to cope with both the communicable and non communicable diseases. The increase in non communicable diseases is as a result of demographic changes; increasing urbanization and associated changes in risk factor levels e.g. tobacco smoking, obesity and physical inactivity. The paucity of data on prevalence of diabetes mellitus in the community was the rationale for this study.

Main objective: Determine the prevalence of diabetes and other cardiovascular risk factors in an urban community setting.

Research Design: Cross sectional community survey.

Methodology

Cluster sampling of households in eight villages of the Kibera slum with target population of adults 18 years or older who were residents for more than three months with a calculated sample size of 2000 using a prevalence of 10.7%

Outcome variables:

- 1. Demographic
- 2. Clinical: obesity parameters i.e. BMI, waist circumference, waist hip ratio.
- 3. Laboratory profiles: RBS, FBS, Lipid profile, highly sensitive C reactive protein.

Data collection: Questionnaires, physical examination, laboratory parameters.

Data analysis: Descriptive statistics

Results

A total of 2200 individuals were screened of whom 2061 were enrolled into the study. The population was generally young with 53.9% of the study population being in the 25-44 years age group and only 5.2% being 55 years or older. The diabetes prevalence was 3.2% (95% CI 2.5-4.1%) and when the prevalence was calculated for those older than 40 years the prevalence increased to 9.2% (95% CI 6.9-12.1%). Just above half (53%) of the patients with diabetes were newly diagnosed. The diabetics were found to be more of females with an M: F of 1:1.3. There was a high proportion of overweight and obesity in the overall study population of 45% and this increased in the diabetic population to 67.2% using BMI measurements. The proportion of those engaging in tobacco smoking and alcohol consumption in the diabetic population was13.8% and 23.7% respectively. The duration of smoking and mean pack year history was statistically significant in the diabetic population compared to the non diabetic population. Alcohol ingestion was not statistically significant. Both the overall study population and diabetic population participated in high levels of physical activity either work and travel related. Only 10.6% of the overall study population had had their blood sugar evaluated in their lifetime. In the diabetic population, 96% of the patients were found to have desirable total cholesterol of less than 5.17mmol/l with 94% having a low HDL of <1.05mmol/l, 88% having normal triglycerides of less than 1.8mmol/l and 66% having a LDL of less than 3.4mmol/l. When highly sensitive C reactive protein was analyzed, 33% of the patients were excluded due to levels more than 5mg/dl. Of the remaining diabetes patients, 39.4% had levels in the high risk category of cardiovascular outcomes, 4.5% were in the medium risk category while 22.7% were in the low risk group with levels of below 2 mg/dl.

Conclusion

The prevalence of diabetes mellitus in adults in Kibera slum is 3.2% and associated cardiovascular risk factors were found to be common despite a high level of physical activity in the Kibera slums.

INTRODUCTION

Diabetes mellitus represents a group of metabolic disorders characterized by hyperglycemia resulting from defects of insulin secretion, insulin action or both. Deficient insulin action results from inadequate insulin secretion and/or diminished tissue response to insulin and both frequently co-exist.

The American Diabetes Association (ADA) 2008 classifies diabetes into four clinical classes which are type 1diabetes; type 2 diabetes; gestational diabetes mellitus and other specific types of diabetes due to other causes e.g. genetic defects. The most common types of diabetes are type1 and 2 diabetes mellitus.

Patients with diabetes mellitus have an increased incidence of atherosclerosis which manifests as cardiovascular, peripheral arterial and cerebrovascular disease. Chronic hyperglycemia is associated with long term damage, dysfunction and failure of organs especially the eyes, kidneys, nerves, heart and blood vessels.

The global prevalence of all leading non communicable diseases including diabetes and hypertension is increasing with the greatest burden in developing countries. The developing countries have a double burden of disease where the non communicable diseases are on the increase while they still have to deal with the infectious diseases.

The number of people with diabetes is increasing due to population growth, aging, urbanization and increasing prevalence of obesity and physical inactivity. Diabetes is a major risk factor for the development of cardiovascular disease which is a leading cause of morbidity and mortality.

There is paucity of data regarding diabetes prevalence in Kenya. Christensen et al in 2006 found a prevalence of 2.7% in rural regions and 10.7% in urban areas using oral glucose tolerance test. Recently Mathenge et al in October 2010 found a diabetes prevalence of 6.6% in a cross-sectional study conducted in individuals who were 50 years or older using a random blood sugar. The prevalence of diabetes and other non communicable diseases is unknown in low socioeconomic regions in Kenya.

The economic cost of diabetes care and management is unaffordable by most Sub-Saharan Africans and diabetes poses an additional burden on the limited health care delivery system. Quantifying the prevalence of diabetes now and in the future is important to allow rational planning and allocation of resources. Studies have shown that weight loss, diet and exercise can prevent or delay diabetes in people with impaired glucose tolerance. Physical activity may exert an independent effect on prevention and control of diabetes.

The aim of this study was to determine the prevalence of diabetes, obesity, cigarette smoking, alcohol consumption and physical inactivity in the urban Kibera slums.

<u>2. LITERATURE REVIEW</u>

A non communicable disease (NCD)¹ is a disease which is not infectious and results from genetic/lifestyle factors including smoking, alcohol use, unhealthy diets and physical inactivity. Examples of non communicable diseases include diabetes, hypertension, cancer, obesity, cardiovascular diseases, chronic respiratory conditions and mental health problems. Diabetes is a chronic illness that requires continuing medical care and patient self management education to prevent acute complications and decrease risk of long term complications.

Diabetes is broadly classified into type 1 and 2 diabetes mellitus ² according to both ADA and WHO. Type 1 DM patients have absolute deficiency of insulin secretion and can be identified by serological evidence of a pathological autoimmune process occurring in the pancreatic islet cells and accounts for approximately 5% of diabetes.

Type 2 DM is caused by a combination of resistance to insulin action and an inadequate compensatory insulin secretory response. Type 2 DM accounts for 90-95% of DM patients and most present with obesity which contributes to some degree of insulin resistance. Patients who are not obese by traditional weight criteria may have an increased percentage of body fat distribution in the abdominal region. Risk of developing Type 2 DM increases with increasing age, obesity, physical inactivity, women with prior gestational diabetes mellitus, individuals with hypertension or dyslipidemia.

A degree of hyperglycemia sufficient to cause pathologic and functional changes in various target tissues but without clinical symptoms may be present for a long time before type 2 DM is detected. During this asymptomatic period, it is possible to demonstrate an anomaly in carbohydrate metabolism by measurement of plasma glucose in the fasting state or after a challenge with an oral glucose load or measurement of glycated haemoglobin (HbA1C)

2.1 Criteria for diagnosis ADA 2008³

 Symptoms of diabetes plus casual plasma glucose concentration > 11.1mmol/l (200mg/dl).Casual is defined as any time of day without regard to time since last meal. The classic symptoms of diabetes include polyuria, polydipsia, and unexplained weight loss. OR

- Fasting plasma glucose >7.0mmol/l (126mg/dl). Fasting is defined as no caloric intake for at least 8 hours. OR
- 2 hour post load >11.1mmol/l (200mg/dl) during an OGTT. The test should be performed as described by WHO, using a glucose load containing the equivalent of 75g anhydrous glucose dissolved in water.
- 4. In 2009, ADA⁴ has included HbA1C as a criterion for the diagnosis of diabetes mellitus. A diagnosis is made when HbA1C is > 6.5% and confirmed with a repeat HbA1C test.

In the absence of unequivocal hyperglycemia, these criteria should be confirmed by a repeat testing on a different day. OGTT is not recommended for routine clinical use.

Confirmation is not required in symptomatic patients with plasma glucose >11.1mmol/l. If HbA1C is not possible, previously recommended diagnostic methods with confirmation are acceptable.

Pre diabetes³

These are individuals not satisfying the diagnosis of diabetes but have a sugar level that is high to be considered normal. Classified as impaired fasting glucose (IFG) and impaired glucose tolerance (IGT). IFG and IGT are both associated with the metabolic syndrome. Abnormal glucose metabolism can be documented years before the onset of overt diabetes.

Normal fasting plasma glucose (FPG) is defined as : <5.6 mmol/l (<100mg/dl).

Impaired fasting glucose (IFG): 5.6-6.9mmol/l (100-125mg/dl).

Provisional diagnosis of diabetes is when FPG >7mmol/l and confirmed with an OGTT where:

Normal 2hr post load glucose tolerance: <7.8mmol/l (100-125mg/dl).

Impaired glucose tolerance (IGT): 7.8-11.1mmol/l (140-199mg/dl).

Provisional diagnosis of diabetes is when 2hour post load glucose is>11.1mmol/l.

Although the natural history of IFG and IGT is variable, approximately 25 percent of subjects with either will progress to diabetes over three to five years⁵. Subjects with additional diabetes risk factors, including obesity and family history, are more likely to develop diabetes. The Framingham Offspring Study compared several models to predict incident diabetes⁶. The simple clinical model included information typically available at clinic evaluations, such as age, parental history of diabetes, BMI, blood pressure, HDL, triglycerides, and impaired fasting glucose. Each of the metabolic syndrome traits (elevated blood pressure and triglyceride concentrations, low HDL levels, and impaired fasting glucose), obesity, and parental history were highly associated with developing diabetes. Adding more complex measurements (oral glucose tolerance, insulin sensitivity, and insulin resistance) did not improve the model, nor did adding a genotype score based upon the presence of a number of risk alleles confirmed to be associated with type 2 diabetes⁷.

2.2 Prevalence

WHO estimated that there were 135 million people in the world with diabetes in 1995 and that this would increase to 154 million in 2000⁸. The prevalence of diabetes in all age groups worldwide is estimated to be 2.8% in 2000 and 4.4% in 2030. The prevalence of diagnosed diabetes in the UK using the Health Survey for England as a source of data is 3% amongst adults aged 16 years and above. It is clear however that not all diabetes is diagnosed and Diabetes UK estimates that that there are approximately one million people in the UK who have diabetes that has yet to be diagnosed.⁹ Studies which have examined the total prevalence of diabetes (both diagnosed and undiagnosed) suggest that nearly half of diabetes may be undiagnosed. The SHIELD study (Study to Help Improve Early evaluation and management of risk factors Leading to Diabetes $)^{10}$ was conducted in US in 2004 to estimate the prevalence of self reported diagnosis of DM and prevalence of risk factors associated with DM in a community based population. The SHIELD screening survey revealed that the overall prevalence of self reported diagnosis of DM (either type 1 or type 2) was 8.2% of the 211,097 respondents. The SHIELD study also showed that individuals were more likely to be diagnosed with type 2 DM if they had abdominal obesity (OR= 3.50) or hypertension (OR=4.82). A BMI >28kg/m² also put individuals at a significantly higher risk of being diagnosed with type 2 DM (OR= 4.04) as did a prior cardiovascular event (OR= 3.38). Lower household income and increased age were also associated with increased odds of type 2 DM diagnosis. ¹⁰

Communicable diseases still make up the greatest disease burden in developing countries but it is projected that by 2020, non communicable diseases including hypertension and diabetes will outstrip communicable diseases as a cause of death.^{11,12}

Non communicable diseases have not simply displaced acute infectious diseases in developing countries. Rather, such countries now experience a double burden of disease.¹³ This situation is as a result of demographic change (older age structures); increasing urbanization (WHO 1998)¹⁴ and associated changes in risk factor levels such as tobacco smoking, obesity and physical inactivity.¹⁵ The urban population in developing countries is projected to double between the year 2000 and 2030 as a result of urbanization. Over recent years, rates of overweight and obesity have escalated rapidly in many parts of the world to epidemic proportions, reflecting increased consumption of energy dense diets high in fats and sugars, compounded by declining levels of physical activity. More than 1.1 billion people are estimated to be overweight, of which approximately 320 million are now calculated to be obese. The International Obesity Task Force (IOTF) ¹⁶ estimates that up to 1.7 billion people may be exposed to weightrelated health risks and more than 2.5 million deaths each year are attributed to a higher BMI, a figure that is expected to double by 2030. However, the most important demographic change to diabetes prevalence across the world appears to be the increase in the proportion of people more than 65 years.

These events indicate that the 'diabetes epidemic' will continue even if levels of obesity remain constant. Given the increasing prevalence of obesity, it is likely that these figures provide an underestimate of future diabetes prevalence. ¹⁶

The most recent IDF (International Diabetes Federation) Atlas ¹⁷ estimated that 10.8 million people in 2006 had diabetes in Sub Saharan Africa and that this would increase to 18.7million by 2025 an increase of 80% exceeding the predicted worldwide increase of 55%.

Until about 40yrs ago, diabetes was considered rare in Africa. The reported prevalence using predominantly urine analysis in localized settings in a number of countries including Ethiopia, Ghana, Lesotho, Uganda and Malawi between 1960 and mid 1985 was <1% with two exceptions Ivory Coast 5.7% and South Africa 2.2-2.7%. The prevalence of diabetes in Africa currently ranges from 1% to 10% as shown in table 1 below. The estimated prevalence of diabetes in Africa is 1% in rural areas, up to 5-7% in urban Sub Saharan Africa and 8-13% in more developed areas such as South Africa and in populations of Indian origin.¹⁸

Country	Author	Site	Sample A	ge range	Method	Prevalence
Cameroon	Mbanya 1997	Rural	750	24-75	OGTT	0.7
	2	Urban	1054	24-74		1.5
	Mbanya 1999	Rural	384	24-74	OGTT	0.8
	,	Urban	295	24-74		2.0
	Cambod 2004	Urbar	n 9377	>15	OGTT	6.06
Ghana	Amoah 2002	Urban	4733	>25	OGTT	6.4
Mauritania Ducorps 1996		Rural/	744	30-64	FBG/	2.8
	-	Urban			CBG	
Nigeria	Cooper 1997	Rural	247	>25	FBG	2.0
	Owoaje 1997	Urban	247	>30	FBG	2.8
	Okesina 1999	Rural	500	>40	FBG	2.6
Tanzania	Mclarty 1989	Rural	6097	>15	OGTT	1.1
	Aspray 2000	Rural	928	>15	FBG	1.7
		Urban	770	>15		5.8
South	Levitt 1993	Urban	729	>30	OGTT	8.0
Africa	Omar 1993	Urban	485	>15	OGTT	4.4
	Alberts 2005	Rural	2106	>30	FBG	8.8
Sudan	Elbagir 1996	Rural	458	>25	OGTT	2.6
		Urban	826			3.9
	Elbagir 1998	Urban/ Rural	724	>25	OGTT	10.4
Zimbabw	e WHO STEPS 2005		/ 3081 ban	>25	FBG	10

 TABLE 1: Studies showing prevalence of diabetes in cross-sectional community

 surveys in sub-Saharan Africa: 1985-2005
 19

CBG- casual blood glucose FBG – Fasting blood glucose OGTT- Oral glucose tolerance test A cluster sampling study done in Kenya by Christensen et al in 2006 emphasized the role of urbanization in the increase in the prevalence rate of type 2 diabetes mellitus.²⁰ The study was carried out among 1416 adult Luo, Kamba, Maasai (17-65 years) from rural and urban areas and an OGTT was used. The prevalence of type 2 diabetes was 2.7% in the rural area and 10.7% in the urban population.

Mathenge et al²¹ carried out a cross sectional population based survey in Nakuru in subjects who were 50 years or older using a random blood sugar. The prevalence of diabetes was 6.6 % (5.6-7.7%) and was more in the urban regions while that of obesity was 13 % (11.7-14.5%).

2.3 Diabetes and cardiovascular disease

Cardiovascular disease, the major cause of mortality and morbidity in the developed world is set to overtake infectious diseases in the developing world as the most common cause of disease. The increasing prevalence of major and emerging cardiovascular risk factors accounts for the growing burden of cardiovascular disease in the world.

Diabetes increases the risk of CVD but it also magnifies the effect of other risk factors for CVD such as raised cholesterol, hypertension smoking and obesity. People with diabetes are also more likely to develop many of these other risk factors for CVD, further magnifying their risk.³

The INTERHEART study²² showed that diabetes is one of the main cardiovascular risk factors for acute myocardial infarction (AMI). Globally, the INTERHEART study found that smoking, lipids, hypertension, DM, obesity, diet, physical activity, alcohol consumption and psychosocial factors were significantly associated with AMI. These risks were consistent in all regions, ethnic groups, and in men and women worldwide. The risk factors with the strongest relationship to AMI in the African sample were previous history of diabetes and hypertension. In the African group, participants who had one or more of the risk factors of current/former smoking, history of diabetes and hypertension had an odds ratio of 17.4 and a population attributable risk (PAR) of 64.5% compared to the overall INTERHEART study group with an OR of 13 and a PAR of 57.7% The five factors of smoking, lipids, hypertension, diabetes, and obesity accounted

for approximately 80% of the PAR. The PAR was significantly greater in the younger than in the older individuals.

In the UK there are approximately 33,000 deaths each year that are attributable to diabetes which accounts to one in every seven of all deaths. At least a half of these deaths are from cardiovascular disease. Still in the UK, about a quarter of people with newly diagnosed diabetes already have cardiovascular disease.¹³

Data available from African populations show that diabetes is present in more than one third of patients presenting with coronary events and ischemic heart disease is present at the clinical onset of diabetes in up to 4.8% of newly diagnosed patients.²³

In a South African study, the subjects with diabetes were three to four times more likely to present with a stroke than non diabetic patients and were at a greater risk of permanent cerebral ischemia without prior warning of a transient ischemic attack than their non diabetic counterparts.²⁴

In a clinical and resting ECG study of 139 patients with diabetes from Dar es Salaam , Tanzania , 34% of patients had clinical or ECG findings compatible with ischemic heart disease.²⁵

A dual (retrospective and prospective arm) study by Kamotho et al^{26} in black Kenyans with angiographically detected CAD found diabetes to be the most strongly associated risk factor in the population affecting 38.5% of this population.

2.4 Determinants of cardiovascular diseases in diabetes in Sub Saharan Africa

Adoption of Western lifestyles has been established as a cause in the rise in the prevalence of diabetes and other non-communicable diseases in Sub-Saharan Africa.²⁷ The common elements of 'Westernization' include a diet higher in total calories and fat but lower in fiber and less need to expend energy because of labor saving devices. Obesity is also on the rise in many Sub Saharan African countries. The evolution of a 'thrifty genotype' is postulated to have resulted in a selective survival advantage in times of fluctuating plenty and famine by allowing highly efficient storage of calories in times

of plenty.²⁸ This thrifty genotype becomes detrimental when food supplies are constant and abundant and is postulated to have led to an increased prevalence of obesity and type 2 diabetes mellitus in some populations.

2.5 Risk factors of type 2 diabetes mellitus

The risk factors are similar to other regions of the world. Both genetic and environmental factors are responsible for diabetes. The development of type 2 diabetes is influenced significantly by obesity and a lack of physical activity.²⁹

Under-nutrition is a common problem in children of the Sub- Saharan region. Childhood under-nutrition confers a two to sevenfold risk for being overweight in adulthood.³⁰

Certain risk factors implicated in the development of diabetes are also known to be associated with socioeconomic status. Obesity, physical inactivity, smoking, and low birth weight have all been described as risk factors for type 2 diabetes. In Western societies these factors are associated with low socioeconomic status. An ecological study conducted in the UK³¹ found an inverse relation between the prevalence of type 2 DM and socioeconomic status. However, few published studies have investigated this relation. A study done in Northern India also found a high prevalence of diabetes, obesity and dyslipidemia in rural –urban migrants who have settled in an urban slum dwelling which was attributed to the lifestyle changes and in particular the dietary habits.³²

2.6 Cost of diabetes

The Global Burden of Disease Project estimates that in established market economies such as the UK 3% years of life lost in disability are due to diabetes as compared to 4% for cancer.³³

The economic cost of diabetes and its complications are unaffordable by most individuals and families in Sub Saharan Africa. The limited resources available are shared between fighting poverty, implementing education strategies, provision of housing and appropriate sanitation and the socioeconomic and health economic burden of fighting HIV/AIDS. Early implementation of preventive measures is therefore necessary thus the need to know the prevalence of diabetes and evidence of the burden of the disease in our community. In Africa, DM accounts for a third of all the patients who are admitted to dialysis units where renal replacement is both expensive and not widely available.³⁴ Human resources are lost due to both the ill health and time spent weekly in the dialysis units. Diabetes in Sub Saharan Africa occurs at two peak ages of 45-64 and over 65yrs thus complications like retinopathy and neuropathy which cause disability decrease the work force.

Studies on the economics of diabetes care in Sub-Saharan Africa are limited. In Tanzania about US\$4 million would have been required to take care of all patients with diabetes in 1989/90, which translates to US\$138 per patient per year. This sum is equivalent to 8.1 percent of the total budgeted health expenditure for that financial year and well above the allocated per capita health expenditure in Tanzania of US\$2 for the year (Chale et al 1992).^{35,36}

A structured and organized diabetes health care system is non existent in most parts of Kenya thus knowing the diabetes prevalence assists in better planning.

<u>2.7 Survey methods</u>

A NCD surveillance system helps in assessing prevalence of the NCD, establishing risk factors and monitors trends in population health behaviors. The surveillance system guides in the planning and evaluation of prevention and control programs by providing a comprehensive database.

The WHO STEPS questionnaire ³⁷ (The WHO STEPwise approach to surveillance of non communicable diseases) is a validated instrument developed by WHO for collection of surveillance data on NCD's in resource poor settings. It is a sequential process made up of 3 main sections which are the risk stratification questionnaire (step1), anthropometric measurements (step 2) and biochemical measurements (step3). The STEPS instrument provides a standard tool for surveillance as it is a validated tool.

, The diagnosis of diabetes can be through; self report, blood sugar measurement and HbA1C measurement. About one-third of persons with diabetes are unaware they have diabetes because their diabetes has not been diagnosed.³⁸ Therefore, self report may underestimate the true incidence of diabetes. Diabetes can be suspected if a urinalysis specimen shows glucose excretion, however, glycosuria needs to be confirmed by doing a blood glucose test as there are other causes of excretion of glucose via the urine.

Studies done show that when a FBS and OGTT are done together, there is an association between IGT and IFG detected in 39% of subjects with IFG.³⁹ Missing this association is risky since subjects with IGT are at an increased risk of developing DM and cardiovascular disease. Performing a FBG is however, practical in all clinical settings unlike an OGTT. The ADA recommends the use of FBG instead of the 2 hour post glucose load for diagnosing DM because it is difficult to perform an OGTT in routine clinical practice.³⁵WHO has adopted that whenever feasible, individuals with IFG should receive an OGTT to exclude the presence of DM.⁴⁰ FBG is less expensive and intrusive than OGTT. The OGTT also requires more time to perform leading to loss of wages to the patient or an inability to engage in other desired activities. A few patients are unable to tolerate the glucose challenge drink making the results of the test un-interpretable because the full glucose load was not ingested. Some patients inaccurately report that they have fasted resulting in a falsely elevated FBG but this has less impact in the interpretation of an OGTT. Studies have shown FBG is more reproducible than the OGTT. The day to day intra individual co-efficient of variation ranges from 6.4-11.4% for FBG and 14.3-16.7% for the OGTT. 41 In addition the overall test to test reproducibility using the OGTT is unsatisfactory.⁴² The San Antonia group ⁴³ reported that patients diagnosed with DM exclusively on the basis of an OGTT were five times more likely to revert to non diabetic status after 7-8 years of follow up than those meeting the FBG criterion.

In 2009, ADA⁴ included HbA1C as criterion for the diagnosis of DM. HbA1C has several advantages which include: does not require a fasted state, not affected by short term lifestyle changes, is the measurement best proven to co-relate to diabetic retinopathy/nephropathy and neuropathy. HbA1C however, is also associated with is several disadvantages which include: an expensive test affected by haemoglobinopathies or any condition causing increased red blood cell turnover (hemolytic anemia, major blood loss, blood transfusion and chronic malaria), increases with increasing age and has racial disparities.

Recent evidence shows that inflammation plays a pivotal role in the inception and progression of atherosclerosis. The majority of patients who develop coronary events are

not in a high risk group according to the Framingham risk assessment of traditional risk factors for CAD ⁴⁴ and half of those who suffer myocardial infarcts have normal lipid levels. Measurement of inflammatory markers has been suggested as an adjunct to lipid testing to better identify individuals at a higher risk.⁴⁵ C reactive protein (CRP) is produced by the liver in response to pro-inflammatory cytokines released from activated cells at the site of inflammation.⁴⁶ Currently, it is not clear whether an increased concentration of CRP merely reflects the inflammatory process smoldering within atherosclerotic lesions or whether CRP assumes an active role in the development of atherosclerosis. To assess the cardiovascular disease risk, CRP must be measured by highly sensitive methods (hsCRP) that are capable of reliably measuring concentrations within the healthy reference interval.

<u>3. Study Justification</u>

Diabetes mellitus is a prevalent NCD with significant morbidity and mortality. It is postulated that by 2020 NCD including diabetes will be the major cause of mortality. There is paucity of data for the prevalence of diabetes mellitus and other cardiovascular risk factors in the Kenyan population and in particular the urbanized low income population. Establishing this data will assist and allow the rational planning of the health care resources and the implementation of the various lifestyle changes in the prevention of diabetes mellitus.

The economic cost of diabetes and its complications are unaffordable by most individuals and families in Sub Saharan Africa. The limited resources available are shared between fighting poverty, implementing education strategies, provision of housing and appropriate sanitation and the socioeconomic and health economic burden of fighting HIV/AIDS. Early implementations of preventive measures against diabetes mellitus are therefore necessary. Strategies to lay out preventive measures are only possible once the prevalence and the burden of the disease are laid out.

Most individuals still believe that diabetes is a disease of the affluent and the elderly and thus continue engaging in risky lifestyles e.g. lack of physical activity and increased alcohol consumption. Studies however, show that populations in low socioeconomic status are at an increased risk of acquiring diabetes mellitus

4. BROAD OBJECTIVE

To determine the burden of cardiovascular NCD and risk factors in an urban Kenyan community.

5. SPECIFIC OBJECTIVES

5.1 SPECIFIC PRIMARY OBJECTIVES

In the selected urban community setting:

- To determine the prevalence of diabetes mellitus in the Kibera high density slum utilizing RBS/FBG or history of current use of insulin or oral hypoglycaemic agents.
- 2. To determine the prevalence of obesity by using BMI/WHR.
- 3. To determine the prevalence of cigarette smoking and alcohol use.
- 4. To assess the level of physical activity.

5.2 SPECIFIC SECONDARY OBJECTIVES

In the sub-sample of identified diabetes patients:

- 1. To determine the prevalence of hypertension.
- 2. To determine the fasting lipid profile.
- 3. To determine the hs-CRP profile.

6. METHODOLOGY

6.1 STUDY DESIGN

Cross sectional community survey study

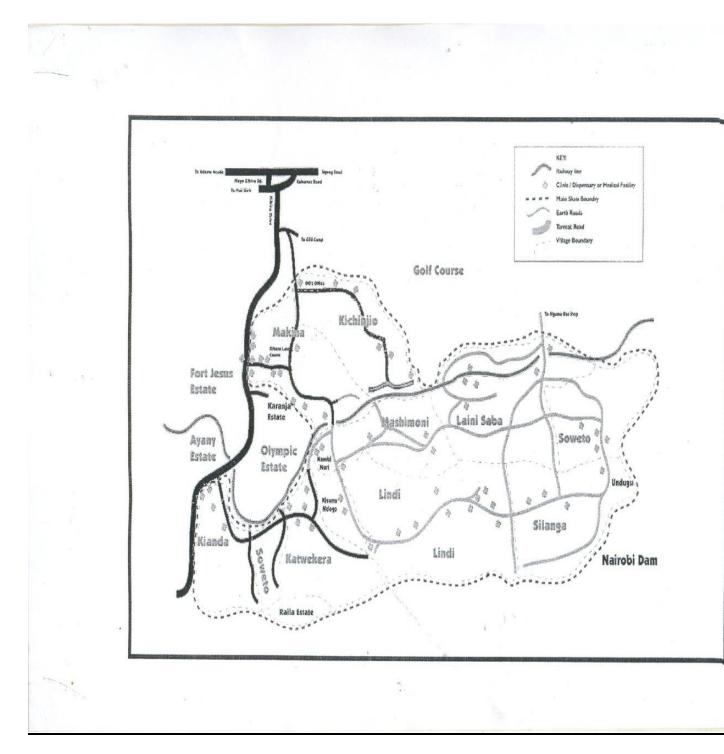
6.2 STUDY SITE

Kibera sub location.

Study Area

Kibera is located southwest of Nairobi city centre and is approximately 2.5 square kilometers, 256 hectares, or 630 acres. Kibera is in Langata division which is in Nairobi West district. It is sited approximately 5 km south west of the city centre of Nairobi. There are nine villages which are Kianda, Soweto, Gatwekera, Kisumu Ndogo, Lindi, Laini Saba, Siranga/Undugu, Makina and Mashimoni.

According to the 1999 Kenyan census⁴⁷, the total population of Langata was projected to be 429,394 with Kibera taking up 64% of that population which is approximately 274,812. The adult population of Kibera is postulated to be 70% of the total population which gives an approximate figure of 192,368. The 1999 census projected an annual growth rate of the Kibera population to be 4.4 to 4.8% per year. Taking the median growth rate of 4.6%, the projected adult population of Kibera is 301,605. The 2009 census however, reports that Kibera residents are approximately 170,000.



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3.3 STUDY POPULATION

Adults above 18 years residents of the Kibera slum for more than 3 months.

6.4 INCLUSION CRITERIA

- 1. Adults more than 18yrs.
- 2. Informed consent.
- 3. Residents of Kibera.

6.5 EXCLUSION CRITERIA

- 1. Non consenting individuals.
- 2. Pregnant mothers.

6.6 SAMPLE SIZE AND SAMPLING CALCULATION

The following formula will be used 48

 $n = (Z^2 x p(1-p)/d^2) x f$

Description:

n = required sample size

Z= confidence level at 95% (standard value of 1.96)

p = estimated prevalence of diabetes in the project area = 10.7%

d = margin of error at 2% (standard value of 0.02)

f= design effect=2

The estimated prevalence used was 10.7% based on the study done by Christensen et al.

The estimated sample size of 1728 participants was arrived at.

Adjusting for 5% spoilt samples, 5% declination to participate in the study procedures and 5% data loss on account of a non-fasted state; the sample size was adjusted to **2000** participants.

6.7 Sampling procedure

Cluster sampling with probability proportional to size was used. Using the area map and existing villages, the area was divided into 9 study areas. Each study area was divided into 80 clusters each containing 25 households. A sampling frame with the list of villages and the projected populations of each was obtained. A sampling interval was then obtained by dividing the total population by the number of clusters to be visited i.e. 2000/80= 25. A random number which is less than or equal to the sampling interval was selected and was known as the random start. The number had to have the same number of digits as the sampling interval. Next the village in which cluster 1 is located was identified. This was done by locating the first community listed in which the cumulative population equals or exceeds the random start .Identifying the village in which cluster 2 and subsequent clusters was located was done by adding the sampling interval to the running total of adding the sampling interval to the random number/start.

The households in each cluster were visited in a random walk method. Using this method, the nearest health centre or church or school was used as the focal point in each cluster. The direction to be followed was randomly selected by using a random number between 11 and 49. The first digit indicated the direction (1= North 2= East 3= South and 4= West). The second digit indicated how many households were to be skipped before the first household in the cluster was identified. The next household was taken as the one nearest to the one previously visited until the sample size for the given cluster was achieved.

Data was collected by the primary investigator assisted by 12 study assistants who were registered clinical officers assisted by interviewers from the respective villages. Study assistants with a medical background and training on how to take the anthropometric measurements was conducted to ensure consistency. The interviewers were residents of Kibera with a minimum of an O level of education. Local guides from the community who were fluent in English and Kiswahili assisted in the introduction of the research team as well as providing security for the group. The interviewers and guides had also been used in other research studies done in the community. The primary investigator was the supervisor of the data collection.

6.8 Data collection instrument

The WHO STEPS-wise approach for collecting surveillance data for non communicable diseases (NCD's) was used to collect data.

6.9 Data collection and methods

After approval from the UON Department of Clinical Medicine and Therapeutics, the KNH Ethics and Research committee, the Ministry of Science and Technology, the Nairobi City Council and the provincial administration, the Kibera community leaders and elders were informed of the study.

The research assistants were trained over a one week period on the different aspects of the STEPS questionnaire and anthropometric measurements were standardized. The research assistants were divided into 12 pairs where each pair comprised of an interviewer and a registered clinical officer.

The field trips were conducted on a daily basis for a period of two weeks from 8am to 5 pm and data collection was supervised by the primary investigator with overall supervision by the faculty supervisor. Each investigative pair covered approximately eight to ten (8-10) households per visit with an estimated two to three (2-3) adults per household. The household members who were not present on the visit day were sort after on the next day and if they were still not available, arrangements were made to visit the household over the weekend. An average of 20 household members was interviewed by each pair per visit day.

Consent was obtained from willing participants in the randomized households who fulfilled the inclusion criteria. The participants then completed the risk factor stratification questionnaire which covered the smoking habits, alcohol use and physical activity pattern and also history of prior evaluation for diabetes and if any, the medication and lifestyle counseling that had been given.

A standard alcoholic drink for the local brews was calculated as volume of container in liters multiplied by percentage alcohol by volume (ml/100ml) multiplied by 0.789 (Specific gravity of ethyl alcohol). The percentage content of changaa was taken as 34% while for busaa was 4%.⁴⁹, for the standard brews, 300ml of beer was recorded as one standard drink.

Anthropometric measures were recorded i.e. waist and hip circumference, waist: hip ratio, body mass index. Height was measured to the nearest 0.5cm using a metal measuring tape against a wall and a flat headboard at right angles to the wall. Weight was determined by a good quality bathroom scale with the subject in light clothing and without shoes. Mid upper arm circumference was measured to the nearest 0.5cm. Waist circumference was taken with a flexible tape measure placed on a horizontal plane at the level midpoint of the superior border of the iliac crest and the inferior margin of the last rib mid-axillary plane and the recording was at the point of normal expiration.

The blood pressure was recorded after the risk factor questionnaire had been filled to ensure that subjects had been seated for at least fifteen minutes. A mercury sphygmomanometer was used connected to a standard cuff (12.5x23cm) for participants with a mid upper arm circumference less than 33cm and a larger cuff (15.5x32.5cm) for participants with a mid upper arm circumference more than 33cm. The systolic pressure was recorded as the appearance of the Korotokoff sound (phase 1) and the diastolic blood pressure as the disappearance of the Korotokoff sound (phase 5) as described by the American Heart Association guidelines for measuring blood pressure. Three intermittent readings were taken and an average used. A random blood sugar was recorded using an Accucheck ^R (Roche Germany) glucometer.

The participants who had a RBS >11.1 or were on anti-diabetic medication were requested to come to the nearest health facility at a later date after an over night fast of at least 8 hours. The fasting specimens were collected over a period of six weeks over the weekends to ensure availability of the participants. Five milliliters (5 mls) of blood was drawn from a peripheral vessel preferably the ante-cubital fossa. The serum was used to get the fasting blood sugar, total cholesterol, and HDL and LDL cholesterol using enzymatic calorimetric methods using AEROSET / ARCHITECTC (Abbot Laboratories South Pasadena) systems. The serum was used to get the hs CRP using photometric systems at turbid metric immunoassay done at 37 degrees Celsius.

7. Case definitions

A diagnosis of diabetes was as described by WHO/ADA in the literature review as a RBS >11.1 and a FBS > 7.0mmol/L or on insulin or oral hypoglycaemic agents.

7.1 Outcome variables

Body mass index was used as a measure of total body obesity while waist circumference and waist: hip ratio was used as measures of abdominal obesity. Body mass index (BMI) was calculated as weight (kg)/height (m²).

BMI <18.5 was recorded as underweight, 18.5-24.9 as normal, 25-29.9 as overweight and BMI more than 30 was recorded as obesity.

Significant waist circumference was recorded as more than 102cm (40 inches) for males and more than 88cm (35 inches) in females.

Significant waist to hip ratio was considered abnormal in females with a ratio of >0.9 and males >1.0.

Hypertension was classified according to the JNC VII⁵⁰ classification with systolic BP >14OmmHg and/or diastolic BP >90mmHg or on anti- hypertensive medication.

hs crp <2mg/dl was classified as low risk, 2-3 moderate risk and >3 as patients with high risk of a cardiovascular event.

Normal triglycerides was recorded as < 1.7mmol/l, normal LDL <3.4mmol/l, desirable HDL >1.05 mmol/l, desirable total cholesterol < 5.17mmol/l.

Cigarette smoking was defined as use of cigarettes, pipes or cigar in the last 12 months. Alcohol use was defined as the use of beer, wine, spirit or local alcoholic brews in the last 12 months.

8. QUALITY ASSUARANCE

The research assistants underwent training on how to take the anthropometric measurements to ensure standardization. The sphygmomanometers, weighing scales and tape measures were assessed daily by taking measurements of one person on each of the machines to ensure they were standard.

Recommended procedures for specimen collection, preparation and storage were followed to minimize pre-analytical errors.

Before analysis, all the assays were calibrated according to the manufacturer's specifications. Commercial controls were used to validate the calibrations. Results were only accepted if controls were within the accepted limits.

Results were transcribed onto data sheets which were checked by two people to minimize post analytical transcriptional errors.

<u>9. Data management</u>

All participant data did not bear the names or unique identifiers of the participants but rather a serial number. Data forms were kept in a secure lockable cabinet only accessible to the study investigator and the statistician. Data was entered into a password protected MS Access database prepared by the statistician. The primary investigator checked all the entered data against the hard copy forms after completion of data entry and sorted out any inconsistencies.

Data analysis

Statistical analysis was done using statistical package for social scientists (SPSS) version 16.0. Continuous data e.g. age, Blood pressure, weight, height, BMI, blood sugar, Lipid profile, High sensitivity C-reactive protein was presented as means, standard deviations, medians, proportions and frequencies while categorical data such as smoking habits, alcohol intake and physical activity was presented in proportions, frequencies and percentages. Analyzed data was presented in the form of tables and graphs.

10. Ethical considerations

The study was carried out after approval from the department of Clinical Medicine and Therapeutics (U.O.N) and KNH scientific and ethics committee. Approval was also sought from The Ministry of Science and Technology, The Nairobi City Council and the Provincial Administration.

Only patients who gave informed consent were enrolled and patients were free to withdraw during the study period without discrimination. Information gathered from patients was kept confidential.

The laboratory results of the tests performed on the patients was appropriately communicated to them and advice given depending on the results.

Follow up care for clinical conditions detected were referred to Kenyatta National Hospital or Mbagathi District Hospital as appropriate.

11. FEASIBILITY

Kibera is a densely populated area with a projected population of 170,000 figures given in the 2009 census. Achieving the minimum sample size of 2000 individuals was therefore possible. Research assistants and local guides were used to assist in data collection. A lot of research has been conducted in Kibera and the residents were very receptive.

12. RESULTS

12.1. OVERALL STUDY POPULATON

The study was carried out between June 2010 and August 2010. A total of 2200 individuals were screened and 2061 individuals were enrolled into the study. Of the 139 individuals who were excluded, 38 were pregnant, 50 declined to give consent and 51 had not attained 18 years. The response rate was high at 97.5%.

Of the desired nine villages in Kibera, we visited eight and left out Laini Saba village as we were not assured of adequate security for the investigators. We visited 936 households in these 8 villages. It was noted that we missed a high proportion of 80% of the household heads who were reported to be at their places of work even after two other attempts of tracing them and going back to the households over the weekends.

The male to female ratio of the overall study population was 1.1:1.

Sex	Frequency n=2046 (%)	
Male Female	1050 (50.9) 996 (48.3)	

Table 2: Gender distribution in the study population

<u>12.1.1 Age distribution in study population</u>

The overall population had a mean age of 33.4 years with SD of 11.6 years and a range from 18 to 90 years.

This population was generally young with 53.9% of the overall population being in the 25-44 years age group and only 5.2% being 55 years or older.

Age	0verall n=2055(%)	
15-24	578(28)	
25-34	656(31.8)	
35-44	455(22.1)	
45-54	258(12.5)	
55-64	78(3.8)	
65-74	25(1.2)	
>=75	5 (0.2)	

Table 3: Age distribution in the study population

12.1.2 Level of education in the overall study population

This population had a high level of literacy with 87% of the population having either a primary or secondary level of education. Only 1.7% of the population had no form of education

Level of education	Overall n=2030 (%)	
None	36(1.7)	
Primary level	986 (47.8)	
Secondary level	808(39.2)	
Tertiary level	197(9.6)	

<u>12.1.3 Tobacco smoking in the study population</u>

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Table 5: Tobacco smoking in the overall study population

Tobacco use	Frequency n=269
Currently smoking n (%)	269(13.1)
Smoking daily n (%)	213(79.2)
Age in years of beginning to smoke daily me	an(SD) 19.7(5.5)
Duration of smoking in years mean (SD)	16.5(10.0)
Pack years median (IQR)	6(2.5-10.9)

It was noted that 13.1% of the enrolled individuals were current smokers of whom 79.2% were smoking on a daily basis. The mean age at which smoking was commenced was 19.7 years with a mean duration of smoking of 16.5 years and a median pack year history of six pack years.

12.1.4 Alcohol consumption in the study population

Table 6: Alcohol consumption in the overall study population

alcohol consumption	Frequency (%)/median(IQR) n=2061
Ever consumed an alcoholic drink (n=2061)	618(30)
Alcohol consumption within the past 12 mor	ths(n=618) 463(74.9)
Alcohol consumption within the past 30 days	384(62.2)
Frequency of alcohol consumption in the l	ast 12months
Daily consumption	91(19.7)
Consumption on 5-6days/week	64(13.8)
Consumption on 1-4days/week	137(29.6)
Consumption on 1-3 days/month	107(23.1)
Consumption less than once/month	63(13.6)
Unknown level of consumption	1(0.2)
Average number of standard drinks dranl	x per sitting 4(3-6)
Largest number of drinks drank per sitting	ng 6(4-9)

In the study population, 30% of those interviewed reported to have consumed an alcoholic drink in their lifetime. Of those 618 individuals, 74.9% reported to have consumed an alcoholic drink in the last 12 months and 62.2% in the previous 30days. It was also noted that 63.1% consumed an alcoholic drink on one to seven days of the week of whom 19.7% consumed on a daily basis.

In the overall study population 4.4% consumed an alcoholic drink on a daily basis.

12.1.5 Level of physical activity in the study population

Physical activity was divided into work related, travel related and leisure related. The work and leisure related was further divided into vigorous or moderate level of activity.

	I		
Intensity	Proportion n=206	51 (%) Days median(l	QR) Time hrs median(IQR
Vigorous (work)	610(29.6)	6(5-7)	8(3-9)
Moderate (work)	946(45.9)	6(5-7)	6(3-8)
Walk/bicycle (travel)	1589(77.1)	6(5-7)	1(0.75-2)
Vigorous (recreational)	312(15.1)	2(1-3)	2)1-2)
Moderate (recreational)	335(16.3)	3(1-6)	1(0.7-2)
Time sitting/reclining*			4(2-6)

Table 7: Level of physical activity in the overall study population

*sleeping time not included

The study population had a high level of physical activity whether work or travel related. A huge proportion 77% of the population was involved in travel related physical activity with a median of six days of the week. It was also noted that 75.5% of the population performed some physical activity which was work related and was either moderate or vigorous in intensity.

12.1.6 Obesity status in the study population

Obesity status was assessed using Body Mass Index (BMI), Waist circumference (WC) and Waist: Hip Ratio (WHR)

1. Body Mass Index (BMI)

Table 8: Assessment of BMI in the study population

BMI	FREQUENCY n=2027 (%)
Underweight	93(4.5)
Normal	1007(48.9)
Overweight	592(28.7)
Obese	335(16.3)

In the study population, 45% were found to be either obese or overweight using BMI measurements, while only 4.5% were underweight and 48.9% had a normal BMI.

2. WAIST CIRCUMFERENCE Table 9: Assessment of waist circumference in the study population

Waist circumference	Frequency n=2032(%)
Elevated/abnormal	437(21.2)
Normal	1595(77.4)

There was a high level of abdominal obesity with 21.2% of the population having an elevated waist circumference.

3. WAIST:HIP RATIO

Table 10: Assessment of waist to hip ratio in the study population

WHR	Frequency n=2061 (%)	
Undesirable	269(13.1)	
Normal	1758(85.2)	
Missing data	34(1.6)	

The level of obesity reduced when the WHR measurements were used and only 13.1% of the population had an undesirable WHR as compared to 21.2% who had abdominal obesity when WC measurements were used and 45% having obesity/overweight when BMI was used.

Obesity and gender

BMI	MALE n=1033	FEMALE n=982	p value
Underweight	61(5.9)	31(3.2)	< 0.001
Normal	626(60.6)	376(38.3)	< 0.001
Overweight	272(26.3)	316(32.2)	< 0.001
Obese	74(7.2)	259(26.4)	< 0.001
WC	n=1044	n=988	
Elevated	27(2.6)	410(4.5)	< 0.001
Normal	1017 (97.4)	578(58.5)	< 0.001
WHR	n=1042	n=985	
Abnormal	33(3.2)	236(24)	< 0.001
Normal	1009(96.8)	749(76)	< 0.001

Table 11: Comparison of obesity measurements with gender

There was a significant difference in the proportions when the level of obesity was assessed, when females were compared to males. Females were found to be more obese or overweight using all the parameters. Majority of the males (60.6%) were found to be in the normal range of BMI as compared to females who were only 38.3%. Females were found to be more obese when compared to males with a proportion of 26.4% versus 7.2% (p<0.001). When WC or WHR measurements were used majority of the males fell in the normal range i.e. 97.4% and 96.8% respectively. Females were found to have a higher proportion of abdominal obesity using WHR as compared to males i.e. 24% versus 3.2% which was statistically significant with a p value<0.001.

12.2 PREVALENCE OF DIABETES

Table 12: Diabetes prevalence

Diabetes	n=2061(%)
Yes	66 (3.2)
No	1995 (96.8)

Of the 2061 individuals who were screened the diabetes prevalence was 3.2% (95%CI 2.5-4.1%).

|--|

SEX	Overall n=2061	DIABETES		р
		YES n= 66	No n=1980	
Male	1050 (51.3)	29(43.9)	1021(51.6)	0.223
Female	996(48.7)	37(56.1)	959(48.4)	

Of the 66 patients found to have diabetes, 56.1% were females and 43.9% were males with a male to female ratio of 1:1.3 which was not statistically significant.

Only 10.6% of the study population had ever had their blood sugar measured in their lifetime.

Of those diagnosed with diabetes, 53% were newly diagnosed. Of the remaining 47% who were known to have diabetes, 22.6% were on insulin, 48.4% were on oral hypoglycaemic agents, 54.8% were on a diabetic diet and 12.9% were taking herbal treatment during the interview. In terms of lifestyle modification counseling, 35.5% had been advised on weight management, 22.6% on smoking cessation and 35.5% on exercise.

12.2.1Diabetes and age

Variable	Overall,	Overall, Diabetes		P value
	n=2061 (%)	Yes	No	
Age				
15-24	578 (28.0)	2 (3.0%)	576 (29.0%)	< 0.001
25-34	656 (31.8)	10 (15.2%)	646 (32.5%)	
35-44	455 (22.1)	15 (22.7%)	440 (22.1%)	
45-54	258 (12.5)	27 (40.9%)	231 (11.6%)	
55-64	78 (3.8)	6 (9.1%)	72 (3.6%)	
65-74	25 (1.2)	4 (6.1%)	21 (1.1%)	
>=75	5 (0.2)	2 (3.0%)	3 (0.2%)	
	6 (0.3)	. ,	. ,	

Table14: Distribution of subjects with diabetes by age

The study population was relatively in the young age group with 53.9% of the population being in the 25-44 year age group and only 5.2% were 55 years or older. The 45-54 years age group had a sizeable proportion of 40.9%. The prevalence of diabetes was noted to increase with age with a prevalence of 9.2% (95% CI 6.9-12.1) in those 40 years and older.

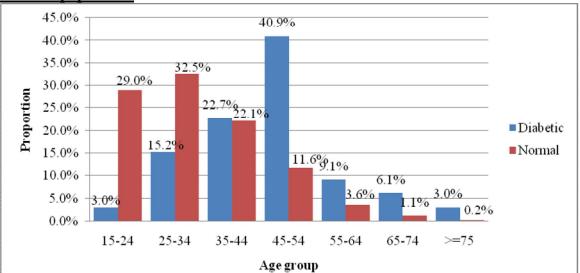


Figure 1: Age distribution differences between the study population and the diabetes population

14.2.2Diabetes and education level

Variable	overall n=2061	Dia	betes	р
Education		Yes	N o	
None	36(1.7)	3(4.9)	33(1.7)	0.003
Primary	986 (47.8)	41(67.2)	945(48.1)	0.003
Secondary	808 (39.2)	14(23)	794(40.4)	0.002
Tertiary	197(9.6)	3(4.9)	194(9.9)	< 0.001
None	34(1.6)			

Table 15: Distribution of subjects with diabetes by level of education

The patients with diabetes were found to have a high level of literacy with 90% of them having attained either a primary or secondary level of education. When the diabetic population was compared to the non diabetic population there was no statistical significance with both groups having a high level of literacy.

14.2.3 Diabetes and smoking

Table 16: Smoking habits amongst the study population with diabetes

Variable	Study population	Diabe	etes	p value
	n=2061	Yes n=66	No n=261	-
Currently smoking n (%)	269(13.1)	8(13.8)	261(13.4)	0.936
Daily smoking n (%)	213(79.2)	7(53.8)	206(55.3)	0.915
Age at daily smoking mean	n SD 19.7(5.5)	20.1(1.5)	19.7(5.5)	0.844
Smoking duration mean SE	D 16.5(10.0)	28.6(11.6)	16.0(9.8)	0.001
Pack years 6(2.5-10.9)	12.8(8.8-20.3)	6(2.2.5-)	10.5)	0.049

13.8% of patients with diabetes were cigarette smokers. This proportion was not statistically different from that observed amongst the non diabetic population with a p value of 0.936.

Of statistical significance was the smoking duration in years which was 28.6 (SD11.6) as compared to the non diabetic smokers which was 16 (SD 9.8) with a p value of 0.001. The mean pack year history was also statistically significant with the diabetics having a 12.8 pack year history and the non diabetics a six pack year history which was statistically significant with a p value 0.049.

14.2.4 Diabetes and alcohol consumption

Table 17: Comparison of alcohol consumption in the stu	dy population and the
diabetes population	

Variable	Frequency	Ι	Diabetes	р	
Alcohol consumption	%/median IQR		No	ľ	
•	2061	n=			
Ever consumed n=2061	618 (30.0)	14(23.7)	604(30.6)	0.260	
Alcohol in past 12 months n=618	463(74.9)	11(84.6)	452(69.8)	0.247	
Alcohol in past 30 days	384(62.2)	9(69.2)	379 (76.4)	0.529	
Frequency of alcohol consumption in last 12 months Daily consumption 5-6 days/week 1-4 days/week 1-3 days/month < once/month	91(19.7) 64(13.8) 137(29.6) 107(23.1) 63(13.6)	4(30.8) 1(7.7) 4(30.8) 3(23.1) 1(7.7)	92(18.7) 70(14.2) 142(28.9) 115(23.4) 73(14.8)	0.843	
Average no of drinks/sitting	4(3-6)	4(4-6)	4(4-6)	0.596	
Largest no of drinks/sitting	6(4-9	8(5-9	6(4-8.5)	0.483	

The individuals with diabetes were found to have a relatively high intake of alcohol with 23.7% reporting to have ever consumed an alcoholic drink in their lifetime. Of that

population, 84.6% had consumed alcohol in the previous one year and 69.2% in the last one month. Of those who consumed an alcoholic drink daily, there was no statistical significance with 30.8% in the diabetes group and 18.7% in the non diabetic group with a p value of 0.843.

14.2.5 Diabetes and physical activity

Intensity		p value	
	Yes	No	
Vigorous (work)	13(19.7)	597(30.1)	0.068
Moderate (work)	26(44.1)	920(48.1)	0.540
Walk/bicycle (travel)	47(71.2)	1543(78.2)	0.204
Vigorous (recreational)	8(12.5)	304(15.4)	0.521
Moderate (recreational)	14(25.5)	321(16.8)	0.092
Sitting/reclining	4.2 (2-8)	4(2-6)	0.299

Table 18: Level of physical activity amongst study subjects with diabetes.

The individuals with diabetes group had a high level of physical activity with 63.8% engaging in work related physical activity and 71.2% in travel related physical activity. A sizeable proportion of 38% also engaged in recreational type of physical activity. There was no noted statistical significance in the different forms of physical activity between the diabetes and the non diabetes group.

14.2.6 Diabetes and obesity

<u>1. BMI</u> Table 19: Patterns of body mass index of study subjects with diabetes

Variable	Frequency (%)	Dia	P value	
	n=2061	Yes n=64	No n=1963	
BMI				
Underweight	93 (4.5)	3 (4.7%)	90 (4.6%)	< 0.001
Normal	1007 (48.9)	18 (28.1%)	989 (50.4%)	< 0.001
Overweight	592 (28.7)	14 (21.9%)	578 (29.4%)	< 0.001
Obese	335 (16.3)	29 (45.3%)	306 (15.6%)	< 0.001
Missing	34 (1.6)			

In the diabetes group, 67.2% were found to be either overweight or obese and this was statistically significant when compared to the non diabetic group which was 45% of the overall population and this was statistically significant with a p value of <0.001. The non diabetic group had a higher proportion of individuals in the normal range of BMI 50.4% as compared to those in the diabetes group 28.1% and this was statistically significant with a p value of <0.001.

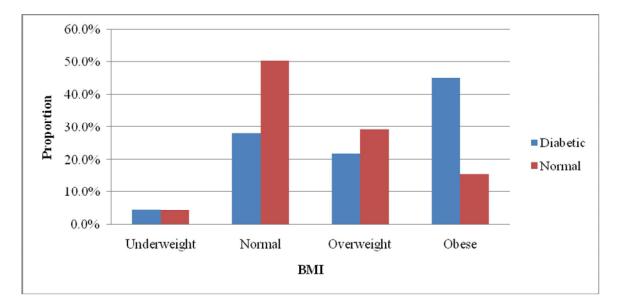


Figure 2: Comparison of BMI among the study population and the diabetes population

2. Waist circumference

Table 20: Assessment of waist circumference in the diabetes population

Waist circumference	Overall n=2061 Diabetes		S	p value
	(%)	Yes n=65	No n=19	67
High	4(21.2)	29(44.6)	408(20.7)	< 0.001
Normal	1595 (77.4)	36(55.4)	1559(79.3)	< 0.001

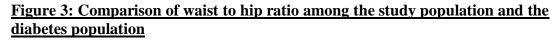
The individuals with abdominal obesity in the diabetes group were 44.6% which was statistically significant when compared to the non diabetic group with a proportion of 20.7% and a p value of <0.001.

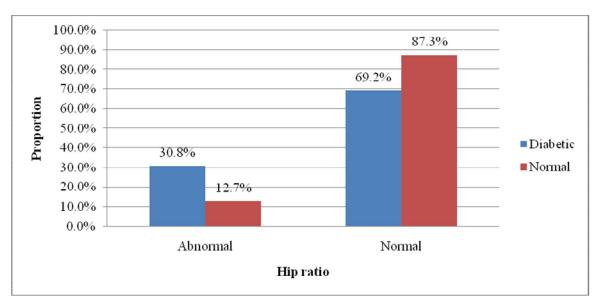
4. <u>WHR</u>

WHR	Overall	Diabetes		p value
	n=2061	Yes n=65	No n=1962	
Abnormal	269(13.1)	20(30.8)	249(12.7)	< 0.001
Normal	1758 (85.2)	45(69.2)	1713(87.3)	< 0.001
Missing	34(1.6)			

Table 21: Assessment of waist to hip ratio in the diabetes population

The level of obesity using the WHR measurement further reduced in the diabetes population to 30.8% and this was statistically significant when compared to the non diabetic population with a p value of <0.001.





12.2.7 Diabetes and hypertension

Table 22: Distribution of hypertension in the diabetes population

BP classification	Frequency n=66 (%)
Normal	7(10.6)
Pre-hypertension	29(43.9)
Stage 1 hypertension	17(25.8)
Stage 2 hypertension	13(19.7)

*Includes patients who were known to be hypertensive and were on anti-hypertensive medication.

Hypertension was classified according to the JNC VII⁴⁶ classification and 45.5% of the individuals in the diabetes group were also found to be hypertensive. A significant proportion of 43.9% were also in the pre-hypertension group with only 10.6% having a normal blood pressure. Of those who were found to be hypertensive, 40% were newly diagnosed hypertensive.

12.3 BIOCHEMICAL RESULTS IN THE DIABETES POPULATION

12.3.1 Diabetes and fasting lipid profile.

Of the 66 diabetic subjects, fasting blood specimens were obtained from 50 individuals giving us a 15% specimen loss. Ten of the subjects were not available for the specimen collection. Six specimens were rejected during laboratory analysis due to haemolysis (3) and spillage leading to inadequate sample volume (3).

Table 23:	Fasting	lipid	profile in	n subjects	with diabetes

Cholesterol	Frequency	
Total cholesterol <5.17mmo/l	48(96)	
Total cholesterol >5.18mmol/l	2(4)	
Triglycerides <1.7mmol/l Triglycerides >1.7mmol/l	44(88) 6(12)	
HDL >1.05mmol/l	3(6)	
HDL<1.05mmol/l	47(94	
LDL <2.6mmol/l LDL >2.7mmol/l	33(66) 17(34	

It was noted that 96% of the individuals with diabetes had a total cholesterol <5.17 mmol/l with 88% with triglycerides <1.7 mmol/l, 66% with an LDL <2.6 mmol/l and 94% having a low HDL of <1.05 mmol/l.

14.3.2 Diabetes and hsCRP

In addition to the 10 individuals who did not come back to have a fasting specimen withdrawal, 22 other specimens were withdrawn as the hsCRP was markedly elevated at >5mmol/l.This gave us a 48% result loss.

Table 24: Categories of hsCRP in the study subjects with diabet	es

Variable	Frequency (%) n=34		
Hs CRP			
<2 low risk	5 (14.7)		
2-3 moderate risk	3 (8.8)		
>3 high risk	26 (76.4)		
No results 32			

Of the individuals whose specimens were analyzed, it was noted that 76.4% had an elevated hsCRP in the high risk category and only 14.7% had a low risk category.

13. DISCUSSION

This was a cross-sectional cluster sampling study conducted at the Kibera slums with a good response rate of 97%. The overall population was relatively young with 53.9% being in the young age group of 25-44 years. Of the 936 households that were visited, 80% of the household heads were missing and whom were assumed to be probably 30years of age or older. Only 5.5% of the population were 50 years or older.

The population was representative to the population described in the 2009^{51} census which showed that the Kenyan population is made up of 48.8% of males and 51.2% females. The 2009 census also found that 67.7% of the Kenyans are residing in the urban regions while only 32.3% are in the rural regions. In Nairobi, the male to female ratio was found to be 1.04:1 in the 2009 census which compares to our study population with a male to female ratio of 1.1:1

The prevalence of diabetes of 3.2% (95%CI 2.5-4.1%) was noted to be high in this relatively young population. The worldwide prevalence of diabetes for all age-groups was estimated to be 2.8% in 2000 and projected to be 4.4% in 2030 by WHO Global Burden of Disease Study⁵². The data included adults who were 20 years or older with a diagnosis of diabetes based on an OGTT except in Tanzania who used a fasting blood sugar. WHO also documented that diabetes prevalence was similar in men and women but slightly higher in men less than 60 years and in women of older age groups. In the developing countries, majority of the patients were 45-64 years. In our study we used a FBS and not an OGTT which was used in the WHO study which could have given us a lower prevalence. Our study also showed no statistical significance in the proportion of the affected men and women similar to the WHO Global Burden of Disease Study⁵².

Mathenge et al ²¹ conducted a cross-sectional population based survey in Nakuru in individuals who were 50 years or older and found a prevalence of 6.6% using a random blood sugar. Our study included individuals who were 18 years or older and required a fasting blood sugar to make the diagnosis. When prevalence was calculated in those who were 40 years or older in the Kibera region, the prevalence increased and was 9.2% (6.9-

12.1). This shows that the prevalence of diabetes is higher in this urban low income setting. If the household heads that were not included in this study were included, the prevalence would have probably being even higher than was found.

A prevalence survey of various atherosclerosis risk factors carried out on rural – urban migrants settled in urban slums in a large metropolitan city in northern India, found a high prevalence of diabetes and obesity in the residents.³²

The overall prevalence was 10.3% (95% CI 7.8 - 13.2). Based on BMI, obesity was more prevalent in females (15.6%; 95% CI 10.7 - 22.3) than in males (13.3%; 95% CI 8.5 - 19.5). High WHR was observed in 9.4% (95% CI 5.4 - 14.8) of males and 51.1% (95% CI 45.8 - 56.3) of the females. These findings were similar to our study which also showed a high prevalence of 3.2% in a relatively young population. The mean age in the Indian population was 34.3 years SD (12.1) compared to our study which had a mean age of 33.4 years and FBS was used to make a diagnosis of diabetes in both studies. Our lower prevalence could be attributed to a possibility of genetics as a higher prevalence has been found in the Indian population and possibly a higher level of physical activity.

Connolly et al³¹ from the UK records that type 2 diabetes is inversely related to socioeconomic strata. In this study, the prevalence of diabetes in the least deprived quintile was 13.4 per thousand persons (95% CI 11.44 – 15.36), compared to 17.22 (95% CI 13.84 - 17.11) in the most deprived.

It was noted that 53% of those diagnosed with diabetes were newly diagnosed which is in keeping with studies⁹ that show that half of those with diabetes are not diagnosed until when complications occur. Of those who were already known to have diabetes, it was also noted that they had a low level of knowledge on the associated cardiovascular risk factors and the various lifestyle modifications that were necessary.

There was a high prevalence of overweight and obesity in the overall population and in the diabetes population. This is in keeping with studies which report that obesity is a risk factor for diabetes development and this suggests that the prevalence might probably increase in the future and preventive measures need to be instituted.

There was a high level of physical activity in both the overall population and the diabetic population and this might explain the lower prevalence as compared to other studies like Christensen et al (2006)²⁰ who found a prevalence of 10.7% in the urban areas using an OGTT. The high level of physical activity might also be responsible for the high proportion of normal total cholesterols, triglycerides and LDL. However, a large proportion was found to have low HDL which might have been secondary to dietary habits that were not studied.

C.F Otieno et al at Kenyatta National Hospital found elevated levels of total cholesterol and triglycerides requiring therapeutic intervention in type 2 diabetic patients with no obvious chronic complications.⁵³ Our population was different because it was from the community with more than half the patients being previously undiagnosed with type 2 diabetes unlike the former hospital population which was more selective and probably presented with other co-morbidities.

There was a high prevalence of hypertension in the diabetes population. This is important as this population is at a higher risk of cardiovascular outcomes. The INTERHEART²² study reported diabetes and hypertension to be the risk factors with the strongest relationship to AMI in the African sample. In the African group, participants who had one or more of the risk factors of current/former smoking, history of diabetes and hypertension had an odds ratio of 17.4 and a population attributable risk (PAR) of 64.5% compared to the overall INTERHEART study group with an OR of 13 and a PAR of 57.7%.

Due to cost of biomedical care and medications, traditional and faith healers often offer more accessible and affordable services. Additionally some healers offer a "cure" for diabetes or hypertension, which gives the patient the hope of eliminating any future burden related to his or her condition. For example, a study among traditional healers in the northern province of South Africa indicates that traditional and faith healers prescribe cures for diabetes patients, as opposed to treatment or management, and in fact, believe that diabetes can be reversed or cured ⁵⁴. It was further reported that many community health workers believe in traditional medicines and home-brewed beer as the best treatment for hypertension and that people who receive medical treatment become sicker and their health deteriorates rapidly. These healing practices are a representation of cultural beliefs, which influence health behaviors and serve as a framework for interpreting disease conditions. In our study, it was noted that 12.5% of the diabetics were on herbal medication for their diabetes

Highly sensitive C reactive protein is used as a cardiovascular risk stratifier. The hsCRP was performed only on the diabetic population. Prospective data from the Women's Health Study (WHS) ⁵⁵ demonstrated the relationship of hsCRP and development of Type 2 Diabetes having a four fold increase in risk after adjusting for BMI and other risk factors. High levels of hsCRP can be induced by smoking, alcohol, obesity and seasonal variations

Majority of the patients had an elevated hsCRP in the high risk category. The hsCRP was not performed on the non diabetic population, thus comparisons were not done. Studies have also not being performed on our normal population to assess the normal reference ranges and it is thus difficult to explain this finding. The elevated hsCRP could have been secondary to inflammation from the diabetes, obesity, smoking and alcohol use.

CONCLUSION

The prevalence of diabetes mellitus in the Kibera slum was 3.2 % with an increase in prevalence in the older age groups. The prevalence of smoking and alcohol in the overall study population and the diabetic population was also high. There was a high level of physical activity in both the study population and the diabetic population. More than half of the diabetics' were newly diagnosed with a low level of awareness in the study population. Majority of the diabetic patients had a desirable total cholesterol levels with normal triglycerides and LDL levels but with low HDL levels. A high proportion of the diabetic subjects were also found to have hsCRP levels in the high risk and medium risk categories.

LIMITATIONS

We excluded individuals less than 18 years and pregnant mothers which probably gave us a lower prevalence due to exclusion of some type 1 diabetics and gestational diabetes. The dietary practices of this community were not studied and this is important as it might have explained why the prevalence is high despite a high level of physical activity.

RECOMMENDATIONS

The recommendations suggested after this study are the need to implement screening programs for NCD's and the health education of cardiovascular risk factors associated with inception of diabetes mellitus to enable early detection and preventive strategies. The dietary practices should also be studied as these might be associated with the high prevalence of overweight, obesity and diabetes that was noted despite a high level of physical activity. An OGTT would be advised for those individuals who were found to have a RBS>11.1 but a FBS <7.0 to rule out diabetes mellitus or IGT which is associated with cardiovascular morbidity and mortality.

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15. APPENDICES

APPENDIX 1: CONSENT EXPLANATION

I am Dr Rosemary Wanjiru, a Post-graduate student in the department of Medicine University of Nairobi.

I am conducting a study at Kibera division of Nairobi.

I would like to introduce you to a study I am conducting entitled:

"PREVALENCE OF DIABETES AND OTHER ASSOCIATED CARDIOVASCULAR RISK FACTORS IN KIBERA"

What is the study about?

The study is about getting to know the number of people with diabetes in the community and also the other associated cardiovascular risk factors like hypertension, lipid abnormalities, obesity, smoking and alcohol consumption.

What does the study involve?

The study involves taking history from you and filling a questionnaire. I will examine you which will include taking your weight, height, waist circumference and blood pressure. It also involves taking about 5mls of your blood sample for measurement of lipid profile, blood glucose, high sensitivity C- reactive Protein. All information you shall provide shall be kept confidential.

Are there any dangers involved?

Apart from the slight pain of taking your blood, there are no dangers involved.

Will I benefit from the study?

Yes. After analyzing this study results I will be able to make new suggestions on the prevalence of diabetes in our urban area and this can be used in planning for prevention and treatment of Diabetes and associated risk factors. If I diagnose you with diabetes, I will counsel you on the lifestyle modifications required and refer you to the nearest health facility for further management.

Can I withdraw from the study?

You are free to withdraw from the study and this shall not affect your care in any way and you will not be discriminated in any way.

Thank you for your co-operation.

Dr. Rosemary Wanjiru (Student Investigator)

Tel 0722384012

APPENDIX 2: CONSENT FORM.

Study number.....

Sex.....

Name:..... Age.....

I, the above named, has been requested to take part in a study concerning "Prevalence of diabetes and other cardiovascular risks in urban Kibera of Nairobi Kenya".

This will involve taking a full history, general examination including blood pressure, waist circumference measurements, weight, and height. This study will also involve taking sample of my blood (5mls) for assessment of Lipid profile, Blood sugar and High sensitive CRP. I will also be required to respond to a study questionnaire. The blood results and any information provided shall be confidential.

This will put me at no risk.

I understand that I am free to either agree or refuse to participate in the study And this shall not interfere with my medical care.

Having agreed on the above I voluntarily agree to participate in the study.

Signed..... Date.....

Witnessed by.....Date.....

APPENDIX 3: INVESTIGATOR'S STATEMENT.

I the investigator have educated the research participant on the purpose and implications of this study.

Signed...... Date.....

APPENDIX 4: LABORATORY METHODS

CHOLESTEROL

Enzymatic assay of serum or plasma for quantification of cholesterol was performed on the OLYMPUS AU 400 machine.

Cholesterol esters are enzymatically hydrolyzed to cholesterol and free fatty acids. Free cholesterol is oxidized to Cholesterol-4-ene-one and hydrogen peroxide. Hydrogen peroxide combines with Hydroxybenzoic acid.

Patients were required to have fasted for at least 8 hours

TRIGLYCIRIDES

Enzymatic Hydroxylation of the Triglycerides by the lipases to Free fatty acids and glycerol.

Methodology is by Glycerol Phosphate Oxidase on OLYMPUS AU 400.

Reference Range:

Normal	-	<1.7mmol/l (<150mg/dl)
Borderline hi	gh -	1.7-2.25mmo/l (150-199mg/dl)
High	-	2.26- 5-64 (200 - 499mg/dl)
Very High	-	<5.65mmo/l (>500mg/dl)

LOW DENSITY LIPOPROTEIN (LDL)

LDL	was	calculated	using	the	Friedewald-Fredrickson	formula.
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REFERENCE RANGE

Desirable	3.4mmo/l (<= 130mg/dl)
Borderline Risk	3.4-4.1mmo/l (130-160mg/dl)
High Risk	>4-1mmol/l (>160mg/dl)

HIGH DENSITY LIPOPROTEIN

Direct homogenous Test for determination of HDL cholesterol by enzymatic colorimetric Test at 37 C using OLYMPUS AU400 analyzer.

Assay combines two specific tests: in the first step chylomicrons, VLDL, and LDL cholesterol are specifically eliminated and destroyed by enzymatic reactions. In the second step remaining Cholesterol from the HDL fraction is determined by well established specific enzymatic surfactants for HDL.

HIGH SENSITIVITY C- REACTIVE PROTEIN

Determination of the CRP in human serum or plasma on Photometric systems by turbidimetric immunoassay done at 37 C. Preferred specimen 1 ml of serum. Overnight fasting preferred but not required. Minimum 0.5ml of serum Collection TECHNIQUE – Red topped bottles Chemistry Analyzer- OLYMPUS AU400.

Reference Range Adults- <5mg/dl

RANDOM BLOOD SUGAR AND FASTING BLOOD SUGAR

An Accucheck glucometer ^R was used.

APPENDIX 5: BUDGET

1. RESEARCH ASSISTANTS	60,000
2. LABORATORY AND EQUIPMENT	
RBS	60,000(2000 patients)
LIPID PROFILE	50,000(66 patients)
HsCRP	25,000(66 patients)
VACUTAINERS AND NEEDLES	10,000
WEIGHING SCALES	30,000
SPYGNONANOMETERS	30,000
	22.000
3. PRINTING AND STATIONARY	25,000
4. DATA ENTRY AND ANALYSIS	50,000
5. TRANSPORT COSTS	5,000
TOTAL	<u>345,000</u>