SCREENING OF GESTATIONAL DIABETES IN KENYATTA NATIONAL HOSPITAL

INVESTIGATOR:

Dr Bosire Alex Nyakundi

MBChB

Registrar, Obstetrics and Gynaecology, University of Nairobi

SUPERVISORS:

Professor Joseph Karanja

MBChB, M.MED Obs/Gyn, Associate Professor of Obstetrics and Gynaecology, University of Nairobi, Consultant Obstetrician and Gynaecologist Kenyatta National Hospital,

Dr. Zahida Qureshi

MBChB, M.MED Obs/Gyn, Senior Lecturer, University of Nairobi, Consultant Obstetrician and Gynaecologist, Kenyatta National Hospital

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Section 1.1 Declaration

This dissertation is my original work and has not been presented elsewhere. This research project is my original work and has not been presented for academic award in any other university. References to work done by others have been clearly indicated.

Signature…….. Date 30/12/11

Dr. Bosire Alex Nyakundi

Approval:

This dissertation has been submitted with our approval as University supervisors:

Signature…….. Date 03/01/2012

Prof. Joseph Karanja

Signature…….. Date 31/12/11…

Dr. Zahida Qureshi

CERTIFICATE OF AUTHENTICITY

This is to certify that this dissertation is the original work of Dr Bosire Alex Nyakundi; Mmed student registration number H58/71876/08 in Obstetrics and Gynecology department, University of Nairobi (2008-2012). The research was carried out in the department of Obstetrics and Gynecology, School of Medicine, College of Health Sciences. It has not been presented in any other University for award of a degree.

1). Signed: _____ Date: 26/01/2012

Professor Koigi Kamau.
Associate Professor of Obstetrics and Gynecology,
Consultant Obstetrician and Gynecologist,
Chairman: Department of Obstetrics/Gynecology
University of Nairobi.

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Section 1.4 Table of contents

Section 1.5 Abbreviations

ADA	-	American Diabetic Association
AIDS	-	Acquired Immuno Deficiency Syndrome
ANC	-	Ante-Natal Clinic
ATP	-	Adenosine Tri-Phosphate
BMI	-	Body Mass Index
BOH	-	Bad Obstetric History
C/S	-	Caesarean section
DM	-	Diabetes Mellitus
FBS	-	Fasting Blood Glucose
FFA	-	Free Fatty Acid
GCT	-	Glucose Challenge Test
HAPO	-	Hyperglycemia and Adverse pregnancy outcome study
HIV	-	Human Immunodeficiency Virus
HPL	-	Human Placental Lactogen
IADPSG	-	International Association of Diabetes in Pregnancy Study Groups
IDF	-	International diabetic federation
KNH	-	Kenyatta National Hospital
NBU	-	New born unit
NDDG	-	National Diabetic Data Group
OGTT	-	Oral Glucose Tolerance Test
RBS	-	Random Blood Sugar
WHO	-	World Health Organization

Section 1.6 ABSTRACT

TITLE: SCREENING OF GESTATIONAL DIABETES IN KENYATTA NATIONAL HOSPITAL

Background: Gestational diabetes is a common medical condition complicating pregnancies worldwide with a global prevalence estimate of 4-14%. Despite this high prevalence, there is still lack of proper screening, diagnostic and management guidelines for this condition in spite of the attendant risks to both mother and her unborn baby. There is still a lot of discussion as to the best screening method and even who and when to screen for this condition.

Objectives: To determine the prevalence of glucose intolerance with screening using the 50g Glucose Challenge Test and of Gestational diabetes by use of the World Health Organization recommended 75g Oral Glucose Tolerance Test. Other objectives were to further determine the specificity, sensitivity, positive and negative predictive values of the risk factor screen using the Glucose Challenge Test as a gold standard and to establish correlation of the socio demographic risk factors to Glucose intolerance and Gestational Diabetes Mellitus.

Methods: This was a cross sectional descriptive study. The study was conducted in the antenatal clinic in Kenyatta National Hospital. All eligible and consenting patients were administered a standardized structured precoded questionnaire aimed at establishing risk factors for Gestational Diabetes Mellitus. These clients were then offered a 50g glucose load after which a blood glucose test was done. The clients who screened positive for glucose intolerance by the 50g Glucose Challenge Test were then requested to have repeat 75g glucose test which was used as the diagnostic gold standard for diagnosis of Gestational diabetes within 2 weeks after the initial test.

Results: From 371 participants, Using a cut off of 7.2mmol/l for the 50g glucose challenge test, 92 (24.8%) had positive glucose challenge tests and of these 43(11.6 %) were diagnosed as having gestational diabetes by use of the World Health Organization 75g oral glucose tolerance test. With a cut off of 7.8mmol/l for the 50g glucose challenge test then the glucose intolerant population is at 46(12.6%) and that of gestational diabetes is 33(8.9%). The risk factor screening was also noted to have a low sensitivity of 43.49% and specificity of 75.27% as compared to the 50 glucose challenge test screening tool. Factors associated with gestational diabetes were; family history of hypertension, education level, age > 25 yrs of age, presence of glycosuria.

Conclusion: prevalence of glucose intolerance was 24.8% while that of gestational diabetes was 11.6%. Universal screening with 50g glucose challenge test has good sensitivity and specificity as compared to risk factor screening. Significant associations with gestational diabetes were with age greater than 25 years, higher education levels, family history of blood pressure and history of glycosuria.

Recommendations: Considering the high prevalence noted in the study universal screening of glucose intolerance should be done in our setting by use of 50g glucose challenge test, as opposed to targeted screening. The cut off employed for the 50g glucose challenge test should be 7.8mmol/l. The timing of the testing should be between 24 -32 weeks. High risk women would benefit from World Health Organization 75g oral glucose tolerance test.

Section 2.1 Introduction

Gestational diabetes is a common medical condition in pregnancy. It is defined as any degree of glucose intolerance with onset or first recognition during pregnancy. World Health Organization (WHO) defines it as carbohydrate intolerance resulting in hyperglycaemia of variable severity with onset or first recognition during pregnancy [1,] and is the most common metabolic disorder of pregnancy. Its global prevalence is approximately 3%- 8% [2](1-14%). Its incidence has also been calculated at 17.8% by recent study [3]. Its prevalence is noted to be on the increase as are the cases of diabetes mellitus [4, 5.] This is due to the increase in obesity and other associated risk factors for diabetes [6] .Its prevalence is also bound to increase due to the introduction of newer screening and diagnostic criteria that were derived from the Hyperglycemia and Adverse Pregnancy Outcome (HAPO) study[3], as more women are likely to be diagnosed as having gestational diabetes (GDM). GDM is associated with increased morbidity and mortality in both mother and fetus/neonates. Its prevalence in sub Saharan Africa and even Kenya is unknown; this is due to lack of research in this field [7]. Most of the research and effort is made toward other disease conditions like HIV/AIDS and other communicable diseases. The overall prevalence rates in Kenya are not available but estimates of up to 7% prevalence of GDM in some African countries have been cited [8]. A study done by Githaiga in Kenyatta National hospital (KNH) in 1991 reported an incidence rate of 0.15% with ethnic variation [9]. A study in Nigeria documents prevalence of gestational diabetes at 5.4% [10] In Kenyatta national hospital, one study revealed prevalence of glucose intolerance of 36% and of GDM at 16.7%which is quite high though comparable to other studies done elsewhere [11-14]. This finding will likely contribute to inform screening procedures in this country [15]. In Kenyatta national hospital, in the year 2008, there were 55 documented cases of diabetes in pregnancy while in 2009 there were 41(0.23%) in the total antenatal mothers seen in this institution. This is likely to be a much underreported figure due to the poor screening and diagnosis of this condition.

Section 2.2 Literature review

Diabetes is a major disease condition affecting pregnancy. It is estimated that approximately 10% of pregnancies are affected by diabetes. Approximately 87.5% of pregnancies complicated by diabetes are estimated to be due to gestational diabetes (which may or may not resolve after pregnancy), 7.5% being due to type 1 diabetes and the remaining 5% being due to type 2 diabetes [16]. It is thought that gestational diabetes is a variant of type 2 diabetes.

Clinical importance of GDM is at three levels—1. The adverse consequences of poorly controlled GDM for the fetus and neonate. T his includes increased rates of still births, macrosomia, and respiratory distress. 2. The adverse consequences for the mother, especially the predisposition to type 2 DM in later life [18, 19], increased frequency of hypertension [20, 21] and operative delivery [23]. 3. The increased risk of type 2 DM in later life for the infant [17]. To the society as a whole there is the economic cost and the productivity of the family that is affected by this condition [24].

Pathophysiology

Normal glucose intolerance involves control of plasma glucose within a narrow range despite the varying levels of glucose coming in through the intestinal tract. This is due to balance between the glucose entering the cell and that leaving into extracellular tissues. Insulin facilitates this transfer and conversion of the glucose to glycogen through the action of glucokinase in the liver and hexokinase in other tissues [25].Some of the extra glucose is converted into triglycerides and free fatty acids and deposited in tissues. Glucose entry into cells is facilitated diffusion through Glucose transporters [26]. Insulin also inhibits lipolysis and proteolysis. In insulin deficiency or resistance these actions are impaired resulting in increased plasma glucose levels, lipolysis and proteolysis with subsequent accumulation of ketones and FFA's. There are several disorders of glucose intolerance characterized by elevated blood glucose levels beyond normal values. These are caused by insulin deficiency, receptor abnormality or post receptor abnormality resulting in reduced glucose entry into cells with subsequent stimulation of lipid and protein metabolism [27].Glucose metabolism disorders are classified depending on etiology and clinical presentation. They include Diabetes Mellitus :(type 1 and 2, gestational diabetes), impaired glucose tolerance and impaired fasting glycemia

The pathophysiology behind gestational diabetes is similar to type 2 diabetes. Like all forms of hyperglycemia, GDM is characterized by insulin levels that are insufficient to meet insulin demands. The causes of pancreatic β-cell dysfunction that lead to insulin insufficiency in GDM are not fully defined [27]. Three general categories have been identified: *1*) autoimmune β-cell dysfunction, *2*) highly penetrant genetic abnormalities that lead to impaired insulin secretion, and *3*) β-cell dysfunction that is associated with chronic insulin resistance. It has long been held that pregnancy-induced insulin resistance unmasks the onset of β-cell defects that underlie GDM. Evidence indicates that the defects are chronic rather than of acute onset. Although studies to date are limited in scope, they uniformly reveal a chronic β-cell defect that is present before and after pregnancy and accompanied by increasing blood glucose concentration[27,28] . This hypothesis suggests that when GDM is diagnosed, it includes some women with preexisting glucose intolerance that is revealed by routine glucose tolerance screening in pregnancy.

Approximately 90% of patients with GDM have a deficiency of insulin receptors prior to pregnancy or a marked increase in weight in the abdominal region. The other 10% have a deficient insulin production. There is also involvement of the placental hormones and especially human placental Lactogen (HPL)[22]. During the first trimester of normal pregnancy, HPL starts to increase giving an anabolic effect. HPL together with cortisol, estrogen, progesterone lower blood glucose, promote fat deposition and stimulate appetite. They also increase insulin production and secretion while increasing tissue sensitivity to insulin. The overall effect is lowering of fasting and postprandial glucose levels with increased adiposity. In the 2nd trimester, HPL stimulates lipolysis reduces hunger sensation and impair glucose uptake. These together with increased hepatic glucose production results in high fasting and postprandial glucose levels to facilitate transport across the placenta. The increase in free fatty acids and triglycerides further increases insulin resistance. Late in the third trimester, plateau in HPL with reduced glucose absorption reduces nutrient delivery across the placenta with resultant reduction in placental hormone production. Individuals predisposed to glucose intolerance have insufficient compensatory insulin production to counter the effects of the diabetogenic hormones. The persistently high glucose levels cross the placenta to stimulate fetal pancreatic islet cells causing hyperplasia with increased insulin production. This leads to delays in fetal organ maturation and promotes fat deposition in trunk and cardiac muscles and perinatal hypoglycaemia [22].

At cellular level, mechanisms of glucose intolerance include low levels of adiponectin, increased tumor necrosis factor alpha, Interleukin 6 and leptin mRNA in placental tissue which promote glucose intolerance. Abnormalities in the insulin receptor and signalling cascade, abnormal localization of the glucose transport protein Glucose transporter 4 as well as inherited mitochondrial dysfunction with subsequent reduction in adenosine tri-phosphate (ATP) production have been implicated[29].

Risk factors

It is estimated that 40-50% of GDM patients lack specific risk factors [17]. The documented risk factors include maternal race (increased prevalence in Hispanic and African American population) , obesity with body mass index >30, maternal weight of > 85 kgs , and older maternal age >25 yrs. Previous unexplained perinatal death, still birth or repeated abortions, previous congenital abnormality, history of fetal macrosomia(Previous baby >4kg), previous history of GDM . Other risk factors in the current pregnancy include fetal macrosomia, recurrent glycosuria (2 or more episodes of glycosuria on routine testing) , presence of polyhydramnios, multiple gestations, family history of diabetes. Use of these risk factors is shown to have low sensitivity for diagnosing GDM especially among primiparas, The 50g glucose challenge test (GCT) will provide a higher pick up rate for glucose intolerance than risk factors alone [30]

The 5th international conference on GDM held in 2007, further has classified the risk factors as low, average and high risk. Low risk includes member of an ethnic group with a low prevalence of gestational diabetes, no known diabetes in first-degree relatives, age less than 25 years, weight normal before pregnancy, no history of abnormal glucose metabolism, no history of poor obstetrical outcome. The consensus for screening for this group was that glucose screening was not required if a patient fulfilled all of these criteria. The next group is average risk that includes women of Hispanic, African, Native American, South or East Asian origins. For this group, screening is encouraged between 24 – 28 weeks. The last group is the high risk, i.e. women with marked obesity, strong family history of type 2 diabetes, prior gestational diabetes, or glycosuria. It was recommended that women in the high risk category should have blood glucose testing as soon as feasible. If gestational diabetes is not diagnosed, blood glucose testing should be repeated at 24–28 weeks or at any time a patient has symptoms or signs suggestive of hyperglycemia.

Effects on mother and fetus/child

The main effect of GDM to the foetus/neonates is macrosomia [3] which is defined as birth weights above 90th percentile of the population i.e. 4kg [7]. Except for the brain, most organs in the fetus are affected by the macrosomia. The perinatal focal point is avoidance of difficult delivery due to macrosomia, with concomitant birth trauma from shoulder dystocia. Macrosomia is compatible with the long-recognized association between fetal hyperinsulinemia resulting from maternal hyperglycemia, which in turn stimulates excessive somatic growth [31, 32]. Similarly, neonatal hyperinsulinemia may provoke hypoglycemia within minutes of birth. It has been reported that 4 percent of infants of women with gestational diabetes required intravenous glucose therapy to correct hypoglycaemia. The risk of major congenital abnormality in foetuses of diabetic mothers is 3-8 times that of the general population especially in patients with a fasting blood sugar of 6.1mmol/l or more while patients with a fasting sugar level greater than 5.8mmol/l are prone to still births and prematurity [33]. Other perinatal complications include preterm premature rupture of membranes, breech delivery and preterm birth[3].The neonates are predisposed to hypoglycaemia, respiratory distress syndrome, hypocalcaemia, polycythemia with resultant hyperbilirubinaemia and hypertrophic cardiomyopathy[2, 34]. There are also potential long-term consequences to the infant, such as development of obesity and diabetes during childhood and adolescence, impaired fine and gross motor functions and higher rates of inattention and/or hyperactivity [3, 35]. Early detection and management of glucose intolerance in women thus is associated with reduced rates of these complications to the infants[3].

Fifty percent of mother's who suffered from GDM are at an increased risk of suffering from overt diabetes mellitus 10 – 20 years later [18,19]. Published reports indicate a nearly linear increase in the cumulative incidence of diabetes during the first 10 years after pregnancy. The risk is similar among all ethnic groups with GDM [28].Women with gestational diabetes are also at risk for cardiovascular complications associated with abnormal serum lipids, hypertension, and abdominal obesity—the *metabolic syndrome* [36]. It is thus important to have an effective method of identifying diabetes mellitus in pregnanacy so as to reduce incidence of complication [37]. Randomized controlled trials in GDM suggest that rates of macrosomia, maternal weight gain, shoulder dystocia and hypertension in pregnancy can be reduced through glycemic control of women diagnosed at international association of diabetes in pregnancy study groups (IADPSG) thresholds [3, 16].

Controversies on GDM Screening and diagnosis

Universal Vs selective screening: Due to the lack of uniform diagnostic criteria for more than 40 years, there has been no global consensus about the appropriate screening/diagnostic test, whether it should be applied selectively or universally and about the diagnostic thresholds of each test [2], Different regions in the world use different screening methods with some choosing universal screening and others using selective screening by using risk factors to screen the women[13, 16, 17]. Examples of available screening tests include; WHO risk factor selection [1] more than one of following: age above 25 yrs, previous glucose intolerance, previous history of large-for-gestational-age infant, certain ethnic groups(Hispanics and Africans), raised fasting or random blood glucose. An alternative to this is American Diabetic Association (ADA) glucose challenge[39] Plasma venous glucose 1 hour after 50 g oral glucose ≥7.8 mmol/L. Another screening alternative is offered by the UK St Vincent Task Force [40] Random venous plasma glucose at 28 weeks' gestation >6 mmol/L fasting, >7 mmol/L within 2 hours after food. The WHO Fasting blood glucose is a cheap and less time consuming method although it has a low sensitivity[41, 42]. Other screening methods include use of presence of glycosuria, random blood sugar although these methods are proven to have poor specificity and sensitivity. Others are looking at serum fructosamine and HbA1 c, though these methods are being used primarily for research currently. The problem with selective screening is that use of risk factors as criteria may lead to missing out 40 – 50% of patients with GDM which is unacceptable [30] The ADA in its more recent position statement of 2010 suggests that all pregnant women should be screened for GDM between the 24th and 28th week of gestation, unless they are of low risk status [44]. Women of low risk are defined as those that fulfil all of the following characteristics: age below 25 years, normal pre-gestational weight, and member of an ethnic group with low prevalence of diabetes, no history of glucose intolerance and poor obstetrical outcome, and no known diabetes in first degree relatives.

One or two step screening approach: Two approaches are suggested for screening for GDM (at 24-28 weeks). In the two-step approach, women are initially screened by measuring plasma glucose 1 hour after 50 g glucose load; women with glucose concentration ≥7.2 or ≥7.8mmol/l(depending on the diagnostic sensitivity one wishes to achieve) undergo a 100 g Oral Glucose Tolerance Test (OGTT) on a separate day. In the one-step approach, the 100 g OGTT is performed directly without any initial screening. In both occasions, the diagnosis of GDM is established by the Carpenter and Coustan criteria. This places abnormal values of

fasting blood glucose greater than 5.3mmol/l, 1 hour postprandial glucose level of greater than 10.0mmol/dl, a 2 hour glucose level of 8.6 mmol/l and 3 hour level of 7.8 mmol/l. At least 2 abnormal values are required to make a diagnosis of GDM. The 50g GCT is a test that many institutions are looking at as a screening method for GDM. It is currently the most utilized screening test for GDM. In 1973 the GCT was proposed as a screening test for the early detection of GDM [51]. It is an easier test to administer and is cheaper to perform and studies show that it has a high sensitivity and specificity compared to the other screening methods employed. According to published work the GCT has a sensitivity of about 78% and a specificity of 83% [53]. Plasma glucose measurement is done 1 hour after oral administration of 50 g glucose. The patient does not need to have fasted prior to this [52]; however, accuracy of the screening test is increased if the patient is in a fasting state. The second (1985) and third (1991) International Workshop Conferences on Gestational Diabetes Mellitus suggested that this test should be performed between weeks 24 and 28 of gestation; and, if the result was positive, the patient should then undergo a glucose tolerance test (OGTT) with 100 g oral glucose and plasma glucose measurements at baseline and 1, 2 and 3 hours post-load. This was considered to provide the definitive diagnosis of GDM. The values can be analysed using the ADA criteria and the patients with glucose intolerance picked and the more diagnostic 75g OGTT is then done on the patient if they have abnormal blood glucose levels. Thus the 50g GCT would be able to effectively screen for GDM especially in a low to medium prevalence setting after which the clients noted to have elevated blood glucose levels would undergo further glucose tolerance testing. This is important in a resource limited setting in that it would be able to pick up this condition in pregnancy and this would definitely minimise the risk of complications both in the pregnancy and after the pregnancy thus minimizing health care cost in both the short and long run [54]. It has also been shown that it is cost effective to perform universal screening in populations that are high risk and prevalence and equally poor resource setting as it is less expensive and more healthcare savings are made for a health system that has been stretched to the limit [55]. Combined with risk factor screening a few more cases of GDM would be found [56].

Cut off blood sugar levels: With the 50g glucose challenge test, a value of 7.8 mmol/L or higher identifies 80 percent of all women with gestational diabetes. Using a value of 7.2 mmol/L or higher increases the yield to more than 90 percent; however, 20 to 25 percent of women have positive test results compared with 14 to 18 percent when the 7.8mmol/l or greater cut-off value is used. The day-to-day reproducibility of the 50-g screening test has

also been tested [57]. Although 90 percent of normal results were reproducible the next day, only 83 percent of abnormal test results were reproducible. Problems have also been reported for the glucose challenge test: there are many false-positives and sensitivity is only 86% at best. There is still no consensus on the best threshold at which one can state clearly the presence of glucose intolerance, by use of the 50g GCT [39, 46]. The glucose levels cut off that is regarded to be more effective for screening of gestational diabetes is the 7.2mmol/l, from a study done in black patients [50]

WHO 75g OGTT vs 100g OGTT: The American Council of Obstetricians and Gynecologists (ACOG) also suggest screening of all women except for those of low risk status. It supports the use of the 100 g OGTT and application of Carpenter and Coustan criteria. The World Health Organization (WHO) recommends using the 75 g two-hour OGTT and either of the diagnostic thresholds of 7.0mmol/l and 7.8mmol/l for fasting and 2-hour glucose concentrations, respectively [1]. Finally, according to the 2009 International Diabetes Federation (IDF) recommendations, women who are at high risk (history of previous GDM) should undergo an OGTT as soon as possible[43]. For all other women the OGTT should be performed between the 24th and 28th week of gestation. In both cases, a one-step procedure with the 75 g OGTT is preferred. Due to the confusion brought about by the different criteria for screening and diagnosis of GDM, WHO, ADA [44], IDF[43]and other organizations are expected to consider adopting the recently proposed IADPSG diagnostic criteria [3].All pregnancies are to be screened between 24 and 28 weeks' gestation. Extending, the screening time beyond 28 weeks is associated with increased detection rates but little improvement in neonatal outcomes [45].

There is no consensus on the type of diagnostic criteria to be used for diagnosis of GDM [17]. Commonly used diagnostic method however is the 75g glucose load [47]. This is what is used over in Europe and indeed is the recommended WHO standard. Centres in US, follow the ADA guidelines and use the 100g OGTT for diagnosis of GDM. Following the recommendations of the HAPO study, the 100g test will not be frequently used because it was found to be more expensive to carry out, not reproducible in 25 percent of women when repeated 1 week after the initial tests [48,49] and does not improve neonatal outcome criteria as compared to the 75g OGTT [63]. The recent 6th international conference on Gestational Diabetes in Pasadena, USA that was sponsored by the IADPSG, to review results of the HAPO study came up with recommendations that are meant to bring some consistency in screening and diagnosis of GDM worldwide. They recommend that with a liberal suspicion

for diabetes, appropriate patients should be evaluated at the time of their first visit. If the fasting plasma sugar is > 7.0mmo/l, a random glucose is > 11.1 mmol/l, or the HbA1C exceed 6.5%, then the patient will be considered to be an overt diabetic. But if the fasting plasma sugars are 5.1-7.0 mmol/l, these patients should be considered to have GDM. All other clients should empirically have a 75 g 2-hour GTT at 24-28 weeks using the thresholds given in table 2.

It is ironic that the criteria for excluding women from screening are so hard to discern that universal screening will probably be used as a matter of practical convenience.
The HAPO study is now recommending that patients should be screened on basis of the risk factors and compared to the local established prevalence then followed by a 75g OGTT for diagnosis [63]. This has been done so as to standardize the process of screening and diagnosis of GDM and also the management options.

Cost effectiveness of the test is also emphasized and it has been shown that it saves on costs that would have been incurred in management of the long term complications of gestational diabetes and diabetes mellitus, although long term studies are yet to be fully carried out on its real impact[55, 17]. The one step method for screening and diagnosing GDM has also been compared with the two step method and it has been found that the two step method is more cost effective and reduces the burden to both the patient and the health care system and at the same time provide diagnostic accuracy [13]

Glucose testing kits

Use of portable glucometers is not recommended for diagnosis due to inaccuracies, technical errors, sensitivity to climatic changes and cost, [58], although if carried out by a trained technician in presence of good quality control, they offer reasonable quantitative results [59, 60]. A haemocue© glucometer that is quite modern and well calibrated to measure both venous and capillary blood glucose levels was used. Advocacy on its use is also because it is a frequently used machine in clinical practice and its ease of use, accessibility and accuracy especially with the newer machines compares quite well to the laboratory enzymatic method of measuring blood glucose using the hexokinase calorimeters. Some authors have recommended the use of finger-stick capillary blood samples and reflectance meters, which have the advantages of being inexpensive and convenient to use in the office setting [60,61]. When the precision of various reflectance meters was investigated and compared with standard laboratory technology, the reflectance meters had coefficients of variation between

7% and 10%, whereas the standard laboratory technology ranged from 1%-2% [62]. According to the latter study, if reflectance meters were used for screening and full glucose tolerance testing was desired for 95% of subjects with screening results 7.2mmol/l (by standard laboratory technology), then 45% of subjects would require glucose tolerance testing, compared with only 16% when standard laboratory methods were used. It would be possible to apply the findings of this study to most office and hospital settings as these institutions commonly utilize the glucometer.

Section 2.3 Conceptual framework

Section 2.3.1 Narrative

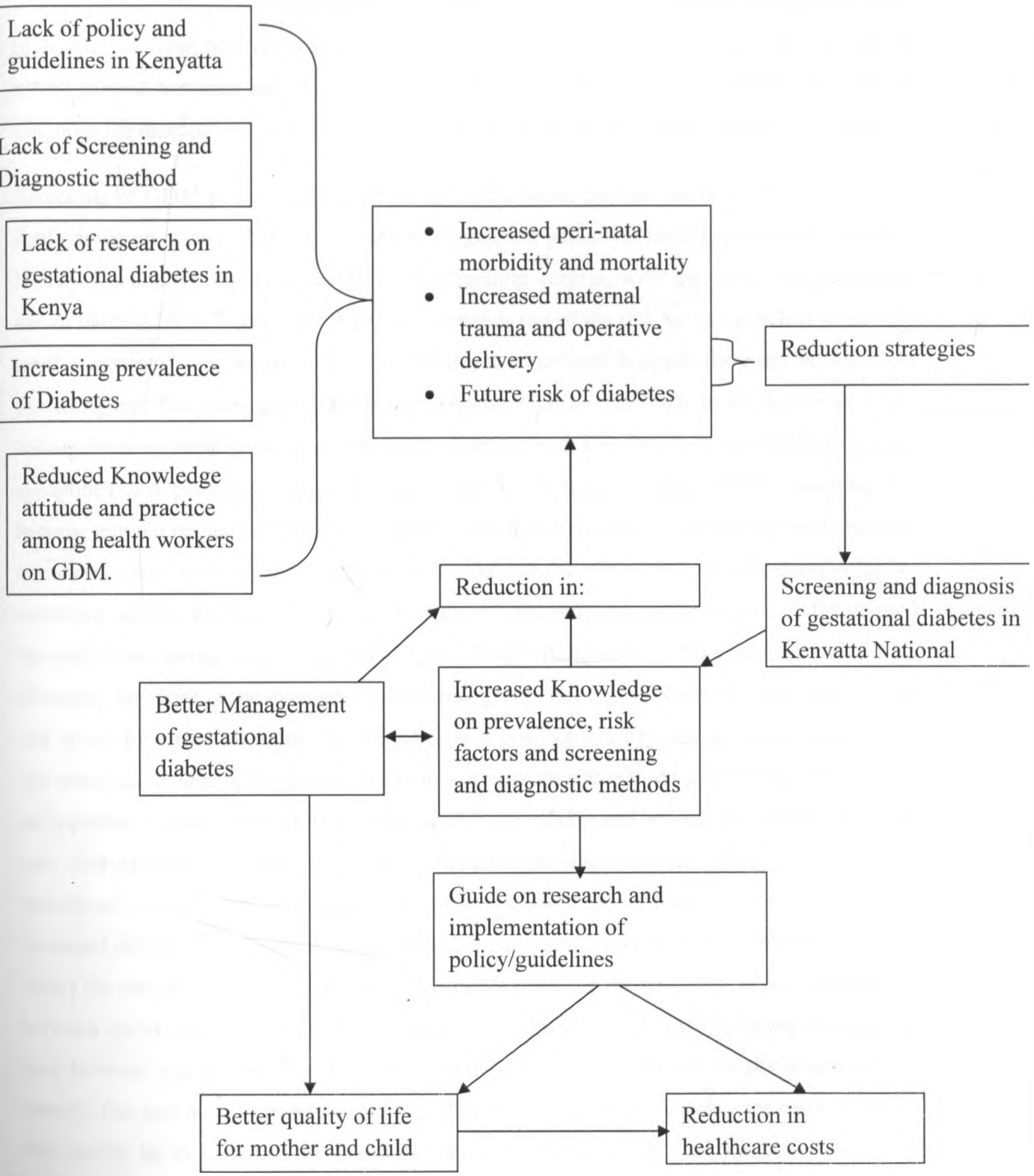
Gestational diabetes is a largely ignored medical condition in our country despite it being classified as one of the most common medical complication noted in pregnancy.

Screening and diagnosis of gestational diabetes is currently controversial as many different institutions have their own methods and cut offs for screening and diagnosis for this condition. This non uniformity of methods currently reduces our ability to front a common policy in management of this condition and use of research is thus confounded.

Outcome of early diagnosis of gestational diabetes is better antenatal and perinatal care of mother and child, with reduction in maternal, fetal, neonatal and long term complications and therefore improved quality of life. It is also an entry point in prevention of development of diabetes mellitus and even early diagnosis and treatment of suspected cases. Thus the long term economic and health benefit milked from this screening is huge, less money would be spent on screening and prevention than is now being spent on managing diabetes and its attendant complications.

In our country there is currently little in terms of research on gestational diabetes Thought has gone into this and thus use of the WHO method of diagnosis of gestational diabetes in Kenyatta National Hospital is being explored as a way to standardize diagnosis of this condition in this country.

Section 2.3.2 Diagrammatic Conceptual frame work



Section 2.4 Justification

Screening of a disease is recommended if the disease is common and clinically important and if a simple screening test exists that will identify the majority of diseased individuals without high rates of false positive and false negative results. Intervention for the disorder should affect clinical outcome and also be cost effective. Thus the purpose of screening is not to diagnose the disease but to identify those at risk to whom the diagnostic test may be offered.

Screening of GDM poses a unique challenge in the sense that the medical society are yet to settle down on criteria that can be used to diagnose a patient as having gestational diabetes. Different school of thoughts use different screening criteria, with the ADA recommending use of the 50g GCT [44] while the WHO recommends use of the risk factors to select those who need screening [1]. In Kenya and even in Kenyatta National hospital there are no clear cut screening and diagnosis guidelines established for GDM. This leads to confusion as to the management of these patients and this percolates through this health system leading to poor guidelines and policies concerning this condition. It is no wonder GDM screening has become a much neglected medical condition in this country despite it being the most common metabolic medical disorder in pregnancy. In addition the issue of universal versus selective screening still arises based on the fact that the 5th international conference on GDM divided the risk factors into groups i.e. low, average and high risk groups [34]. They recommend routine screening for those in the average and high risk group. Patients in Kenya fall into the average risk group by virtue of being African. Thus is it prudent to carry out universal screening in this population? Due to the prevalence then is it also advisable to do a screening test for such an important condition that is of good accuracy – specificity and sensitivity, while at the same way cost effective in time and money, reproducible and reliable? What is seen in this institution is actually more of outcomes of poor diabetic control with macrosomic infants, increased still births and operative deliveries. It has been shown that most antenatal mothers attend the antenatal clinic in Kenyatta National Hospital for the first time in second trimester between 26-30 weeks and using this information it would be convenient to tailor or screening time between this periods [64]. The glucose challenge test cut off used for the study was 7.2 mmol/l, this was done to ensure maximum detection of any glucose intolerant cases, it would also enable us to compare the incidence between 7.2mmol/l and 7.8 mmol/l. It was also documented that 2.6% of the clinic attendees had macrosomic babies >4kg in weight. In 2009, there were 17485 visit attendants in the KNH antenatal clinic, 27.6% of whom were new and 0.234% were having a level of glucose intolerance. There were also 11066 deliveries

in the hospital over this same period, 3.479% of which had birthweights more than 4kg. There was a mean of 3 antenatal visits in the mothers who delivered macrosomic infants. With this information it is clear that there is a lack of good screening and diagnostic criteria for gestational diabetes in the hospital. Even in private practice, obstetricians screen for GDM mostly by using risk factors. It has been shown that 22.7% of obstetricians in Nairobi screen all patients for GDM [65]. Seventy five percent of practitioners screen by use of specific risk factors, 2.3% use glucose challenge test. 50% use obsolete methods like urinalysis and random blood sugar to screen. This is quite a low uptake considering the outcome of poor hyperglycaemic control in pregnancy. It is quite established that not all patients with GDM have risk factors. Screening for GDM is also not part of routine antenatal profile carried out in most institutions, despite it being a good entry point from where health professionals would be able to assess future risk of developing diabetes mellitus in this population. There is also no standardization of this process. ADA recommends that for high risk populations, it is advisable to perform a 100g OGTT for diagnosis of the disease [44]. This is not applicable in this setting due to the costs involved in doing this to the patients and the associated lower specificity and sensitivity

With this is mind then the need to do a study on the usefulness of the Glucose challenge test as a screening test for GDM was noted. The study population were attendees in this hospital. Women with HIV but not on treatment will be included in the study but those on anti-retrovirals were not as these drugs may cause glucose intolerance and thus may give skewed results. It would enable the health care providers to review the use of risk factors for screening of GDM with use of the gold standard for screening of GDM i.e. 50g GCT. This information would let the providers know as to whether one should still rely on risk factors to screen for GDM or does one change to the alternative method. This study was done at the KNH antenatal clinic where many clients come and get seen by doctors and are offered close as to good follow up that they may get in the country. There has not been a study in Kenya that also deals with the question of the GDM prevalence using the Glucose Challenge test as a screening method. The closest study was looking at glucose intolerance amongst antenatal mothers in this hospital and this came up with a prevalence of glucose intolerance of approximately 36% and of gestational diabetes of 16.7% using the American based 100gm OGTT diagnostic test after using the ADA risk factor screening test[14]. The study used the WHO diagnostic protocols for GDM as this is what is recommended by the ministry of Health and indeed used in most of the world.

Section 3.1 Research questions

- What is the usefulness of the 50g GCT in screening for Gestational diabetes among pregnant women being cared in the KNH antenatal clinic?

Section 3.2 Objectives

Broad objective

- To determine the prevalence of Gestational diabetes among women being cared for at KNH antenatal clinic.

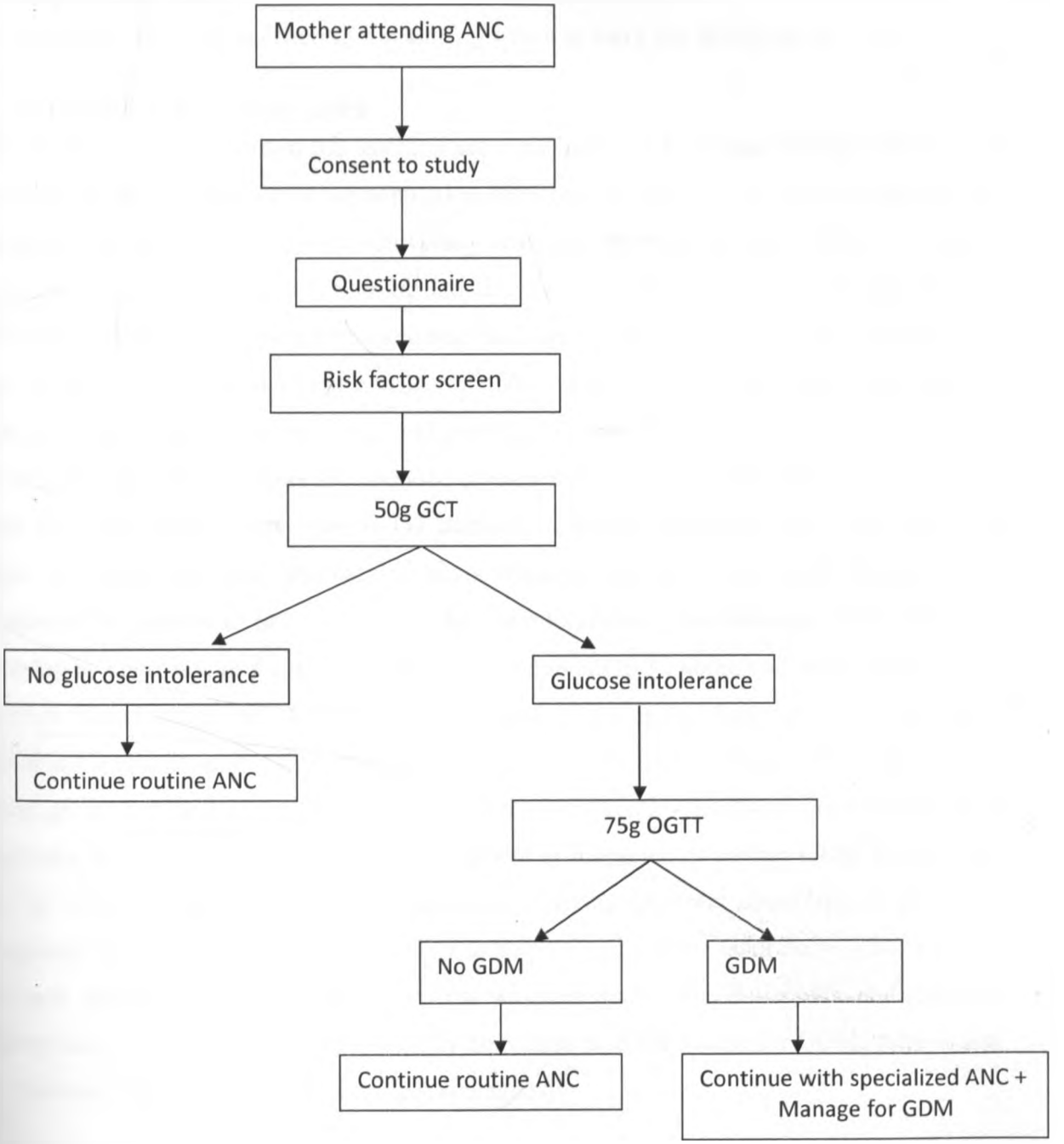
Specific Objectives

- To determine the prevalence of glucose intolerance screened by the GCT among pregnant women cared for at KNH antenatal clinic
- To establish correlation of the socio demographic risk factors to Glucose intolerance and GDM.
- To determine the specificity, sensitivity positive and negative predictive values of the risk factor screen using the GCT as a gold standard.

Section 4.1 Study methodology

Section 4.2.1 Study design

The study was a clinical based cross sectional descriptive study as it sought to establish prevalence of GDM in the antenatal population attending KNH. Eligible patients were enrolled in to the study and a pre-tested precoded standardized structured questionnaire was administered. This questionnaire was used to look for risk factors with patients' socio - demographic characteristics. The patients were then screened by use the 50g GCT. Those patients with glucose intolerance then underwent a 75g OGTT to diagnose GDM as shown in the algorithm below.



Section 4.2.2 Outcome measures

The primary outcome measure was to determine prevalence of glucose intolerance using GCT as a screening method in this setup. This would show us the usefulness of the GCT in the screening in GDM in this setting. With the screening method and subsequent 75g OGTT, the study would also be able to establish the prevalence of GDM in this subset population.

Secondary outcome measures include establishing the correlation of socio-demographic characteristics and risk factors to glucose intolerance and GDM. The study would also be able to provide data as to the specificity, sensitivity, positive and negative predictive value of risk factor screen using the GCT as gold standard. This would help us establish whether use of risk factors is useful as criteria for choosing whom to carry out screening for GDM.

Section 4.2.3 Study sites

This study was carried out in the teaching antenatal clinic in Kenyatta National referral and teaching Hospital. KNH serves the population within and around the city and it is the national referral hospital. It serves as the university teaching hospital for the College of Health Sciences of the University of Nairobi and the Kenya Medical Training College. Several medical specialties are hosted here including the Department of Obstetrics and gynecology is one of them. The obstetrics unit consists of three antenatal/postnatal wards, labor ward, a maternity operating theatre, antenatal and post natal clinics. The institution gets to see a total of 402 new antenatal mothers are attended to each month and together with revisits a grand total of 17485 visits .There were 10737 deliveries over the period of 2009. This trend has been increasing with more antenatal mothers attending the clinic. The clinic mostly serves women in the middle to low income socio-economic groups. The antenatal clinic runs from Monday to Thursday, in the morning hours between 8 am to 12 noon, and in the afternoon on Fridays. The clients in the clinic are first registered then triages, where their vitals are taken, urinalysis is also done. For first time clients an antenatal profile involving VDRL, HIV status, blood group and the haemoglobin. The clients are then seen by the doctors in the clinic both registrars and consultant obstetricians. If a patient is suspected of having GDM in the clinic i.e. by virtue of a previous macrosomic baby, or having recurrent abortions, glycosuria in pregnancy, she is usually sent for an OGTT to be performed in the laboratory. After this they are then reviewed with the results, a process which in itself takes 3-4 weeks, and managed appropriately. In this set up, there is usually no routine screening done for GDM, there is also no standard criteria for GDM screening and diagnosis.

Section 4.2.4 Study population

The study population were the pregnant women being cared for at KNH antenatal clinic at gestation between 24-36 weeks between 15th Dec 2010 to 30th March 2011.

I. Inclusion criteria

- All pregnant women in gestational age between 24-36 weeks.
- Consenting participants..
- Reproductive age between 18 -49 years.

II. Exclusion criteria

- Known diabetic clients.
- Patient on drug/ medication likely to alter glucose metabolism e.g. Sulfonyl ureas, protease inhibitors,stavudine, steroids and thiazide diuretics, beta agonist.
- Very sick patients

Section 4.2.5 Sample size calculation and sampling procedure

4.2.5.a Sample size determination

The prevalence of gestational diabetes is estimated to be 14% among pregnant women in developing countries [2]. Assuming this prevalence a minimum sample size of 185 participants will be required to describe the occurrence of glucose intolerance with a ± 5% margin of error. The formula illustrated below will be used to determine the sample size [68].

$$n = \frac{Z^2_{\alpha/2}\,\sigma(1-\sigma)}{\Delta^2}$$

$Z_{\alpha/2}$ is the standard normal deviation at the 95% confidence level for a two tailed test (1.96)

σ is the estimated prevalence of gestational diabetes (14%)

Δ Error margin

$$= \frac{(1.96)^2\ 0.167(1-0.167)}{(0.05)^2}$$

$$= \frac{3.842 * 0.5345}{0.0025}$$

= 214 participants

An effort was made to get a further 20% to minimize on participants that may have been lost over the study period and therefore a further 157 patients were added over the study period bringing the total study participants to 371.

4.2.5.b Sampling procedure

Convenience sampling was done in that the each patient who fit into the inclusion criteria and consent was considered. The clients were first counselled about the study, the ones who fit the study criteria were recruited and informed consent obtained.

Section 4.2.6 Data management methods

Research assistants comprised of two nursing officers who routinely saw patients at the antenatal clinic, one medical officer and three clinical officers who would help in administering the questionnaires and running the tests. The research assistants were trained on eligibility criteria, consent and enrolment issues, data collection and entry the standard operating procedure and as on data collection methods, sampling of patients, confidential and ethical issues that were to be addressed when performing the study.

A biostatistician was consulted for data entry and analysis. All the information was subsequently entered to the computer and analyzed using Statistical Package for Social Sciences (SPSS 12) for Windows. Data analysis involved use of the precoded data and descriptive statistics like cross tabulation, frequency ranges and mean. Chi square was used for proportions and p value for statistical significance.

4.2.6.a ***Tools:*** Data for this study was collected using precoded questionnaires. These were used to assess for presence of risk factors and symptoms e.g. obstetric and gynaecology history, past history of gestational diabetes or family history of diabetes and hypertension were elicited. The socio demographic data of these clients were also collected by use of the questionnaire. At the end of the questionnaires the results of the client stratification of risk i.e. placing patients in either high, average and low risk as classified by 5th international conference for GDM.(appendix 2E), GCT using the 7.2mmol/l cut off (appendix 2 H) and results of the 75g OGTT using the WHO protocol (appendix 2 I) were documented.

4.2.6.b ***Equipment:*** There was use blood glucose testing kits – to measure the blood glucose levels at time of testing. This included a glucometer with cuvettes. The glucometer was a quality machine that was well calibrated to read both venous and capillary

glucose levels and that will undergo regular quality control. Glucose load, both 75g and 50 g glucose load solution prepared by the clinical chemistry laboratory. There would also be sterile swabs and lancets, syringes and hypodermic needles that were used to collect capillary blood.

The questionnaire and laboratory request forms were pre-tested two weeks prior to the study to ensure that these were applicable and have ease of use.

4.2.6.c ***Procedure***: After obtaining consent to carry out the study, from the Ethics review Board of Kenyatta National hospital. The nursing officer would sensitize the clients about the study at the antenatal clinic. The clients, who consented, were recruited into the study, filled in the questionnaire. Their current weight was attained from measurement using a calibrated weighing scale. The weighing scale used was the weighted health-o meter, which has been shown to have consistency in results over time. The clients were then given a 50g glucose load in 150ml of water which they would ingest within 5- 10 minutes. They were then sent to the lab for blood glucose measurement which was done an hour after ingestion of the glucose load. This was by use of finger prick testing .The clients were then given their results. Those who were not glucose intolerant as based on the values of the 50g GCT continued with the clinic. Those clients who were glucose intolerant were advised on a subsequent visit that involved the client starving from midnight then to come to the clinic early in the morning between 8 – 9 am, from where they were tested for fasting blood glucose before being given a 75g load in 250ml of water, to be taken over 5-10 minutes and then subsequently sent to the lab for capillary blood glucose measurement after 1 hour and 2 hours. Patients were advised to restrict physical activity over the duration of the test. Opportunity was taken then to educate the study participants on nutrition and management of glucose intolerance in pregnancy using a qualified diabetic nurse. The clients were then given their results after the stipulated 2 hours. Those who were not diagnosed as having GDM were released to continue with the antenatal clinic whilst those who were GDM were given a consultation by the principal investigator and referred to care as per the KNH protocol. The data was entered into a data base once collected. Double entry and logical syntaxes were performed to reduce errors of data entry. All patient paper records were kept in locked cabinets and electronic records within the clinic. The database was password protected, and only data entry personnel, clinicians overseeing the database, and researchers involved on this project

had access. Some of the information in the questionnaire was derived from the clients ANC card for example the weight at 20-24 weeks gestation of the current pregnancy.

4.2.6.d ***Laboratory method***: After arrival in the laboratory, capillary blood for the clients undergoing the GCT and OGTT was withdrawn by use of finger prick method and the blood sugars were measured using the glucometer/reflectance meters. The results were entered into a data base by double entry method. The clients were then given a copy of their results which they took back to the ANC. Those who were diagnosed as having gestational diabetes were given additional consultation by the principal investigator to take to the relevant specialist clinic for follow up. The patients, who had the OGTT, were then allowed to have their snacks after the test. Patients who experienced vomiting due to gastric irritation caused by the glucose load were advised to be seen subsequently and a glucose load mixed with chilled water was given.

4.2.6.e ***Test interpretation***

Table 1. Fifth International Workshop–Conference on Gestational Diabetes: Recommended Risk Assessment for Detecting Gestational Diabetes
GDM risk assessment: Should be ascertained at the first prenatal visit
Low Risk – if all of these are present no need for routine screening
Member of an ethnic group with a low prevalence of gestational diabetes
No known diabetes in first-degree relatives
Age less than 25 years
Weight normal before pregnancy
No history of abnormal glucose metabolism
No history of poor obstetrical outcome Weight Normal at birth
Average Risk – screen at 24 – 28 weeks. Screen with either o Two-step procedure: 50 g glucose challenge test (GCT) followed by a diagnostic oral glucose tolerance test in those meeting the threshold value in the GCT. o One-step procedure: Diagnostic oral glucose tolerance test performed on all subjects. Include Women of Hispanic, African, Native American, South or East Asian origins
High risk – **screen as soon as feasible if one or more are present** Women with marked obesity, strong family history of type 2 diabetes, prior gestational diabetes, or glycosuria, delivery of large-for-gestational-age infant
If GDM is not diagnosed blood glucose should be repeated at 24 -28 weeks and anytime patient exhibits signs and symptoms of hyperglycemia

Those who are greater than those of low risk of GDM, including those above not found to have diabetes early in pregnancy are typically classified as average risk. Thus this will include > 25 years old, Abnormal weight before pregnancy, High risk ethnic/racial heritage (Hispanic American, Native American, Asian American, African American, or Pacific Islander) Family history of either type 1 or type 2 diabetes in first-degree relatives, History of abnormal glucose tolerance, History of poor obstetric outcome, History of polyhydramnios, History of congenital malformations, History of fetal macrosomia (infant weight > 4000 grams.

The 50 g glucose challenge test results would be interpreted according to the following criteria:

- Plasma venous glucose 1 hour after 50 g oral glucose ≥7.2 mmol/L

The 75 g OGTT would be interpreted according to the WHO criteria:

- WHO criteria require one abnormal plasma glucose level from the range given in the table 2. Individuals with hyperglycemia indicative of diabetes outside of pregnancy were excluded. The HAPO Diagnostic criterion requires one abnormal plasma glucose level from the range given in the table 2.

Table 2—*Diagnosis of GDM with a 75-g oral glucose load*

diagnostic values	HAPO mmol/l	WHO mmol/l
Fasting	5.1	5.3
1 -h	10	-
2 -h	8.5	7.8

Section 4.2.7 Data Analysis and Presentation of Results

Patient names and identifiers were removed from all patient records before analysis

4.2.7.a Descriptive analysis

This involves summaries of the clients' socio-demographic data, obstetric and gynaecological history that were collected and presented in forms of means, medians, ranges and standard deviation and presented in forms of tables, graphs and charts. Data was collected in the numerical and logical precoded form in order to ease interpretation of the data collected and to minimize errors in data entry.

Section 4.3 Research ethics

Section 4.3.1 Participants

4.3.1.a ***Ethical approval***

Consent for the study was sought from the ethics review board in Kenyatta national hospital/University of Nairobi, and was approved before the study was undertaken - Section 8.3 appendix 3.

4.3.1.b Risk to Subjects

There was minimal risk to subjects who underwent this study. This is because the subjects ingested a glucose load that was clean and not contaminated. The side effects found to be present include gastric irritation, delayed emptying, and gastrointestinal osmotic imbalance, leading to nausea and vomiting although these side effects were in very few patients. This was minimized by giving chilled water with glucose. The clients would have a total of 5 ml of blood drawn from their veins (equivalent to one teaspoon) for carrying out the test. These tests are recommended by WHO and routinely done in KNH for patients suspected to have GDM. Infection prevention and safety was observed while collecting blood samples. There was use of clean sterile methods of collecting the blood samples and injection safety and body tissue rules when it comes to disposing of the sharps and blood collected from the subjects. The research assistants were trained on this. The study referred all patients' diagnosed with GDM for care as per KNH protocol. The study did not offer treatment to this patients'.

Confidentiality was maintained by the research assistants who were trained by the Principal Investigator on ethical issues before the start of the study. The research assistants were medical practitioners and this reduced risk and increased the confidentiality. All patient paper records were kept in locked cabinets and electronic records within the database were password protected, and only data entry personnel, clinicians overseeing the database, and researchers involved on this project had access hence confidentiality was maintained . In addition, patient names and identifiers were removed from all data tables and records prior to data analysis. Written informed consent was given in English for literate patients. Informed verbal consent was taken in English and Kiswahili for illiterate patients. Informed consent was obtained from patients before start of the study. Patients were free to leave the study any

time they felt uncomfortable without any penalties or loss of any benefits to which they were entitled to them in the hospital.

Section 4.3.2 Benefits of the study

The mothers who participated in the study without any cost inducement and the study was sponsored by the principle investigator. The clinic attendance was not altered with to favor the study. Direct benefit for the client was in the fact that they were able to get to know their blood glucose levels and if diagnosis of GDM was made then the client was managed in accordance to KNH protocols. This decreased morbidity and mortality associated to diabetes in pregnancy. The overall benefit of this study was the expected improvement in patient care. This resulted in benefits to the community of science as a whole, and may have a broader positive effect on health care for antenatal mothers, locally and across the African continent.

Patients were given their lab results and counseled and appropriately referred and managed as per KNH protocols.

This study availed important data that will serve to give the way forward as to methods for screening for GDM in this setting. It also served as pilot data for future studies. The data from the study is also useful in developing guidelines to this and other settings similar to that of KNH.

Section 4.4 Limitations of the study

Presence of clients who dropped off from the study/did not return for OGTT, either because they did not put proper phone numbers or having adverse pregnancy outcomes e.g preterm delivery therefore were not included in the overall analysis.

Problematic fasting: Patients needed to fast for the 75gm OGTT, this may not be easy to achieve as some patients may forget and come having eaten something. To counter this, Patient phone numbers were taken for follow up prior to day of testing to remind them to fast before the test. Subsequently the principal investigator called the selected participants a week prior and remind them on their return visit. A text messages sent the day before was included to encourage patient return. There were those clients who would request to have the test done on their return clinic days and these requests were accommodated. After the study patients were allowed to eat whatever they had brought from home. However some patients may have taken some food and did not disclose this information on day of the OGTT

Section 5 Results

The study period extended from 15th Dec 2010 to 30th March 2011. Table 3 summarizes the patient and demographic characteristics of the participants.

Table 3: Socio-demographic characteristics (n=371)

Patient characteristics	**Mean(SD)**
Age in years	28.6 (4.8)
Blood pressure	
Systolic	108.9 (13.2)
Diastolic	70.9(9.8)
Body mass index	27.76 (4.74)
Demographic characteristics	**n (%)**
Marital status	
Single	40 (10.8)
Married	329(88.7)
Separated	2(0.5)
Current residence	
Rural formal	7 (1.9)
Urban – High income	5(1.3)
Urban Middle income	187(50.4)
Urban Low income	165(44.5)
Urban Informal	7(1.9)
Education level	
Lower Primary	5(1.3)
Upper Primary	53(14.3)
Secondary	152(41)
Tertiary	160(43.1)
None	1(0.3)
Employment status	
Self employed	154(41.5)
Formal Employment	117(31.5)
Unemployed	100(27)

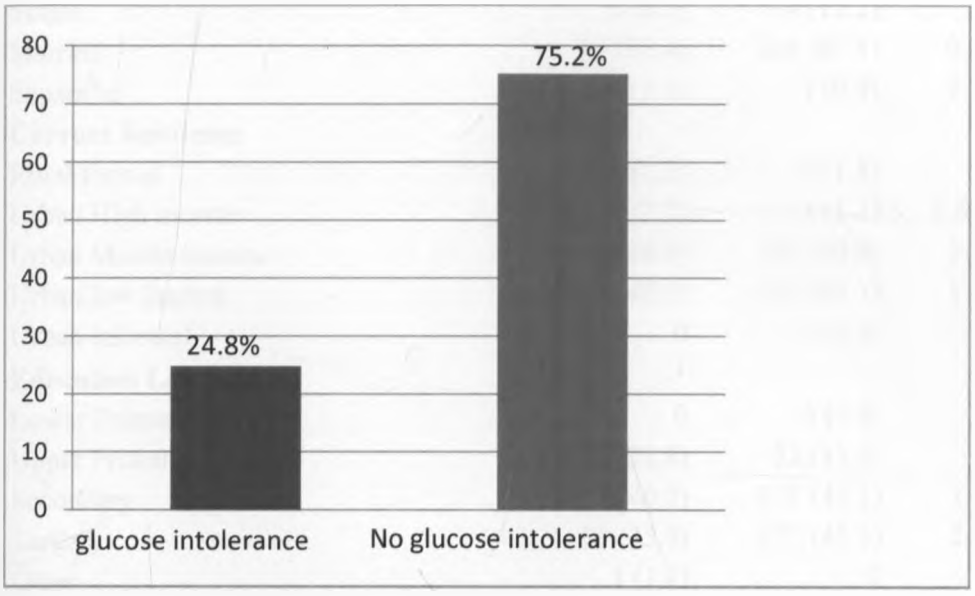
Monthly income	
<6000 Ksh/month	41(11.1)
6,000- 15,000 Ksh/month	139(37.5)
15,001- 30,000 Ksh/month	134(36.1)
>30,000 Ksh/month	57(15.4)

A total of three hundred and seventy one participants (n= 371) were recruited into this study, all of who underwent the 50g glucose challenge test. The median age of the participants was 28 years. Majority of the patients were above the age of twenty five years (73.6%). 73.6% of patients had income of between Ksh 6000-30000.

Section 5.1 Prevalence of glucose intolerance

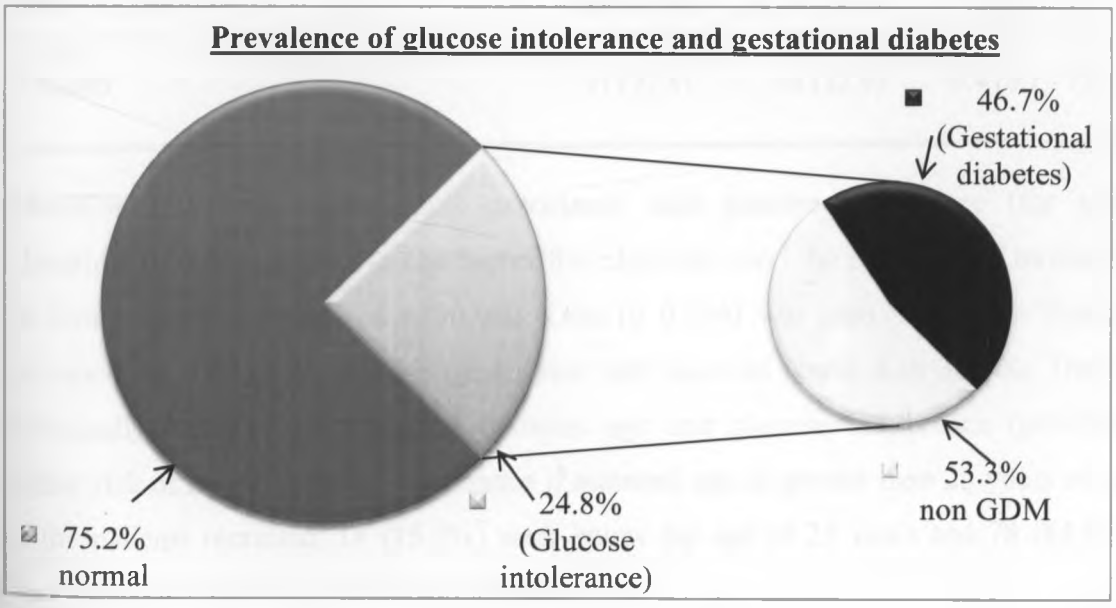
The prevalence of glucose intolerance with the glucose challenge test cut off >7.2mmol/l is estimated at 24.8% (95% CI; 20.7% to 29.4% n=92) as illustrated in figure 1.

Figure 1: Distribution of glucose intolerance using the 7.2mmol/l cut off (n=371)



This level of 24.8% is by use of 7.2mmol/l cut off for the 50g glucose challenge test. Use of 7.8mmol/l cut off reduces the prevalence to 12.4%.

Figure 2: Prevalence of glucose intolerance and gestational diabetes with use of 7.2mmol/l cutoff



1 in 4 patients in study had glucose intolerance, 46.7% of them being gestational diabetics.

Table 4: Association between demographic characteristics and glucose intolerance

Baseline Characteristics	Glucose Intolerance, n(%)	Normal, n(%)	OR (95% CI)	P-value
Age (in Years)				
25 years and below	14 (15.2)	84 (30.1)	Ref.	***0.005***
Above 25 years	78 (84.8)	195 (69.9)	1.5 (0.2 - 8.7)	
Marital Status				
Single	6 (6.5)	34 (12.2)	Ref.	-
Married	85 (92.4)	244 (87.5)	0.5 (0.2 - 1.3)	0.191
Separated	1 (1.1)	1 (0.4)	0.2 (0.0 - 7.6)	0.309
Current Residence				
Rural formal	2 (2.2)	5 (1.8)	Ref.	
Urban High income	2 (2.2)	3 (1.1)	0.6 (0.0 - 11.8)	1
Urban Middle income	45 (48.9)	142 (50.9)	1.3 (0.2 - 7.7)	0.677
Urban low income	43 (46.7)	122 (43.7)	1.1 (0.2 - 6.9)	1
Urban informal	0	7 (2.5)	-	
Education Level				
Lower Primary	0	5 (1.8)	-	
Upper Primary	21 (22.8)	32 (11.5)	Ref.	
Secondary	37 (40.2)	115 (41.2)	2.0 (1.0 - 4.2)	***0.034***
Tertiary	33 (35.9)	127 (45.5)	2.5 (1.2 - 5.2)	***0.01***
Other	1 (1.1)	0		
Employment Status				
Self employed	46 (50.0)	108 (38.7)	Ref.	
Formal Employment	25 (27.2)	92 (32.9)	1.6 (0.9 - 2.9)	0.151
Unemployed	21 (22.8)	79 (28.3)	1.6 (0.9 - 3.0)	0.151
Monthly Income				
<6000	7 (7.6)	34 (12.2)	Ref.	
6000 - 15, 000	29 (31.5)	110 (39.4)	0.8 (0.3 - 2.1)	0.756
15,001 - 30,000	35 (38.0)	99 (35.5)	0.6 (0.2 - 1.5)	0.328
>30,000	21 (22.8)	36 (12.9)	0.4 (0.1 - 1.0)	**0.034**

Education level was significantly associated with glucose intolerance (for secondary education, 0.034,tertiary 0.01).The higher the education level the more risk of having glucose intolerance. I ncome level of > 30,000 Kshs (p 0.034) was also significant finding with increased risk of having glucose intolerance with incomes above Ksh 30,000. There was a statistically significant association between age and glucose intolerance (p=0.005).With higher risk of having glucose intolerance if maternal age is greater than 25 years of age. Out of the patients recruited, 14 (15.2%) were below the age of 25 years and 78 (84.8%) were above 25 years and had glucose intolerance.

Table 5: **Association between obstetric and gynecological history and glucose intolerance.**

	Glucose Intolerance			
Obstetric Characteristic	**Glucose Intolerance, n(%)**	**Normal, n(%)**	**OR (95% CI)**	**P-value**
Gestation at Miscarriage (weeks)				
6 to 12	14 (51.9)	36 (64.3)	Ref.	-
13 to 28	13 (48.1)	20 (35.7)	0.6 (0.2 - 1.5)	0.278
None	65	222		
History of Congenital Abnormalities				
Yes	3 (3.8)	1 (0.6)	Ref.	
No	75 (96.3)	167 (99.4)	6.7 (0.6 – 67.3)	0.061
History of Delivery of babies > 4 kgs				
Yes	10 (13.3)	10 (6.2)	Ref.	
No	65 (86.7)	152 (93.8)	2.3 (0.9 - 5.9)	0.065
History of CS				
Yes	25 (33.3)	52 (31.1)	Ref.	-
No	50 (66.7)	115 (68.9)	1.1 (0.6 - 1.9)	0.735
Indication for Previous CS				
Big baby	3 (13.0)	5 (9.8)	Ref.	-
Failed induction	3 (13.0)	9 (17.6)	1.8 (0.2 - 19.1)	0.642
Prolonged labour	5 (21.8)	13 (25.5)	1.6 (0.2 - 12.7)	0.667
Fetal distress	3 (13.0)	13 (25.5)	2.6 (0.3 - 26.3)	0.362
other	9 (39.1)	11 (21.6)	0.7 (0.1 - 5.2)	1
Indication for admission to NBU				
RDS	3 (37.5)	9 (39.1)	Ref.	-
Prematurity	1 (12.5)	5 (21.8)	1.7 (0.1 - 54.5)	1
Jaundice	1 (12.5)	6 (26.1)	2.0 (0.1 - 63.8)	1
Other	3 (37.5)	3 (13.0)	0.3 (0.0 - 3.9)	0.344
Occurrence of elevated blood pressure				
Yes	22 (23.9)	33 (11.8)		
No	70 (76.1)	246 (88.2)	2.3 (1.3 - 4.3)	***0.005***
Presence of glycosuria				
Yes	2 (2.2)	1 (0.4)		
No	90 (97.8)	278(99.6)	6.2 (0.7 – 68.9)	0.092
Problem with Conceiving				
Yes	10 (10.9)	22 (7.9)		
No	82 (89.1)	257 (92.1)	1.4 (0.6 - 3.1)	0.377

Majority of miscarriages occurred in first trimester. There was no association between those who delivered infants greater than 4 kg, history of delivering infants congenital anomalies and those with a history of glycosuria although these are high risk factors in development of gestational diabetes. Finding of occurrence of elevated blood pressure (p value 0.005) were associated with increased risk of glucose intolerance.

Table 6: **Family association and risk stratification with glucose intolerance and gestational diabetes**

Family association of 1st degree relatives	Glucose Intolerance				Gestational diabetes		
	Intolerance n(%)	Normal, n(%)	OR (95% CI)	P-value	Positive n(%)	OR (95% CI)	P-value
With DM							
Yes	18 (19.6)	60 (21.5)	Ref.	-	32 (74.4)	Ref.	-
No	74 (80.4)	219 (78.5)	0.9 (0.5 -1.6)	0.692	11 (25.6)	1.1 (0.5 - 2.3)	0.734
With High Bp							
Yes	32 (34.8)	66 (23.7)	Ref.	-	2 (4.7)	Ref.	-
No	60 (65.2)	212 (76.3)	1.7 (1.0 - 2.9)	***0.037***	41 (95.3)	7.9 (1.1 - 57.9)	***0.016***

There was a significant association between diagnosis with glucose intolerance and first degree relatives with hypertension (p=0.0375). Participants who had relatives with hypertension were 71% more likely to be diagnosed with glucose intolerance that those with relatives who did not have hypertension; OR = 1.713, 95% CI (0.90 to 2.93). No significant association found between first degree relatives with diabetes in both 50g challenge test and gestational diabetes.

Glucose intolerance test and risk category

Table 7: Cross tabulation of Risk factor and Glucose intolerance (n=371)

		Glucose intolerance		
		Positive	Negative	Total
Risk factor	High risk	40(43.5%)	69(24.7%)	109(29.4%)
	Average risk	52(56.5%)	210(75.3%)	262(70.6%)
Total		92	279	371

The glucose challenge test was positive in 40 patients 36.7 % in the high risk category. Two hundred and ten patients who tested negative for glucose challenge test were in the average risk category (75.3%, 95% CI; 69.9% to 80%) as illustrated in table 7.

It is assumed that the women in the average risk group are seen as negative for glucose intolerance using the risk classification

Sensitivity = 40/92 = 43.5%

positive predictive = 40/109 = 36.70

Specificity = 210/279 = 75.3%

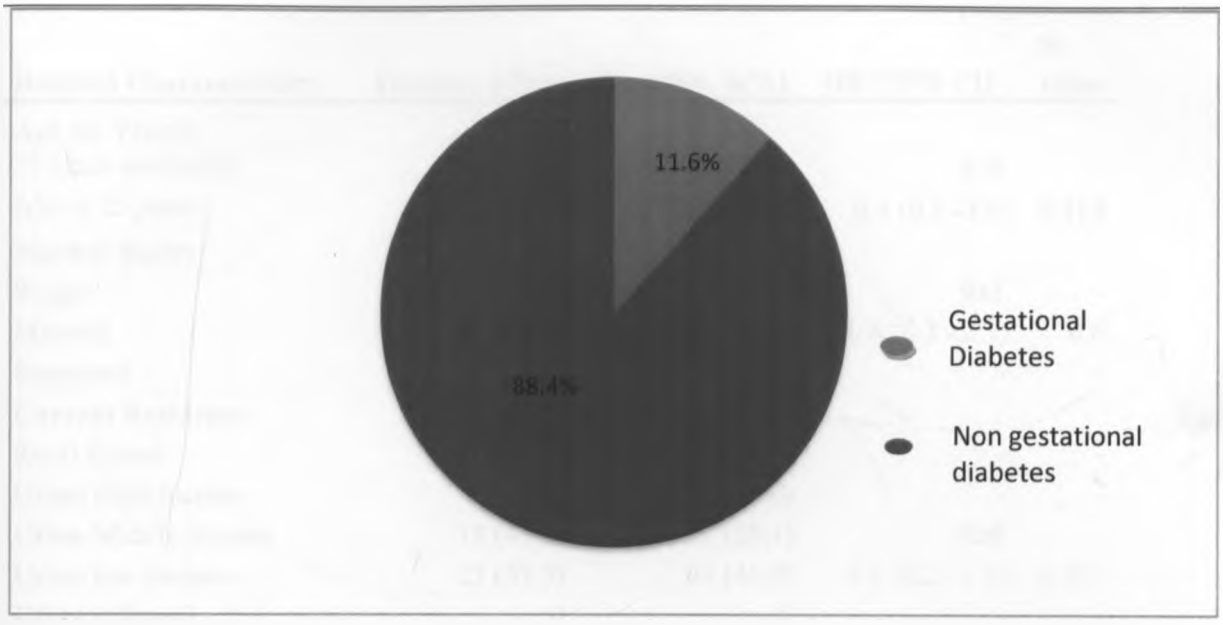
negative predictive = 210/262 = 80.15

Therefore as above, it is clear that the risk factor screening has low sensitivity and specificity as compared to the 50 GCT and a very low positive predictive value hence not an appropriate method to screen for glucose intolerance in our population.

24 (22%) out of 109 patients with the high risk classification turned out to have gestational diabetes while 19(7.3%) out of 262 patients with average risk classification were positive for gestational diabetes. 40(36.7%) of the high risk group actually turned out to be positive for glucose challenge test and thus a higher percentage of those whom would be assumed to be at high risk of having gestational diabetes would actually not have intolerance. This percentage is also higher as compared to the average risk group, in whom only 52(5.7%) had glucose challenge test positive.

Section 5.2 Prevalence of gestational diabetes

Figure 4: Prevalence of GDM (n=92)



These were those with glucose challenge test cut off >7.2mmol/l and WHO GDM criteria

Table 9: Summary of laboratory findings

Above 7.2mmol/l	Positive n (%)	Negative n (%)
Glucose Intolerance	92 (24.8%)	279(75.2%)
Confirmed Gestational diabetes	43(11.6 %)	328(88.4%)
Above 7.8 mmol/l		
Glucose Intolerance	46(12.4%)	325(87.6%)
Confirmed Gestational diabetes	33(8.9%)	338(91.1%)

As shown in table 9, 92 participants (24.8%) were diagnosed to be glucose intolerant i.e. 1 in 4 participants in the study were actually glucose intolerant as screened by the 50g glucose challenge test and with a cut off of 7.2 mmol/l. ***However this changes if the 7.8 mmol/l cut off is used for the 50 g glucose challenge test i.e. glucose intolerance level of 12.4% and a prevalence of gestational diabetes of 8.9%.***Using the HAPO criteria, 30 of the participants had gestational diabetes, i.e. Prevalence of 8.1% of Gestational diabetes in the population

Table 10: **Association between Socio demographic characteristics and gestational diabetes.**

Baseline Characteristics	Positive, n(%)	Negative, n(%)	OR (95% CI)	P-value
Age (in Years)				
25 years and below	10 (10.9)	63 (22.6)	Ref.	-
Above 25 years	82 (89.1)	216 (77.4)	0.4 (0.2 -0.9)	**0.014**
Marital Status				
Single	3 (7.0)	37 (11.3)	Ref.	-
Married	40 (93.0)	289 (88.1)	0.6 (0.2 - 2.1)	0.6
Separated	0	2 (0.6)	-	-
Current Residence				
Rural formal	1 (2.3)	1 (2.0)	-	-
Urban High income	1 (2.3)	1 (2.0)	-	-
Urban Middle income	18 (41.9)	27 (55.1)	Ref.	-
Urban low income	23 (53.5)	20 (40.8)	0.5 (0.2 - 1.5)	0.292
Urban informal	0	0	-	-
Education Level				
Lower Primary	0	5 (1.5)	-	-
Upper Primary	12 (27.9)	41 (12.5)	Ref.	-
Secondary	16 (37.2)	136 (41.4)	2.5 (1.0 - 6.1)	***0.048***
Tertiary	15 (34.9)	145 (44.2)	2.8 (1.1 - 7.0)	***0.023***
Other	0	1 (0.3	-	-
Employment Status				
Self employed	17 (39.5)	137 (41.8)	Ref.	
Formal Employment	13 (30.2)	104 (31.7)	1.0 (0.4 - 2.3)	0.859
Unemployed	13 (30.2)	87 (26.5)	0.8 (0.4 - 1.9)	0.7
Monthly Income				
<6000	4 (9.3)	37 (11.2)	Ref.	
6000 - 15, 000	16 (37.2)	123 (37.5)	0.0 (0.2 - 2.9)	1
15,000 - 30,000	14 (32.6)	120 (36.6)	1.0 (0.3 - 3.4)	1
>30,000	9 (20.9)	48 (14.6)	0.6 (0.1 - 2.3)	0.571

Table 10, significant socio demographic findings were secondary (p value 0.04) and tertiary education (p value 0.023) were significant showing increased risk of diagnosis with gestational diabetes with improved educational status.

Table 11: **Association between obstetric and gynaecological characteristics and GDM**

Obstetric Characteristic	Gestational Diabetes: Positive, n(%)	Gestational Diabetes: Negative, n(%)	OR (95% CI)	P-value
Gestation at Miscarriage (in weeks)				
6 to 12	7 (70.0)	43 (58.9)	Ref.	-
13 to 28	3 (30.0)	30 (31.1)	1.6 (0.4 – 6.9)	0.501
History of Congenital Abnormalities				
Yes	1 (2.6)	3 (3.4)	Ref.	
No	37 (97.4)	205 (98.6)	1.9 (0.2 – 18.2)	0.598
History of Delivery of babies > 4 kgs				
Yes	5 (13.9)	15 (7.5)	Ref.	
No	31 (86.1)	186 (92.5)	2.0 (0.7 - 5.9)	0.201
History of C/S				
Yes	9 (25.0)	68 (33.0)	Ref.	-
No	27 (75.0)	138 (67.0)	0.7 (0.3 - 1.6)	0.341
Indication for Previous C/S				
Big baby	1 (12.5)	7 (10.6)	Ref.	-
Failed induction	0	12 (18.2)	-	-
Prolonged labour	2 (25.0)	16 (24.2)	1.1 (0.0 - 21.5)	1
Fetal distress	0	16 (24.2)	-	-
other	5 (62.5)	15 (22.7)	0.1 (0.0 - 2.2)	0.152
Indication for admission to NBU				
RDS	2 (40.0)	10 (38.5)	Ref.	-
Prematurity	1 (20.0)	5 (19.2)	1.0 (0.0 - 36.1)	1
Jaundice	0	7 (26.9)	-	-
Other	2 (40.0)	4 (15.4)	0.4 (0.0 - 6.2)	0.569
Occurrence of elevated blood pressure				
Yes	14 (32.6)	84 (25.7)		
No	29 (67.4)	243 (74.3)	1.4 (0.7 - 2.8)	0.337
Presence of glycosuria				
Yes	2 (4.7)	1 (0.6)		
No	41 (95.3)	327 (99.4)	16.0 (1.4 –179.8)	***0.003***
Problem with Conceiving				
Yes	5 (11.6)	27 (8.2)		
No	38 (88.4)	301 (91.8)	1.5 (0.5 - 4.0)	0.456
Risk				
Average	20(46.5)	242(73.8)		
High	23(53.5)	86(26.2)	0.3(0.2-0.6)	***<0.001***

In table 11, glycosuria was found to be significant (p 0.003) indicating that presence of glycosuria is associated with increased risk of GDM. There was no association to history of macrosomic infants, congenital anomalies and elevated blood pressure.

Patients who were high risk had a higher risk of having gestational diabetes (p 0.001) as compared to the average risk category.

Association between clinical characteristics and gestational diabetes.

Table 12: Association between clinical characteristics and gestational Diabetes

Clinical characteristic	Gestational diabetes	Normal	p-value‡
	Mean(SD)	Mean(SD)	
Age	30.7 (5.4)	28.3(4.7)	***<0.002***
Systolic Blood pressure	111.6(15.3)	108.5(12.9)	0.156
Diastolic Blood pressure	71.3(9.1)	70.8(10.0)	0.753
BMI	29.6(5.6)	28.1(12.5)	0.445

The mean ages between the patient with GDM and normal glucose tolerance was noted to have a significant value indicating that the patients with GDM were significantly older as compared to the normal population.(p value <0.002). BMI was noted to be not significant (p value 0.445).This is in contrast to most studies that show that BMI as a significant factor in development of gestational diabetes.

Table 13:Logistic Multiple Regression of GDM

	p-value	ODDS	95% CI (B)	
Lab test GDM			lower	upper
Intercept	***0.000***			
Age in Years	***0.010***	3.0	2.8	3.2
Education		1.0	1.0	1.0
Primary	0.206	1.8	1.3	3.8
Secondary	0.365	2.0	1.3	4.9
Tertiary		1.0	1.0	1.0
Family History of elevated BP		1.0	1.0	1.0
Yes	0.502	3.6	1.9	13.4
No		1.0	1.0	1.0
Risk				
Low	0.993	1.0	1.0	1.0
Average	0.910	1.0	1.0	1.4
High	***0.036***	7.9	2.8	58.8

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The significant factors for GDM were age and high risk classification at 0.010 and 0.036 respectively. For every additional year of age, the likelihood of positive GDM increased by 3 times while for the high risk classification the likelihood increased by 8 times.

Section 5.3 Diagnostic utility of GCT against OGTT

Table 14:Glucose intolerance and Lab test GDM Cross tabulation

	Lab test GDM		
Glucose Intolerance	**Positive**	**Negative**	**Total**
Positive	43	49	92
Negative	0	279	279
Total	**43**	**328**	**371**

Sensitivity = 43/43 = 100%

Specificity = 279/328 = 85.1%

Positive PV= 43/92 = 46.7%

Negative PV = 279/279 = 100%

In table 14 above, shows the cross tabulation between glucose intolerance and gestational diabetes, this establishes the applicability of the 50 GCT in picking up the patients who are gestational diabetics with the GCT having a sensitivity of 100% and a specificity of 85.1%. The 50 GCT has a high negative predictive value meaning that it if a patient has negative test result then it is very unlikely that they may have glucose intolerance.

Table 15: Distribution of Glucose intolerance and gestational diabetes associated with gestation by weeks

Gestation(wks)	Normal	GDM	Total number
	N (%)	**N (%)**	**N (%)**
24-27	107(32.6%)	15(34.9%)	122(32.9%)
28-31	125(38.1%)	14(32.6%)	139(37.5%)
32-36	96(29.3%)	14(32.6%)	110(29.6%)

As shown in table 15 above, 34.9% of the GDM patients were between the gestational age of 24 -27 weeks. Combination of groups with a gestational age of 24-31 weeks yields 67.5% of the total patients diagnosed with GDM.

Section 6.1 Discussion

GDM is a well established risk factor in pregnancy and there are clear benefits to be derived by effective screening and treatment. In Kenyatta National Hospital, GCT is not routinely done on all pregnant women. The current policy is to screen women with historical and clinical risk factors e.g. glycosuria for GDM using the 100g OGTT with half hourly blood testing. Few studies have been done locally on GDM and thus prevalence of this condition is largely unknown. Use of the 50g GCT, as a screening test has not been evaluated in our set up. It is important to have a study on this screening method so as to see whether its use is practicable.

The study comprised of 371 clients. The median age was 28 yrs and 273(73.6%) were actually above 25years of age. A total of 78(84.8%) clients diagnosed as glucose intolerant were above 25 years, a statistically significant finding (P value 0.005) lending credence to increases in glucose intolerance in women above 25 years with only 14(15.2%) being below 25 years of age. Of these only 4 clients were positively diagnosed as having gestational diabetes i.e. 10% of the clients diagnosed as gestational diabetes were actually below 25yrs of age. This is consistent with Githaiga's study in 1991 that showed that the majority of mothers with diagnosed diabetes in pregnancy were above 25 years of age[9]. This is also consistent with the defined risk factors of maternal age of above 25 years being a risk for development of gestational diabetes [3, 11]. The 6th international conference on GDM places this as a risk factor for development of gestational diabetes. The American Diabetic association classifies those women below 25 as being low risk[39]. The mean age of participant who tested positive for glucose intolerance was significantly older by 2.3 years ($p<0.001$).

In Baraza's study 2009, it was found that 89% of mother's were married and 11% single[14]. The findings in this study suggest that 88.7% were married, 10.8% single and 0.5% separated. This finding emphasized the presence of an intact family structure in our antenatal clinic attendees. 11.1% of the study population had a combined familial income of less than Ksh 6,000 per month. 37.1% of antenatal attendees had combined income of between 6-15,000 Ksh and 36.1% between 15,001-30,000 Ksh. This income ranges shows the fact that 41.5% of these ladies were self employed, and 27% were primarily housewives. An income of > 30,000 Ksh (p value 0.034) was a significant finding amongst those with glucose

intolerance. This is a reflection of the improved socioeconomic status and thus lifestyle bringing about the increased risk of finding glucose intolerance in this population.

Eight four percent of the study population had attended secondary school, with 43% going on to tertiary education. The education level of the mothers attending the ANC clinic was a significant finding in diagnosis of GDM (secondary school p value= 0.048, tertiary school p value 0.023).Explanation of this could be that those who had a better education were likely to have slightly more combined income, would have come from better placed families, better lifestyles, would be older in age and thus more likely to develop GDM. This fact may be beneficial to health practitioners as these well educated clients would also be receptive to health education especially when it comes to gestational diabetes.

There were 126 primigravidas enrolled in the study, forming 34% of the study population. In terms of age distribution, 83 (65.9%) of the primigravidas were above age of 25 yrs. A total of 14 primigravidas had some glucose intolerance and 4 of these were positively diagnosed as gestational diabetics forming 9.3% of the participants with gestational diabetes and extrapolated to 3 in 100 primigravidas would have gestational diabetes .This shows that a very low percent of the women in the study were primigravidas and gestational diabetics. This also indicates that screening of glucose intolerance in primigravidas may not be feasible as the diagnostic yield is very low (28.6%).Seventy eight (31.8%) of the multigravidas had glucose intolerance, 39(50%) of whom had gestational diabetes confirmed. Thus extrapolated to 3 in 20 multigravidas will have gestational diabetics. This indicates that women who are multigravid and are screened and suspected to be glucose intolerant would actually be gestational diabetics. There could be other confounding factors to this, for example, multigravid women were more likely to be of older age as compared to the primigravidas, and probably of a higher socioeconomic status.

Multivariate analysis of the risk factors show that age greater than 25 years (p value 0.010) and high risk classification { i.e. combination of marked obesity, strong family history of type 2 diabetes, prior glycosuria and delivery of large for gestational age infant }(p value 0.036) place a patient at higher risk of having gestational diabetes. Thus a combination of the two would form a basis of screening criteria for gestational diabetes in our setting. For every additional year of age, the likelihood of positive GDM increased by 3 times while for the high risk classification the likelihood increased by 8 times.

There was no statistical difference between the gestational age of miscarriage, history of previous caesarean section, admission to nursery or difficulties in conceiving. There was no statistical difference in the women who had prior deliveries of babies greater than 4 kg in weight. This could be due to the low numbers of the study for this particular variable and hence the result. An additional explanation is that the cut off weight for macrosomia of 4 kg may not be appropriate for our local settings as other factors like genetics, leading to a higher than average fetal weight. Consideration may be weight above 4.5kg as a cut off.

The finding of glycosuria was statistically significant (p value of 0.016 CI 1.1-58.0) in comparison between gestational diabetic group and the non gestational diabetic group. This indicates that presence of glycosuria indicates likelihood of diagnosis of gestational diabetes in a population. Glycosuria is noted to be associated with high risk of having gestational diabetes [3, 11].

There was a significant association between diagnosis with GDM and first degree relatives with hypertension (p value 0.016 CI 1.0-57.9). This could be due to the likelihood of metabolic syndrome in the family [36]. This is bound to be the cause of metabolic derangements seen in these women.

However, the same could not be said about family history of diabetes, (p value 0.692 for 50g glucose challenge test positive and p value of 0.734 for gestational diabetes).Positive history of diabetes is a known risk factor for development of gestational diabetes, but in this study, there was no association between family history of diabetes and GDM. The likely explanation for this is that unlike hypertension, diagnosis of diabetes requires laboratory test and as such very few people actually get diagnosed with this condition. Screening for diabetes mellitus in the general population should be considered.

The prevalence of glucose intolerance by use of the 50g glucose challenge test and a cut off of 7.2 mmol/l was estimated at 24.8% (95% CI ;20.7% to 29.4% n=92). While that of gestational diabetes is 11.6%. Prevalence of glucose intolerance calculated from a 50g glucose challenge test cut off of 7.8mmol/l is 12.4% while that of gestational diabetes is 8.9%. These are within the value calculated by the 4th international conference of diabetes2, and that of global and WHO estimates of 4-14% [1, 3-4] This is a higher prevalence as compared to that of the study by Githaiga in 1991 that documented a prevalence of diabetes

in pregnancy of 0.15% [9]. The increase in the prevalence may be due to improvement in overall socio economic status and change in lifestyle. The prevalence calculated is also slightly below Baraza's study of 16.7%[14]. Estimates have also shown that prevalence of gestational diabetes in African countries is around 7%[8]. It is possible that the higher prevalence in Kenya is due to the fact that the Kenyan population is far better off socio-economically as compared to the rest of Africa .The World Bank places Kenya as 11th position in Africa in terms of its GDP[69]. WHO recommends a two stage screening process-a 50g glucose challenge test followed by the 75g Glucose tolerance test, this is the method used in the study, and it is shown to be useful and a more effective method to use for screening and diagnosis of gestational diabetes [1]. The Kenyatta National Hospital uses the 3 hour 100g glucose challenge test in diagnosis of glucose intolerance, This amount has been shown to have more side effects and without any added sensitivity or specificity, and with added cost and time implication. The Ministry of medical services policy is to have OGTT 75g to screen for gestational diabetes [67] alt hough common practice is random blood sugar to test for gestational diabetes in pregnant women in the antenatal clinics. This method also has a low sensitivity and specificity and is thus not useful in screening for gestational diabetes.

Use of the risk factor screening method as a single method to diagnose gestational diabetes has a positive predictive value of 36.70 and a negative value of 80.15 as compared to the 50 g glucose challenge test, meaning that it will only strongly negate the presence of likely glucose intolerance in a client but not necessarily pick the likely glucose intolerant ones. The 50g GCT is a simple, cheap and convenient test [17, 55]. It does not require a patient to be fasted and can be easily organized after the consultation. In this study it was found to have a sensitivity of 100% and specificity of 85.1% a finding similar to a study done in Nigeria[10]. Apart from the occasional nausea, it does not bother the patient very much. Most of our pregnant women did not object to the test when the protocol was explained.

The other point of interest is the best glucose cut off level for the 50g glucose challenge test. Studies give either 7.2mmol/l or 7.8mmol/l [1, 38, 46]. In this study it was found that the level of 7.8mmol/l would be most appropriate as 33 (76.7%) of gestational diabetics had glucose levels of above 7.8, Thirteen patients (28.3%) with blood glucose of above 7.8mmol/l were GDM negative as compared to 49(53.3%) of the glucose intolerant population who had glucose levels above 7.2 mmol/l and yet were not GDM.

With the threshold plasma glucose level at 7.2 mmol/l, 92 women or 24.8% needed to undergo the WHO 75g oral glucose tolerance test and 43 women were found to have gestational diabetes. The diagnostic yield was 46.7%, but with 7.8 mmol/l as the threshold value, 46 women or 12.4% needed the 75g oral glucose tolerance test and 33 women with gestational diabetes were detected. The diagnostic yield was 71.7%. Thus a higher diagnostic yield with 7.8mmol/l cut off indicating that it is a better cut off level. It is also more economically viable to use this cut off as less resources would be used to diagnose these women.

Of the high risk patients, 40(36.7%) were glucose challenge test positive and of these 23 (21.1%) were gestational diabetics. This equates to approximately 57.5% of the high risk glucose challenge test positive mothers who were actually gestational diabetics. Of patients who were in the average risk category, 52(19.8%) were glucose challenge test positive and of these 20(7.6%) were diagnosed with GDM. The cross-tabulation of risk factors vs glucose challenge test show that risk factor screening has a sensitivity of 43.48% and specificity of 75.27%. This resulted in a positive predictive value of 36.70 and a negative predictive value of 80.15. This lends credence to the fact that risk factor screening may not be appropriate in screening and diagnosis of gestational diabetes. However, the fact that high risk stratification is significant in increasing likelihood of GDM, it is beneficial for those antenatal mothers who have a combination of BMI greater than 30, history of glycosuria, history of prior GDM, history of delivery of macrosomic infants >4kg and have a strong family history of type 2 diabetes to undergo a one step procedure with the WHO based 75g OGTT. This is in line with the general recommendation of the 5th conference on gestational diabetes[34].

Average gestation for the group was 29 weeks.161 (43.4%) participants were between 24 -28 weeks gestation. Of these 37 (23%) of the 161 were glucose intolerant and 17 (10.6%) of these were gestational diabetes. Interestingly, these levels are within the overall study population prevalence of gestational diabetes and glucose intolerance. In terms of comparison to those above 28 weeks gestation, those below 28 weeks consisted 40.2% of the glucose intolerant group and 39.5% of the gestational diabetic group. It was also found that 67.4% (n=62) of the glucose intolerant population were between 24-32 weeks by gestation with 67.5% (n = 29) of these actually turning out to be gestational diabetics. Thus it is prudent to screen for gestational diabetics past the normal 28 weeks as there is increased detection rates[14, 64].

Section 6.2 Conclusion

- In this study the prevalence of glucose intolerance was 24.8% and a subsequent WHO based 75g Oral glucose intolerant test gave a prevalence of gestational diabetes of 11.6%.This was by use of the 7.2mmol/l cut off for the glucose challenge test. Use of a cut off of 7.8 mmol/l gives a glucose intolerance level of 12.4% and a gestational diabetes prevalence of 8.9%. It is useful to place the cut off for glucose challenge test at 7.8 mmol/l as it has a higher diagnostic yield of 71.7% as compared to the 46.7% for the 7.2 mmol/l cut off. At the same time using 7.8mmol/l cut off is actually more economically viable in this set up.

- Factors associated with gestational diabetes were history of glycosuria, higher levels of education, family history of high blood pressure. Other factors that are used in the risk factor classification were not found to be significantly associated with glucose intolerance. These include history of miscarriages, history of macrosomic infants, history of delivery of neonates with congenital anomaly, strong family history of diabetes and BMI classification. Age greater than 25 yrs and high risk classification were significant in multivariate analysis of GDM. Thus use of these 2 parameters will provide an alternate means of screening for GDM. Screening of the high risk groups is beneficial in a resource poor setting.

- As compared to the 50g glucose challenge test, the risk factor classification had a low sensitivity of 43.48%, and poor positive predictive value of 36.7%. It also has a specificity of 75.27% and a negative predictive value of 80.15. Thus this makes the risk factor classification a poor screening method in our set up. Universal screening using the 50g glucose challenge test has good sensitivity (100%) and specificity (85.1%) as compared to the risk factor screening test. It is also a feasible and convenient test to perform in our set up.

Section 6.3 Recommendations

Universal screening with the 50g glucose challenge test between 24 – 32 weeks is a prudent approach in screening for gestational diabetes in our set up. A glucose challenge cut of level of 7.8mmol/l would be appropriate as this has been shown to have a higher diagnostic yield, is an affordable test to perform and can be accommodated in the routine Antenatal profile.In concert with most guidelines on gestational diabetes, high risk women may benefit from a diagnostic 75G OGTT.

Kenyatta National Hospital should convert to the now wide spread and accepted method of diagnosis of gestational diabetes which is use of the 75 g OGTT as this would lead to standardization of the process of screening and diagnosis of gestational diabetes.

Need to carry out more studies to follow up outcomes of patients diagnosed with gestational diabetes, prevalence of gestational diabetes in our general population and on knowledge attitude and practices amongst both the general public and health practitioners. A follow up study on the outcomes of the women who participated in this study is planned.

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Section 8.0 APPENDIX

Section 8.1 Appendix 1: Standard Operating Procedure for enrolment and testing algorithm

TITLE: SCREENING AND DIAGNOSIS OF GESTATIONAL DIABETES AMONG PREGNANT WOMEN BEING CARED FOR AT KENYATTA NATIONAL HOSPITAL ANTENATAL CLINIC

1. Patient who meet the set criteria will be enrolled into the study, after filling in the consent
2. Patient will fill in the standardized precoded questionnaire that would be administered by the research assistants.
3. Those clients who will fulfill the criteria would then receive the 50g glucose load in 150ml of water, which they would require to drink in 5-10 minutes after which they would be sent to the laboratory from where capillary blood would be withdrawn.
4. The collected blood specimen would then be measured by a glucometer and the result recorded down by double entry and into a lab form that the patient will take back to the review clinic.
5. The clients with confirmed glucose intolerance that is blood glucose above 7.2mmol/l will be advised as to date of return which would be ordinarily one week later and advised to fast on the morning of their arrival. The principal investigator will call the clients the day before the return date and remind them to fast and about the appointment.
6. The WHO 75g OGTT would then be carried out in these clients. Capillary blood would be drawn for fasting blood glucose then the clients are given a 75g glucose load. The blood glucose would then be measured at 1hr and 2 hrs after ingestion of the load.
7. The results of this test would be entered via double entry and also given to the mothers so that they would be reviewed by the attendant obstetrician in the clinic and managed to as KNH protocol.
8. The clients' details would then be collected and analyzed.

The clients' phone number will be taken so as to facilitate communication.

Section 8.2 Appendix 2: Questionnaire

Study number:

Age (yrs) Height (meters):

Blood pressure (mmHg): Systolic Diastolic

The numbers in brackets are precoded numerically.

A: Personal medical history

1. What was your weight in Kg before pregnancy?

   ☐ Wt [1] ☐Unknown [9]

   If unknown, what was your weight at beginning of clinic?

2. What is your current weight today?
3. Have you experienced any of the following symptoms

   ☐ Frequent urination [1]

   ☐ Frequent thirst [2]

   ☐ Increased appetite [3]

4. Have you ever had your blood glucose measured?

   ☐ Yes [1]

   ☐ No [2]

   When was this? ----------

   What was the result?

   ☐ Normal [1]

   ☐ Abnormal [2]

   ☐ Unknown [9]

5. Do you suffer from a chronic disease? Which one?

   ☐ Liver disease [1]

   ☐ Renal disease [2]

   ☐ Cardiac disease [3]

   ☐ None [4]

   ☐ Don't know [9]

6. Are you currently on any medication?

   ☐ Yes [1]

   ☐ No [2]

If yes, specify ----------

7. What is your HIV status

   ☐ Positive [1]

   ☐ Negative [2]

   If unknown what are the results obtained from antenatal clinic screen?

If patient falls under the exclusion criteria then do not continue with the screening

SECTION B: SOCIO-DEMOGRAPHIC, OBSTETRIC AND GYNAECOLOGIC HISTORY

I: Socio-demographic characteristics

8. What is your marital status?

   ☐ Single [1]

   ☐ Married [2]

   ☐ Separated [3]

   ☐ Other. Please state ---------- [4]

9. Where is your current residence? ----------

   ☐ Rural formal [1]

   ☐ Rural informal [2]

   ☐ Urban – High income [3]

   ☐ Urban Middle income [4]

   ☐ Urban Low income [5]

   ☐ Urban Informal [6]

10. How long have you been staying in your current residence?----------

11. What is your level of education?

   ☐ Lower Primary [1]

   ☐ Upper Primary [2]

   ☐ Secondary [3]

   ☐ Tertiary [4]

   ☐ None [5]

12. What is your employment status?

   ☐ Self employed [1]

   ☐ Employed [2]

- ☐ Unemployed [3]
- ☐ Other. Please state ---------- [4]

13. What is the total level of income per month in your family?
    - ☐ <6000 ksh/month [1]
    - ☐ 6,000- 15,000 Ksh/month [2]
    - ☐ 15,000- 30,000 Ksh/month [3]
    - ☐ >30,000 Ksh/month [4]

II: Obstetric and gynaecological history

LMP:

(if not sure of LNMP extrapolated on an early scan, first ANC visit and quickening)

Parity: Gravida: GBD:

14. Have you experienced any problem with conceiving?
    - ☐ Yes [1]
    - ☐ No [2]
15. Have you suffered a miscarriage?
    - ☐ Yes [1]
    - ☐ No [2]
16. If yes to 15 above at how many weeks gestation
    - ☐ 6-12 weeks [1]
    - ☐ 12 – 20 weeks [2]
    - ☐ 20-28 weeks [3]
    - ☐ Not known [9]
17. How many pregnancies have you delivered before 37 weeks?
    - ☐ None [1]
    - ☐ All [2]
    - ☐ Some, specify how many---------- [3]
18. Have you had elevated blood pressures in this or prior pregnancies?
    - ☐ Yes [1]
    - ☐ No [2]
19. Have you been told of you having glucose/sugar in your urine in this or prior pregnancies?

☐ Yes [1]

☐ No [2]

20. Have you been diagnosed with diabetes?

☐ Yes [1]

☐ No [2]

21. If yes to 20 above, when was diagnosis made?

☐ Before becoming pregnant [1]

☐ In the previous pregnancy [2]

22. Have you ever been told that your womb looks bigger than what is expected?

☐ Yes [1]

☐ No [2]

23. If yes to question 22, was it related to increased amount of fluid in the uterus?

☐ Yes [1]

☐ No [2]

☐ Do not know [9]

24. Have you delivered any of your babies by Cesearean section?

☐ Yes [1]

☐ No [2]

25. If yes to 24 above what was the indication of C/S?

☐ Big baby [1]

☐ Failed induction [2]

☐ Prolonged labour [3]

☐ fetal distress [4]

☐ Other. Please state ---------- [5]

26. Have you been assisted to deliver before? If yes, by which method?

☐ Vacuum [1]

☐ Forceps [2]

☐ Don't know [9]

27. Have you delivered any of your babies when they are already dead (still births)

☐ Yes [1]

☐ No [2]

If yes, How many?_____

28. Have you delivered a child who died after delivery?

☐ Yes [1]

☐ No [2]

If yes, How many?----------

29. If yes to 28 above how long after delivery did the baby die?

☐ Less than 24 hours [1]

☐ 1 day – 7 day [2]

☐ 7 days – 28 days [3]

☐ Other [4]

30. Have you delivered a baby with an abnormality?

☐ Yes [1]

☐ No [2]

31. If yes to Q 30 what kind of abnormality

☐ Central Nervous System---------- [1]

☐ CardioVascular System---------- [2]

☐ Genito-Urinary Tract [3]

☐ Gastro-intestinal Tract [4]

☐ Other. Please state---------- [5]

32. Have had a baby with a birth weight of 4 kg or more?

☐ Yes [1]

☐ No [2]

33. Have had any of your babies admitted to nursery/new born unit?

☐ Yes [1]

☐ No [2]

34. If yes to 33 above what was the indication?

☐ RDS [1]

☐ Prematurity [2]

☐ Jaundice [3]

☐ Other. Please state ---------- [4]

☐ Do not know [9]

D: Family history

35. Do you have any relatives with diabetes?

☐ Yes [1]

☐ No [2]

How many? ----------

What is their relationship to you? ----------

36. Have you had any relative with high blood pressure?

☐ Yes [1]

☐ No [2]

What is their relationship to you? ----------

E. Risk Screen (Tick what is appropriate)

I. Low Risk

☐ Member of an ethnic/racial groups with a low prevalence of gestational diabetes

☐ No known diabetes in first-degree relatives i.e. immediate family members

☐ Age less than 25 years

☐ Weight normal before pregnancy

☐ No history of abnormal glucose metabolism

☐ No history of poor obstetrical outcome

☐ Weight Normal at birth

III Average Risk

☐ Greater than 25 years

☐ Abnormal weight before pregnancy

☐ High risk ethnic/racial heritage

☐ Family history of diabetes

☐ History of abnormal glucose intolerance

☐ History of poor obstetric outcome

☐ History of congenital abnormalities

- ☐ History of fetal macrosomia >4kg

II High Risk

- ☐ Women with marked obesity BMI >30
- ☐ strong family history of type 2 diabetes
- ☐ prior gestational diabetes
- ☐ prior glycosuria
- ☐ delivery of large-for-gestational-age infant

RESULTS

F: BMI =

G: Risk factor classification;

- ☐ Low risk: [1]
- ☐ Average risk [2]
- ☐ High risk [3]

H: LABORATORY SCREENING FORM

50g Glucose Challenge Test –

Age *Study number*

Date *Time of last meal:*

Result:

☐Glucose intolerance (>7.2mmol/l) [1]

☐No glucose intolerance (<7.2 mmol/l) [2]

I: LABORATORY REQUEST FOR DIAGNOSIS OF GESTATIONAL DIABETES

75g Oral Glucose Tolerance Test –

Study number *Date* Results:

75g OGTT	mmol/l
Fasting blood glucose	
1 hr Blood glucose	
2hr blood glucose	

☐ Gestational Diabetes [1]

☐No Gestational Diabetes [2]

KENYATTA NATIONAL HOSPITAL
Hospital Rd. along, Ngong Rd
P O Box 20723, Nairobi
Tel 726300-9
Fax: 725272
Telegrams MEDSUP", Nairobi.
Email KNHplan@Ken.Healthnet.org

Ref: KNH-ERC/ A/638

18th November 2010

Dr. Bosire Alex Nyakundi
Dept.of Obs and Gynae
School of Medicine
University of Nairobi

Dear Dr. Bosire

Research proposal: "Screening of Gestational Diabetes among pregnant women in Kenyatta National Hospital" (P273/08/2010)

This is to inform you that the KNH/UON-Ethics & Research Committee has reviewed and approved your above revised research proposal for the period 18th November 2010 - 17th November 2011

You will be required to request for a renewal of the approval if you intend to continue with the study beyond the deadline given. Clearance for export of biological specimens must also be obtained from KNH/UON-Ethics & Research Committee for each batch.

On benalf of the Committee, I wish you a fruitful research and look forward to receiving a summary of the research findings upon completion of the study

This information will form part of the data base that will be consulted in future when processing related research study so as to minimize chances of study duplication

Yours sincerely

PROF A N GUANTAI
SECRETARY, KNH/UON-ERC

c.c. The Deputy Director CS, KNH
The HOD, Records, KNH
The Dean, School of Medicine, UON
Supervisors: Prof. Joseph Karanja, Dept.of Obs and Gynae. UON
Dr. Zahida Qureshi, Dept.of Obs and Gynae. UON

Section 8.4 Appendix 4: client information and consent form

Study: *SCREENING AND DIAGNOSIS OF GESTATIONAL DIABETES AMONG PREGNANT WOMEN BEING CARED FOR AT KENYATTA NATIONAL HOSPITAL ANTENATAL CLINIC*

.**Principal Investigator:** Dr Bosire Alex Nyakundi, Masters of medicine student, Department of Obstetrics and Gynecology, University of Nairobi. No. 0722497268

Supervisors

Prof Joseph Karanja, Consultant Obstetrician/gynaecologist

Dr. Zahida Qureshi, Consultant Obstetrician/gynaecologist

KNH Ethical Review committee: Chairperson, Professor K.M Bhatt, Phone number 0202726300.

Researcher's statement

I am asking you to participate in a research study. The purpose of this form is to give you information about the study on screening and diagnosis of gestational diabetes mellitus attending antenatal clinic at Kenyatta National Hospital. This information will help you decide whether to be in the study or not. Please read the form carefully. You may ask questions about the purpose of the research, what you would be asked to do, the possible risks and benefits, your rights as a volunteer and anything else about the research. When all your questions have been answered, you can then decide to whether participate in the study or not. If you wish, a copy of this form will be will given to for your records.

Purpose and benefit

The purpose of this study is to determine the best screening method for gestational diabetes and to determine the occurrence/prevalence of the same condition in women attending the antenatal clinic in Kenyatta National Hospital. This study will benefit you in that it would be possible to determine whether you suffer from GDM and thus be able to prevent and/or treat any complication that arises from this disease, in either you or your unborn child. You will receive your blood glucose results and be able to be reviewed by the attending obstetrician in the clinic.

Procedure

I and my research assistant will obtain information about you using a questionnaire. You would subsequently give you a glucose drink that you will drink in 5 – 10

minutes. An hour after ingestion of the drink then you will have some blood withdrawn from you for measurement of the blood glucose level. It is requested that over this hour there be no smoking or activity. If your blood glucose is recorded as normal then you will be given your test result and sent back to the antenatal clinic. If abnormal then you will be advised as to a return visit within 2 weeks where you will be advised to come back at 8am in the morning and not having eaten since midnight of that day. On arrival to hospital then you shall have your blood glucose taken, then given another glucose load. This time your blood again will be drawn at 1hour and 2 hours after ingestion of the drink. Your results will then be availed to you and be advised as to review by the attending obstetricians at the ANC clinic. You will still receive standard antenatal care as you participate in the study.

Risk, stress or discomfort

Completing your questionnaire would take approximately 5 minutes of your time.

Blood testing would take less than 5 minutes.

If you are found to have glucose intolerance then you would require follow up in the antenatal clinic

Slight pain will be felt on obtaining the blood for testing. It is estimated that you will undergo a maximum of 4 pricks to get your blood.

You may have slight discomfort to the glucose load, if taken too quickly it would give you nausea.

There is no danger caused by the testing otherwise to you or your unborn child.

Confidentiality

All the information obtained from you will be treated with utmost confidentiality. Your name will not appear on the questionnaire or the lab request form. A study number will be used instead. Your blood glucose test results will be filed with your antenatal clinical records.

You may choose to withdraw from the study, refuse to answer questions or decline the blood glucose tests. Your decision will not affect your antenatal care at KNH.

Subject's statement

I voluntarily agree to participate in the study on screening and diagnosis of gestational diabetes among pregnant women at Kenyatta National Hospital clinic 18. I understand that participation in the study does not entail financial benefit. I have been informed

that information obtained will be treated with utmost confidentiality and my treatment will not be compromised if I decline participation or withdraw from the study.
I have had a chance to ask questions. If I have questions later, I can ask the researcher. If I have questions later about my rights as a research subject or complaints about the study, I can call the ethical review committee at Kenyatta National Hospital on phone number 020726300.

No coercion has been used to influence my decision to participate in the study whose nature, benefits and risks have been explained to me by Dr/Mr./Mrs. ……

Subject's signature……..
Date……
OR

Subject's left thumb print……
Date……..

Subject's
name……

Subject's Telephone number: ……

I ASSURE THAT I HAVE FULLY EXPLAINED TO THE ABOVE STUDY VOLUNTEER/AUTHORIZED REPRESENTATIVE, THE NATURE AND PURPOSE, PROCEDURES AND THE POSSIBLE RISK AND POTENTIAL BENEFITS OF THIS RESEARCH STUDY.

Investigators signature……
Date……

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