# QUALITY OF GLYCEMIC CONTROL AMONG

# DIABETIC WOMEN OF REPRODUCTIVE AGE AT

# KENYATTA NATIONAL HOSPITAL IN 2019, A CROSS-SECTIONAL STUDY


**PRINCIPAL INVESTIGATOR**

**Dr. Justus Malowa Nondi**,
*H58/74123/2014*
*MBChB, M.Med student*
*Department of Obstetrics and Gynecology*
*University of Nairobi*

**SUPERVISORS**

**Dr. Alfred Osoti**
*MB.ChB; M.Med (OBS/GYN), MPH*
*Senior Lecturer, Department of Obstetrics & Gynecology*
*College of Health Sciences*
*University of Nairobi*
*P.O. Box 19676, Nairobi, 00202; Kenya*

**Dr. Kizito Lubano**
*MB.ChB; M.Med (OBS/GYN);*
*Hon.Lecturer, Department of Obstetrics & Gynecology*
*College of Health Sciences*
*University of Nairobi*
*P.O. Box 19676, Nairobi, 00202, Kenya*


A research dissertation, submitted to the University of Nairobi, Department of Obstetrics and Gynaecology in partial fulfillment of the requirements for the award of a degree in Masters of Medicine in Obstetrics and Gynaecology.

## DECLARATION

I declare that this dissertation is my original work compiled with the guidance of my supervisors, and that to the best of my knowledge has not been submitted for degree in any other university or published elsewhere. Where reference was made from other sources, published or otherwise, that source has been duly cited.

Dr. Justus Malowa Nondi

Signature_____

Date_____

## APPROVAL

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

Dr. Alfred Osoti

Signature_____

Date_____

Dr. Kizito Lubano

Signature_____

Date_____

## CERTIFICATE OF AUTHENTICITY

This is to certify that this thesis is the original work of Dr. Justus Malowa Nondi, an M.Med student in the Department of Obstetrics and Gynaecology, College of Health Sciences, University of Nairobi under the guidance and supervision of Dr. Alfred Osoti and Dr. Kizito Lubano. This thesis has not been presented in any other university for award of a degree.

**PROF. OMONDI OGUTU MBChB, M.Med (OBS/GYN), PGDRM**

Associate Professor of Obstetrics and Gynaecology

Chairman, Department of Obstetrics and Gynaecology, University of Nairobi.

Signature _____

Date_____

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## DEDICATION

To my parents, Mr. David Nondi and Mrs. Josephine Nondi and entire family. My wife Winney Chelangat and son Carl-Davies for your enormous support and encouragement throughout my postgraduate training. To you all I say thank you.

## LIST OF ABBREVIATIONS

| | | |
|---|---|---|
| CI | – | Confidence Interval |
| DM | _ | Diabetes Mellitus |
| EDTA | _ | Ethylene diamine tetraacetic acid |
| DWRA | _ | Diabetic Women of Reproductive Age |
| HbA1C | _ | Glycated Haemoglobin |
| KNH | – | Kenyatta National Hospital |
| OHA | _ | Oral Hypoglycemic Agent |
| MDG | – | Millennium Development Goal |
| NGO | – | Non Governmental Organization |
| SDG | – | Sustainable Development Goals |
| SPSS | – | Statistical Package for Social Software |
| UoN | – | University of Nairobi |
| WHO | – | World Health Organization |
| WRA | _ | Women of Reproductive Age |

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# ABSTRACT

**Background.** Diabetes mellitus (DM), is a non-communicable progressive disorder characterized by hyperglycemia due to insulin deficiency or insulin resistance or both. It has emerged as a major national and global health problem. Women of reproductive age (between 15 years – 49 years) are at an increased risk of diabetes especially during pregnancy. About 60 million women of reproductive age have DM worldwide and about 14% of all pregnant women develop gestational diabetes mellitus. These women require special attention owing to their vulnerability to long term micro-vascular and macro-vascular as well as pregnancy-specific complications. The glycemic control status of diabetic patients affects their management and there is evidence that lowering blood glucose as close to normal range as possible is a primary strategy for delaying or slowing these complications. The quality of glycemic control among diabetic women of reproductive age in Kenya has not been studied. This study provides some background into management of diabetic women of reproductive age (DWRA) as well as guiding subsequent research

**Broad objective.** To determine the quality of glycemic control and characteristics of diabetic women of reproductive age (DWRA) at Kenyatta National Hospital.

**Methodology**

***Study Design*** A cross-sectional study to determine the quality of glycemic control among the diabetic women of reproductive age. Hemoglobin A1c (HbA1c) testing done and patients subsequently interviewed using a standardized structured questionnaire.

***Study site***. Diabetic clinic at Kenyatta National Hospital

***Data Management and Analysis*** Data cleaned,entered and analyzed by use of SPSS version 24. Continuous data analyzed by use of means and standard deviation. Categorical data analyzed and displayed by use of frequencies and proportions.

**Results** A total of 176 diabetic women of reproductive age were enrolled into the study. The mean age was 36.5 years. The mean HbA1C was 8.2%. 102 patients (58%) had poor glycemic control i.e. HbA1c more than 7% while 74 patients (42%) had good glycemic control. Majority of the patients (46.6%) were on insulin monotherapy, followed by 27% on oral hypoglycemic agents (OHA). Patients aged 35 years and above were two and a half times as likely to have poor glycemic control compared to younger patients. Patients who don't test blood sugar are 80% less likely to have good glycemic control.

**Conclusion.** There is high prevalence of poor glycemic control among diabetic women of reproductive age at KNH at 58%. Older patients above 35 years of age are 2.5 times as likely to have poor glycemic control compared to younger patients. Patients who don't test their blood sugars are 80% less likely to have good glycemic control.

# 1.0 INTRODUCTION AND LITERATURE REVIEW

## 1.1 Introduction

Diabetes mellitus (DM) is a chronic metabolic disorder characterized by hyperglycemia due to insulin deficiency or insulin resistance or both. It is one of the major causes of morbidity and mortality in both developed and developing countries (1)

An estimated 425 million adults are living with diabetes worldwide and this figure is projected to reach 629million by the year 2045, with the largest proportional increase happening in developing countries. A significant proportion of this population is women of reproductive age (15-49 years) (1). Additionally, the incidence of diabetes has been shown to increase among the younger age groups particularly in developing countries. As younger population becomes more affected by diabetes, an increasing number of women in the reproductive age group also become affected.

In Kenya the National Diabetes Strategy of 2010-2015 estimates the overall prevalence of DM at 3.3%, projected to rise to 4.5% in 2025. This would translate to about 1.8 million people living with diabetes (2).

Care for diabetic patients including women of reproductive age revolves around achieving good glycemic control as this has been shown to minimize the occurrence of micro vascular and macro vascular complications. Good glycemic control reduces occurrence of obstetric complications such as shortened gestational period, miscarriage, macrosomia and increased likelihood of operative delivery. However, no local study has evaluated the quality of glycemic control among diabetic women of reproductive age as an audit of their diabetic care.

## 1.2 Literature Review

Diabetes mellitus (DM) has emerged as a major global public health problem particularly in developing countries owing to increasing numbers of patients with this disorder and the high cost of management.

There are currently 199 million women living with diabetes worldwide and this figure is projected to increase to 313 million by the year 2040 (1). Power dynamics and gender roles is thought to influence vulnerability to diabetes, affect the health seeking behavior and accessibility to health care among women hence amplifying the effect of diabetes among women

Two out of every five women with diabetes are of reproductive age (between 15 years -49 years), accounting for over 60 million women worldwide (1). Women of reproductive age are at an increased risk of diabetes especially during pregnancy and about 3-8% of all pregnant women develop gestational diabetes mellitus. Baraza, Ogutu and Mutungi found a prevalence of glucose intolerance of 36% among antenatal clients at Kenyatta National Hospital in 2011(10). In a different study at Kenyatta National Hospital, B.A. Nyakundi found the prevalence of gestational diabetes of 11.6% (3).

Diabetic women of reproductive age (DWRA) require special attention owing to their vulnerability to long term diabetic complications such as nephropathy, retinopathy and cardiovascular diseases. When they become pregnant, they are at an increased risk of developing conditions such as pre-eclampsia and eclampsia and are more likely to have operative deliveries as well as to suffer complications of child birth including post-partum hemorrhage(2).

Studies have shown the benefits of intensive glycemic control in reducing the risk of macro vascular as well as micro vascular sequelae of DM (5). Additionally, in diabetic women of

reproductive age, optimum glycemic control before pregnancy and during pregnancy is not only achievable and affordable but also reduces the risk of fetal complications including macrosomia, congenital malformations or even perinatal mortality (2). Children of diabetic women with good glycemic control have reduced risk of childhood obesity, glucose intolerance and overt diabetes mellitus (2). However, organized care to diabetic women of reproductive age faces a lot of challenges owing to high cost of management and scarcity of skilled manpower particularly in developing countries. Luckily, the test used in determining patients' glycemic control, the glycated hemoglobin test, is fairly readily available. Glycated hemoglobin (HbA1c) test determines the average glycemic levels over the previous 3 months prior to the time of measurement in a patient (6).

A study done in Kenyatta National Hospital by Otieno et al on quality of glycemic control among ambulatory diabetic patients established that those on diet only as a means of controlling their glycemic levels were found to have the best glycemic control while those who were on oral hypoglycemic agents had the poorest glycemic control (7).This could have been due to relatively lower blood sugars compared to those requiring insulin/drugs. Data in this study was however not disaggregated by age.

In Malaysia a study reported poorer glycemic control among diabetic reproductive women compared to diabetic women of non-reproductive age. OR 1.5(95% C.I 1.2-1.8). The risk factors associated with poor glycemic control were longer duration of DM, patients on oral hypoglycemic agents and being a Malay of Indian race (4). Another cross sectional study in Zambia in 2014 found that 61% of diabetic patients (males and females) had poor glycemic control (HbA1c - 49mm/mol). Insulin therapy alone was associated with poor glycemic control.

Higher BPs were also noted to be associated with poor glycemic control among these patients (8).

Two large studies – the UK Progressive Diabetes Study (UKPDS) and the Diabetes Control and Complications Trial (DCCT) – demonstrated that improving HbA1c by 1% (or 11mmol/mol) for people with type 1 or type 2 diabetes cuts the risks of micro vascular complications by 25% (9) Other studies have also shown that people with type 2 DM who reduce their HbA1c levels by 1% are 19% less likely to suffer cataracts, 16% less likely to suffer heart failure and 43% less likely to suffer amputation or death due to peripheral vascular disease (12).

Kenyatta National Hospital, the largest teaching and referral hospital in Kenya attends to over 3,000 diabetic women of reproductive age annually (10).Most of these patients are seen in the medical outpatient clinic except those who are pregnant who are seen at the high risk pregnancy clinics. Others may be hospitalized for inpatient care.

The quality of glycemic control among diabetic women of reproductive age in Kenya has not been studied. The aim of this study was therefore to determine the quality of glycemic control and characteristics of diabetic women of reproductive age (DWRA) at Kenyatta national hospital.

# CONCEPTUAL FRAMEWORK

## 2.1 Narrative

Glycemic control among diabetic patients has been shown to reduce the risk of development and progression of both micro vascular and macro vascular complications. Studies have shown that a reduction in HbA1c by 1% reduces the risk of micro vascular complications by 25% (9)

Similarly good glycemic control is vital as a component of preconception care to DWRA and this has been shown to greatly reduce incidents of pregnancy loss, pre eclampsia, fatal complications arising from diabetes, complication of child birth among others.

However the quality of glycemic control among DWRA is not known locally. Several factors may influence the quality of glycemic control among diabetic women of reproductive including social demographic factors, duration of the disease, comorbidities, treatment regimen among other factors.

Knowledge of quality of glycemic control among diabetic women of reproductive age locally (KNH) is therefore vital in guiding subsequent research in this field and helping in formulation and implementation of policy guidelines.

## 2.2 Diagrammatic conceptual framework

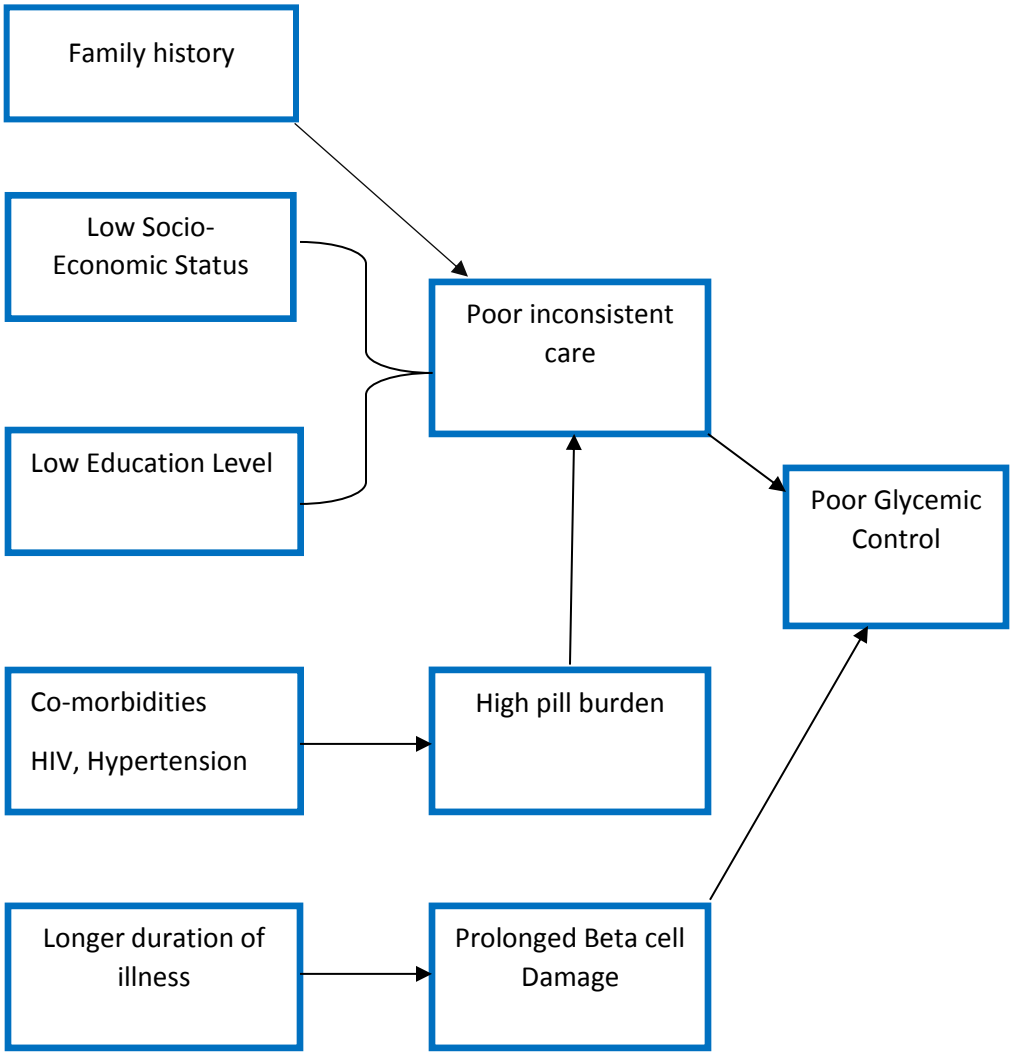



*Figure 1: Diagrammatic conceptual frame work*

## 3.0 JUSTIFICATION

DM, a progressive chronic non communicable disease, is now a major national and global public health concern since it is associated with increased morbidity, mortality and economic costs. In developing countries like the sub-Saharan countries, incidence of diabetes among women of reproductive age is on the rise. Quality of glycemic control among these women is fundamental in the management of their diabetic condition.

There's evidence that good glycemic control prevents or delays the progression and onset of diabetic complications in the central nervous system, cardiovascular, musculoskeletal, reproductive, renal as well as ophthalmic complications.

Knowledge of the quality of glycemic control among DWRA is useful in planning healthcare programs that target improved care among these women. Good quality is achievable and relatively affordable since the tool for monitoring quality is readily available (HbA1c test)

No study has however been done locally looking at quality of glycemic control among DWRA as an audit of their diabetic care

This study informs the caregivers and stakeholders of the blood glucose related risk of adverse outcomes among diabetic women of reproductive age in Kenya.

# 4.0 RESEARCH QUESTION

What is the quality of glycemic control and characteristics of diabetic women of reproductive age (DWRA) at Kenyatta National Hospital?

# 5.0 OBJECTIVES

## 5.1 Broad Objective

To determine the quality of glycemic control and characteristics of diabetic women of reproductive age (DWRA) at Kenyatta National Hospital in 2019

## 5.2 Specific Objectives

**Among diabetic women of reproductive age at Kenyatta National Hospital, to:**

1. Determine the prevalence of poor glycemic control.
2. Describe the socio-demographic characteristics of poor glycemic control.
3. Determine the clinical correlates of poor glycemic control.

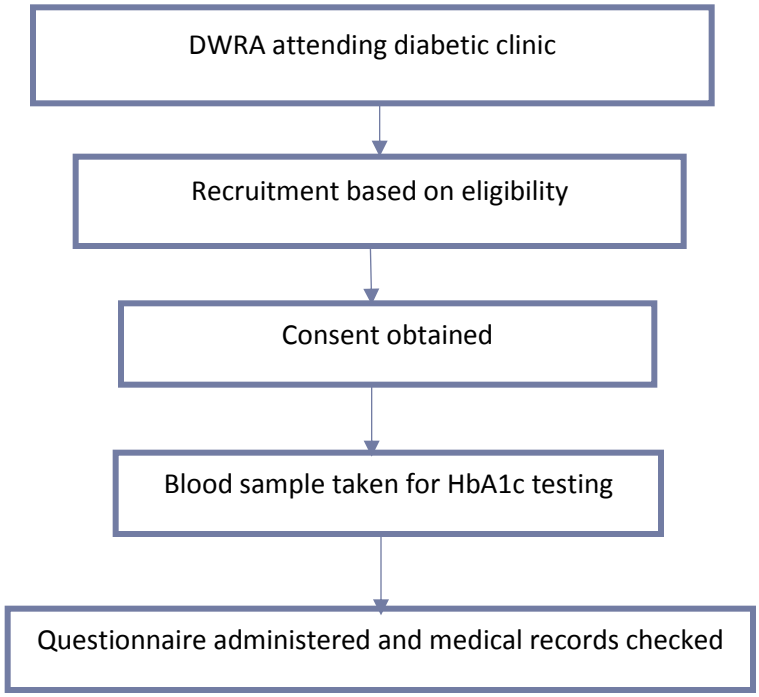
# 6.0 STUDY METHODOLOGY

## 6.1 Study Design

This was a cross-sectional study to determine the quality of glycemic control among the diabetic women of reproductive age (between 18 years -49 years) attending the diabetic clinic at KNH.

These patients were screened for eligibility. Then consent was sought before Hemoglobin A1c (HbA1C) testing was done. This was followed by administration of standardized structured questionnaire and a review of the medical records of the patients (Figure 2)

Poor glycemic control was defined as HbA1C above 7% (2). The questionnaire looked at the clinical characteristics of the patients including the type of diabetes, modes of treatment, duration of illness and other associated comorbidities. It also looked at the socio demographic characteristics among other factors




KEY: DWRA- Diabetic women of reproductive age
HbA1c- Glycated Haemoglobin

***Figure 2: Study flow chart of diabetic patients of reproductive age at Kenyatta National Hospital***

## 6.2 Study Site and Setting

The study was carried out at the diabetic Clinic of KNH. The hospital serves the population within and around the city as well as being one of the national referral hospitals in Kenya. It also serves as the university teaching hospital for the college of Health Sciences of the University of Nairobi.

The clinic attends to about 700 diabetic patients every month. About 35% of the patients (250) are women of reproductive age.

The patient numbers have been increasing over the years plausibly because of the increase in prevalence of non-communicable disease including DM. Increased patient awareness and improvement in service delivery at the hospital could be other possible reasons for this increase Most of these patients are of middle to low socio-economic groups.

The diabetic clinic runs daily from Mondays to Fridays from 8.00 am to 4.00 pm. Patients attending the clinic are first registered and then triaged by trained nursing staff. They then receive nutritional advice and diabetes education either as a group or individually.

Venous blood sample is the taken for glucose levels on every visit. They are subsequently seen by doctors at the clinic (both registrars and consultant physicians).Relevant investigations and management modalities are administered during this time. Patients who require admission to the wards are appropriately admitted.

### 6.3 Study population

The study population is the diabetic women of reproductive age attending clinic at KNH

#### 6.3.1 Inclusion criteria

All consenting diabetic women of reproductive age between 18-49.

#### 6.3.2 Exclusion criteria

This included pregnant diabetic women as well as women who had had blood transfusion in the previous 3 months and those with hemoglobin level less than 10g/dl.

## 6.4 Sample size determination

### 6.4.1 Sample Size

Sample size was calculated using the Fisher's formula (Daniel, 1999);

$$n = \frac{Z^2 x\ P(1-P)}{d^2}$$

Where,

$n$ = Desired sample size

$Z$ = value from standard normal distribution corresponding to desired confidence level (Z=1.96 for 95% CI)

$P$ = expected true proportion (estimated at 12.5%, from a cross-sectional study conducted by Cheong et al. (2013) over a period of one year (between 1st January and 31st December 2009) extracted data of 30,427 Malaysian women with T2D from 282 public primary care clinics, where all patients included were women diagnosed with T2D for at least 1 year and were on treatment (diet control, oral anti-diabetic agents, and/or insulin), and on follow-up, found 12.5% of reproductive women i.e. age group 18-49 years, had achieved glycemic control.)

$d$ = desired precision (0.05)

$$n_0 = \frac{1.96^2 x\ 0.125(1-0.125)}{0.05^2} = 168$$

**Correcting for a finite population**

Currently in Kenyatta national hospital approximately 250 diabetic women of reproductive age are seen monthly. This amounts to approximately 500 patients within the study period of 2 months. Adjusting the sample size for finite populations less than 10,000

$$nf = \frac{n_0}{1 + \frac{n_0 - 1}{N}} = \frac{168}{1 + \frac{168-1}{500}} = 126$$

The final sample size is **126**

### 6.4.2 Sampling method

Consecutive sampling was done in that each patient who fitted into the inclusion criteria and consented to participate was enrolled into the study.

## 6.5 Data Collection

Research assistants comprising of two nursing officers and a clinical officer administered the questionnaires. The research assistants were trained on eligibility criteria, consent and enrolment issues, data collection and entry, patient confidentiality and ethical issues. A biostatistician was consulted for data entry and analysis.

### 6.5.1 Tools

Data was collected using questionnaires which captured information on patients' socio-demographic factors, their clinical characteristics and other factors influencing their glycemic control.

### 6.5.2 Laboratory Procedure

Blood sample collection was done in the laboratory. 3ml of Venous blood was collected in Ethylene diamine tetraacetic acid (EDTA) bottles using aseptic technique by a trained laboratory technologist. The blood was lysed with hemosylate for about 5minutes. An immunoassay method was used and it utilized the interaction of antigen and antibody to directly determine the HbA1C in the whole blood.

Stanbio glycohemoglobin HbA1C machine was used for this procedure. The turnaround time was about 60 minutes.

### 6.5.3 Hemoglobin A1c Test interpretation

The reference range for healthy adults is 4.8%-5.9%. For patients with DM, the goal of therapy is less than 7.0% (2)

## 6.6 DATA MANAGEMENT

Data was cleaned, entered and analyzed in SPSS version 24.

## 6.7 DATA ANALYSIS

Continuous data was analyzed and summarized as means and standard deviation while categorical data was analyzed and displayed by use of frequencies and proportions. Univariate and Multivariate analyses were used to ascertain association between glycemic control and clinical variables. P-values, odds ratio (OR) and 95% confidence intervals (CIs) were calculated. A P value less than 0.05 was considered statistically significant.

## 6.8 RESESARCH ETHICS

### 6.8.1 Ethical Approval

Approval was obtained from University of Nairobi/Kenyatta National Hospital Ethics and Research Committee (KNH/UON ERC: P533/07/2018)

### 6.8.2 Benefits of the study

The clinic attendance was not altered to favor the study. Direct benefits to the patients was the fact that the study participants were able to know their levels of glycemic control and this greatly helped determine their subsequent management.

The overall benefit of this study is expected to be in the improvement of patient care. This in turn will benefit the science community as a whole and will help shape policy issues of diabetic care among women of reproductive age both nationally and internationally.

## 7.0 RESULTS

A total of 181 patients were screened as shown in Figure 3. Those who consented to participate in the study and were finally analyzed were 176 patients. Five patients however declined, two of whom cited lack of feedback from prior unrelated studies at KNH in which they had participated. The remaining 3 patients did not give any reason for declining.

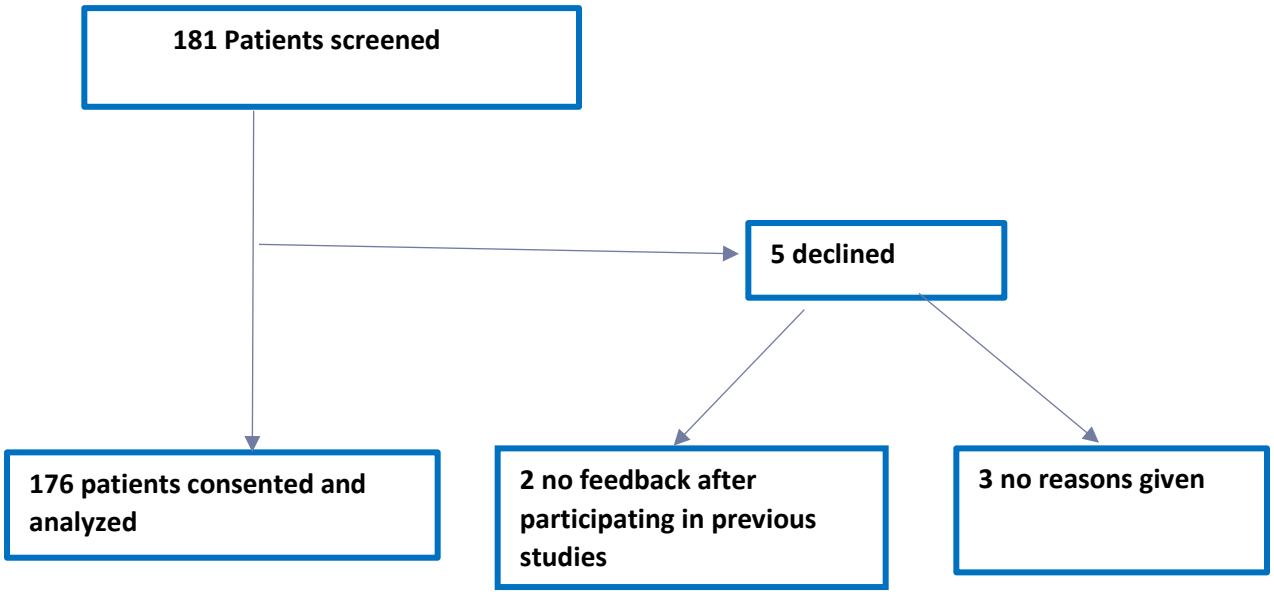
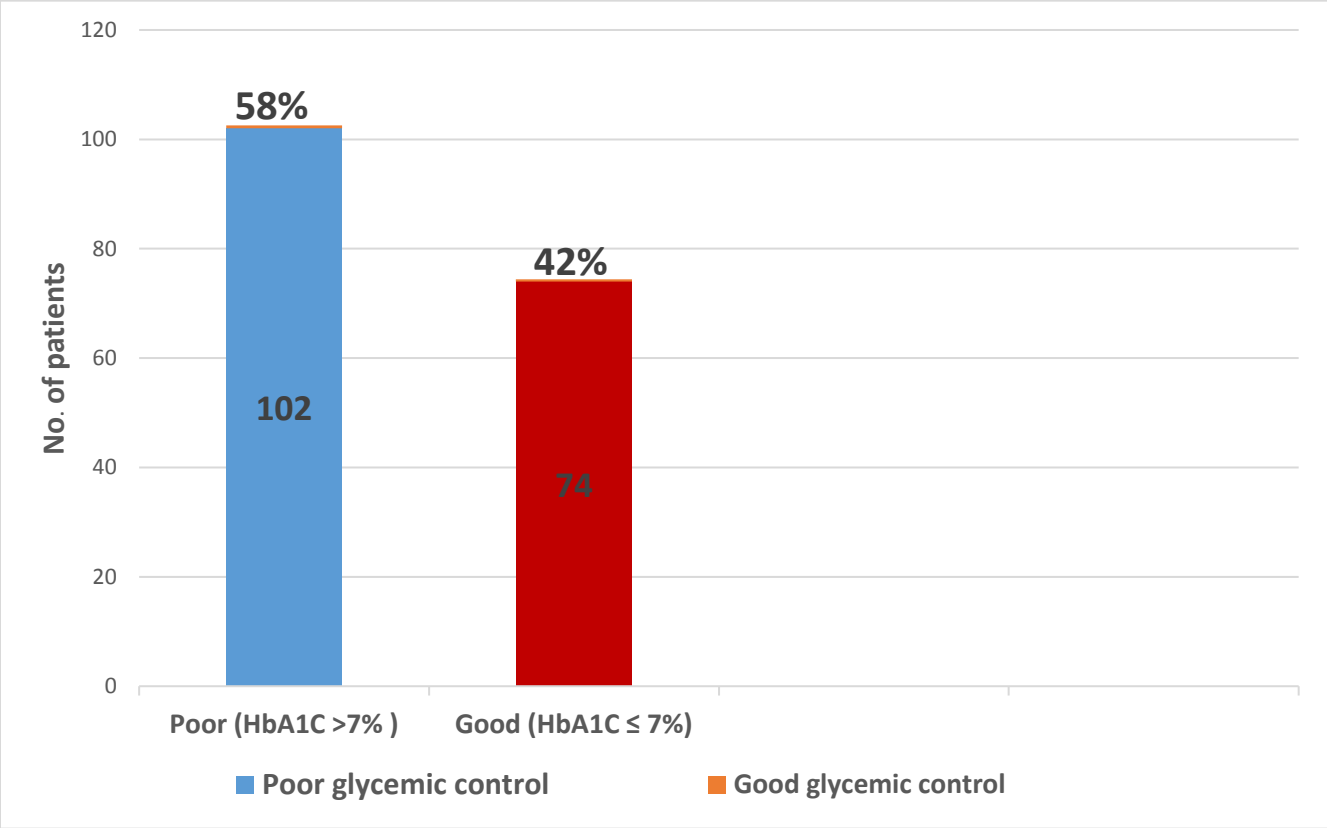



*Figure 3: Recruitment of diabetic women of reproductive age at Kenyatta National Hospital into the study*

**Prevalence of poor glycemic control**

More than half (58%) of the eligible diabetic women of reproductive age were diagnosed with poor glycemic control defined by HbA1c above 7% **(Figure 4).**

Similarly, less than half (42%) DWRA had good glycemic control defined by HbA1c levels equal to or less than 7%.




58% **(95% C.I:51%-65%)**

***Figure 4: Prevalence of poor glycemic control among diabetic women of reproductive age at Kenyatta national hospital, 2018.***

**Severity of poor glycemic control**

When the severity of poor glycemic control was evaluated, more than half (54%) of those who had poor glycemic control had their HbA1c levels between 7.1%-9%. The remaining 46% had severe poor glycemic control with HbA1c values above 9%. The mean HbA1c for patients with poor glycemic control was 9.7% (**Table 1)**

***Table 1: Severity of poor glycemic control among diabetic women of reproductive age at Kenyatta National Hospital, 2018.***

| **HbA1c** | **Frequency n (%)** |
|---|---|
| 7.1 - 9.0 | 55 (53.9) |
| Above 9.0 | 47 (46.1) |
| | |
| Mean (SD) HbA1c | 9.7 (2.23) |
| Median (IQR) HbA1c | 8.9 (3.2) |

**Key: HbA1c- Glycated Haemoglobin**

**Socio-demographic characteristics of diabetic women of reproductive age.**

Diabetic women aged 35 years and above were found to be 2.5 times as likely to have poor glycemic control compared to those aged below 35 years, OR 2.5(95% C.I.1.3-4.7; p=0.004) as shown in Table 2

Factors such as BMI, level of education, religion and marital status were not significantly associated with poor glycemic control**.**

***Table 2: Socio-demographic characteristics of DWRA with good and poor glycemic control at Kenyatta National Hospital, 2019.***

| | Frequency | | Total | OR (95%) | P-value |
|---|---|---|---|---|---|
| | Good N=74 (n%) | Poor N=102 (n%) | N=176 (n%) | | |
| **Age** | 34.5±8.9 | 38.0±8.9 | | | |
| <35 | 35 (47) | 27 (26) | 62 (35) | 2.5 (1.3-4.7) | |
| ≥35 | **39 (52)** | **75 (74)** | **114 (65)** | | **0.004** |
| **BMI** | 26.1±4.6 | 25.9±4.9 | | | |
| Underweight + Normal | 35 (47) | 46 (45) | 81 (46) | 1.1 (0.6-1.9) | 0.773 |
| Overweight +(25.1-35.0+) | 39 (52) | 56 (54) | 95 (54) | | |
| **Education** | | | | | |
| Primary and lower | 14 (18) | 26 (25) | 40 (22) | 0.7(0.3-1.4) | 0.304 |
| Secondary and above | 60 (81) | 76 (74) | 136(77) | | |
| **Religion** | | | | | |
| Christian | 72 (97) | 98 (96) | 170 (96) | 1.5(0.3-8.2) | 0.660 |
| Other | 2 (2) | 4 (3) | 6 (3) | | |
| **Marital status** | | | | | |
| Married | 47 (63) | 69 (67) | 116 (66) | 0.5 (0.1-1.7) | 0.231 |
| Single | 21 (28) | 21 (20) | 42 (23) | 0.7 (0.2-2.7) | 0.569 |
| Divorced/widowed/separated | 6 (8) | 4 (11) | 18 (10) | 1.0 | |

**Key: DWRA- Diabetic Women of Reproductive Age**

**BMI- Body Mass Index**

**Clinical correlates: DM type and comorbidities**.

Majority of study participants (76.1%) had type 2 diabetes, while 51 (29.0%) had hypertension. There were only 7 (4.0%) participants who were asthmatic, and only 4 who were HIV positive. All the comorbidities including the type of diabetes the patients had were however found not to be significantly associated with poor glycemic control **(Table 3)**

***Table 3: Clinical correlates of poor glycemic control of diabetic women of reproductive age at Kenyatta National Hospital, 2018.***

| | Frequency n (%) | | Total n(%) | OR (95% C.l) | P-value |
|---|---|---|---|---|---|
| | Good N-74 n (%) | Poor N-102 n (%) | | | |
| **Type of DM** | | | | | |
| 1 | 21 (28.4) | 21 (20.6) | 42 (23.9) | 0.7 (0.3-1.3) | 0.231 |
| 2 | 53 (71.6) | 81 (79.4) | 134 (76.1) | | |
| **Hypertension** | | | | | |
| Yes | 18 (24.3) | 33 (32.4) | 51 (29.0) | 0.7 (0.3-1.3) | 0.246 |
| No | 56 (75.7) | 69 (67.6) | 125 (71.0) | | |
| **Asthma** | | | | | |
| Yes | 5 (6.8) | 2 (2.0) | 7 (4.0) | 3.6 (0.7-19.2) | 0.108 |
| No | 69 (93.2) | 100 (98.0) | 169 (96.0) | | |
| **HIV** | | | | | |
| Yes | 1 (1.4) | 3 (2.9) | 4 (2.3) | 0.5 (0.05-4.4 | 0.485 |
| No | 73 (98.6) | 99 (97.1) | 172 (97.7 | | |

**Clinical correlates: Duration of diabetes mellitus in women of reproductive age.**

The study did a group comparison as shown by Figure 6, where the participants were grouped into those who had DM for 5 years and above, and those with duration less than 5 years. The duration of DM was found NOT to be a statistically significant factor associated with the quality of glycemic control (p=0.119).

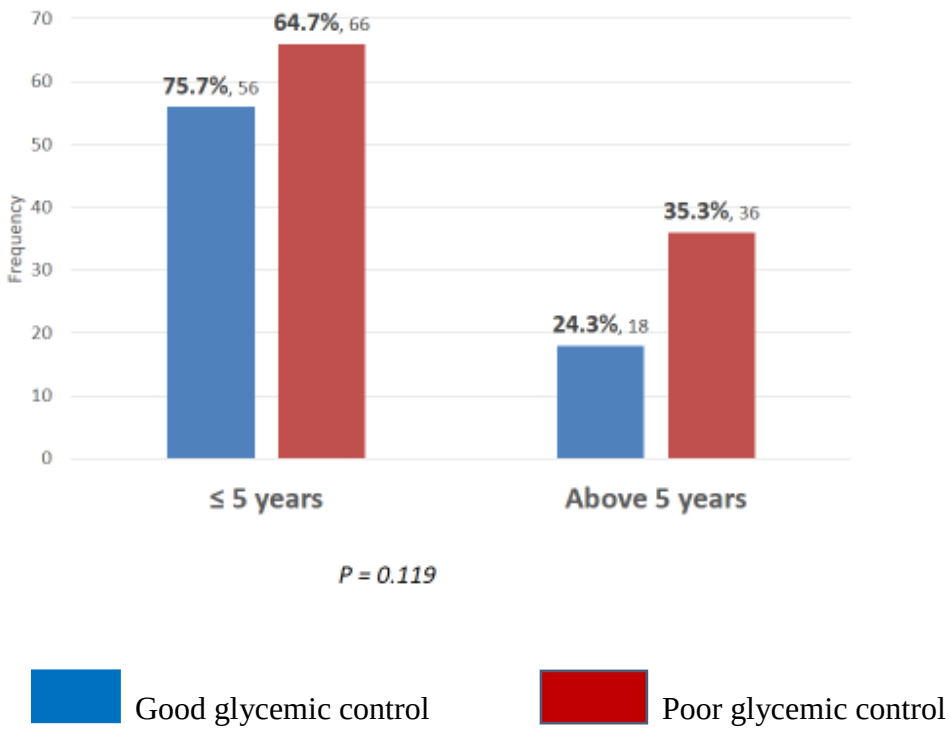
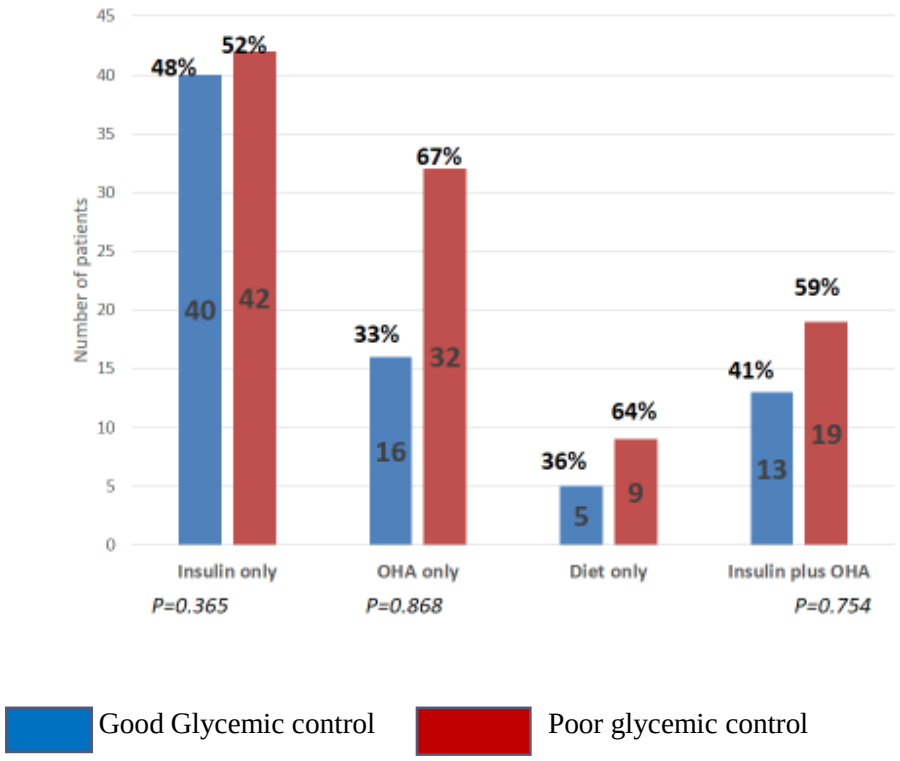



*Figure 5: Duration of diabetes mellitus in women of reproductive age at Kenyatta National Hospital, 2018.*

**Clinical correlates: Management regimen.**

The study participants described the management regime (Insulin only, OHA only, Diet only, Insulin plus OHA) they were on, and this is as shown by figure 7 below. There were no significant difference between those with poor and good glycemic control for the various management regimes.




**Key: OHA- Oral hypoglycemic agent**

***Figure 6: Management regimen of diabetic patients of reproductive age at Kenyatta national hospital, 2018.***

**Clinical correlates: Frequency of blood sugar monitoring.**

Only 39.8% of study participants had weekly testing of their blood sugars, while 18.8% didn't test at all. Patients who did not test their blood sugars at all were 80% less likely to have good glycemic control compared to those who did it daily. OR 0.2(95%C.I: 0.1-0.6; p=0.001).

Other factors such as accessibility to the diabetic clinic, diabetic drugs availability and affordability did not significantly affect the quality of glycemic control. (Table 3)

***Table 4: Comparison of Frequency of blood sugar monitoring and accessibility of diabetic services between DWRA with good and poor glycemic control at KNH, 2018.***

| | **Frequency n (%)** | | **Total n(%)** | **OR (95% C.I)** | **P-value** |
|---|---|---|---|---|---|
| | **Good N-74 n(%)** | **Poor N-102 n(%)** | | | |
| **Frequency of blood sugar monitoring** | | | | | |
| Daily | 30 (40.5) | 27 (26.5) | 57 (32.4) | 1.0 | |
| Weekly | 33 (44.6) | 37 (36.3) | 70 (39.8) | 0.8 (0.4-1.6) | 0.538 |
| Monthly | 5 (6.8) | 11 (10.8) | 16 (9.1) | 0.4 (0.1-1.3) | 0.130 |
| Don't test | **6 (8.1)** | **27 (26.5)** | **33 (18.8)** | **0.2 (0.1-0.6)** | **0.001** |
| **Diabetic clinic accessibility** | | | | | |
| Yes | 72 (97.3) | 96 (94.1) | 168 (95.5) | 0.4 (0.1-2.3) | 0.470 |
| No | 2 (2.7) | 6 (5.9) | 8 (4.5) | | |
| **Diabetic drugs availability** | N=70 | N=102 | | | |
| Yes (all drugs) | 61 (87.1) | 82 (80.4) | 143 (83.1) | 0.6 (0.3-1.4) | 0.245 |
| No | 9 (12.9) | 20 (19.6) | 29 (16.9) | | |
| **Diabetic drugs affordability** | N=70 | N=102 | | | |
| Yes | 53 (78.6) | 87 (85.3) | 142 (82.6) | 1.6 (0.7-3.5) | 0.254 |
| No | 15 (21.4) | 15 (14.7) | 30 (17.4) | | |

**Key: DWRA- Diabetic Women of Reproductive Age**

**KNH-Kenyatta National Hospital**

**Reproductive characteristics of diabetic women of reproductive age**

The association between reproductive characteristics of the study participants and poor glycemic control is shown in Table 5. Majority (78%) of the study participants were multiparous, while 99 (56%) were not on any contraceptives. There were only 8 (5%) study participants who were post-menopausal. Parity, contraceptive use and the menopausal status were not statistically significant factors associated with quality of glycemic control.

***Table 5: Reproductive characteristics of diabetic women of reproductive age at Kenyatta National Hospital, 2018.***

| | **Frequency n (%)** | | **Total n(%)** | **OR (95% Cl)** | **P-value** |
|---|---|---|---|---|---|
| | **Good N-74 n(%)** | **Poor N-102 n(%)** | | | |
| **Parity** | | | | | |
| Nulliparous | 19 (25.7) | 20 (19.6) | 39 (22.2) | 1.4 (0.7-2.9) | 0.339 |
| Multiparous | 55 (74.3) | 82 (80.4) | 137 (77.8) | | |
| **Contraceptive use** | | | | | |
| Yes | 32 (43.2) | 45 (44.1) | 77 (43.8) | 1.0 (0.6-1.9) | 0.908 |
| No | 42 (56.8) | 57 (55.9) | 99 (56.3) | | |
| **Menopausal Status** | | | | | |
| Pre-menopausal | 70 (94.6) | 98 (96.1) | 168 (95.5) | 1.4 (0.3-5.8) | 0.22 |
| Post-menopausal | 4 (5.4) | 4 (3.9) | 8 (8.5) | | |

***Table 6: Multivariate analysis of factors associated with poor glycemic control among diabetic women of reproductive age at Kenyatta National Hospital.***

| | Good control | Poor control | Multivariate analysis | | | |
|---|---|---|---|---|---|---|
| | | | OR | 95% CI for OR | | p-value |
| | | | | Lower | Upper | |
| **Age** | | | | | | |
| <35 | 35 (47.3) | 27 (26.5) | 1.973 | 0.975 | 3.989 | 0.059 |
| 35+ (Ref) | 39 (52.7) | 75 (73.5) | | | | |
| **Frequency of blood sugar monitoring** | | | | | | |
| Daily | 30 (40.5) | 27 (26.5) | 3.728 | 1.275 | 10.896 | 0.016 |
| Weekly | 33 (44.6) | 37 (36.3) | 3.660 | 1.331 | 10.062 | 0.012 |
| Monthly | 5 (6.8) | 11 (10.8) | 2.311 | 0.576 | 9.272 | 0.237 |
| Don't test (Ref) | 6 (8.1) | 27 (26.5) | | | | |

Logistic regression was performed to ascertain the effects of selected significant predictor variables on the likelihood that respondents would have good glycemic control. The predictor variables were respondent's age, and their frequency of blood sugar monitoring.

From results on Table 6 it can be seen that age (p =0.059) did not add significantly to the model. The frequency of blood sugar monitoring was dummy coded using don't test as the reference group. The daily and weekly testing had partial significant effects. This indicates that the odds of having good glycemic control for daily and weekly testing were almost 4 times higher than for the don't test.

## 8.0 DISCUSSION

This study found poor glycemic control prevalence of 58% among diabetic women of reproductive age. The age above 35 years and lack of blood sugar testing were associated with poor glycemic control.

The challenges in diabetic care among women of reproductive age may be very high in the setting of scarce resources, medical expertise and health care facilities. Therefore the observed high prevalence of poor glycemic control could be explained by several probable reasons. The supply of medication and adherence to treatment may not be optimal throughout. The patients in this study are low-income group with major economic disabilities. A study done in Kenyatta National Hospital among male and female diabetic patients by Otieno et.al, in 2003 found high prevalence of poor glycemic control of 60.5% which is comparable to the finding in this study (7). In Malaysia, Cheong, in a cross-sectional study, found a higher prevalence of poor glycemic control of 70% among younger diabetic women aged 18-49 (4). While we appreciate the difference in standards and test methods used in the otieno and cheong studies relative to our study, it is sufficient to note that a significant proportion of patients in these centers did not achieve the required levels of good glycemic control.

Diabetic women aged 35 years and above were 2.5 times as likely to have poor glycemic control compared to those aged below 35 years. The more plausible inference from this observation is that older patients could be having a worse beta cell functional reserve compared to younger patients and hence higher likelihood of poorer glycemic control (). A study in Tanzania found older women above 40 years to be having significantly higher prevalence of poor glycemic control levels of 76 % (17). In Singapore, however, older age above 45 years was associated with good glycemic control (19). This was attributed to the fact that elderly patients have better

understanding of management of their blood sugar, having lived with the condition presumably for long. Studies in Kenya and Malaysia, however, reported that age did not have statistical significance as far as quality of glycemic control is concerned (4, 7). This implied that other factors were responsible for the high prevalence of poor glycemic control. The observed differences in association between age and poor glycemic control could plausibly be explained by the difference in population characteristics and distribution of age in different studies as well as factors like lifestyle, diet and exercise.

Diabetic women of reproductive age who don't test their blood sugar levels were 80% less likely to have good control. This finding could be explained by the fact that most patients in our study were drawned from low socio-economic backgrounds and therefore, affordability of glucometers and reagent strips could be a serious concern. Thus they become prone to poor glycemic control and the antecedent complications. Similar findings were reported in a retrospective case-control study by Wanjohi et.al in Machakos, Kenya among type 2 diabetic patients. They found that type 2 DM patients who did not monitor their blood glucose levels regularly had an increased risk of poor glycemic control compared to those who did regular blood sugar monitoring (OR 5.35, 95% CI 2.09-13.72) (20). On the contrary, a Malaysian study done on type 2 diabetics by Ahmad et.al in 2014 did not find significant association between the frequency of blood sugar monitoring and quality of glycemic control (21).

Patients were categorized into 2 groups regarding the duration of their diabetic illness; those with duration less than or equal to 5 years and those above 5 years. It was noted that the duration of Diabetes Mellitus was not a statistically significant factor associated with the quality of glycemic control. This implied that other factors could be responsible for the observed differences. A similar observation was noted in a Kenyan study (7). Other studies on diabetic patients however

have shown a positive association between the diabetes duration and quality of glycemic control for example in Malaysia (4) and Ethiopia (18).This is probably because longer duration of diabetes has been be associated with poor glycemic control, possibly due to progressive impairment of insulin secretion with time because of the failure of β-cells. This, together with increased insulin resistance leads to eventual decrease in insulin secretion.

Management regimen that the patients were put on prior to the study did not have any statistical significance as far as glycemic control was concerned. This finding is concurrent with observations in a Malaysian study by Cheong et.al, in 2013 (4). There is however differences reported in other studies for example in Kenya, Otieno et.al found that the likelihood of poor glycemic control was lowest in patients on diet-only therapy possibly because these patients had better endogenous insulin production (7). In the same study, patients on oral hypoglycemic agents only therapy had the highest likelihood of poor glycemic control. Lack of an association between the type of treatment and glycemic control in our study could be due to the fact that only a small proportion (18%) of the study participants were using a combination of oral hypoglycemic agents (OHA) and insulin. Since a better glycemic control is usually achieved through the use of insulin in combination with OHA, it is therefore likely that the limited use of OHA and insulin may have contributed to poor glycemic control.

Level of education, marital status and religion had no significant association with the quality of glycemic control. This finding is concurrent with observations made in Malaysia by Cheong et.al (4) and in Ethiopia by Woldu et.al (15). Although our study did not find a direct association between glycemic control and factors such as level of education and other socio-demographic variables, such variables are likely to affect patients access to quality healthcare and could

consequently have a direct effect on glycemic control for example, educated women may have a well-integrated and comprehensive medical care compared to those who are less educated.

Hypertension was found to be the most frequent comorbidity among diabetic women of reproductive age. This is consistent with the established theory of metabolic syndrome. Similar to other studies done in Kenya and Tanzania there was no significant association between hypertension and poor glycemic control (7, 17).

Reproductive characteristics such as parity, contraceptive use and menopausal status were not significantly associated to poor glycemic control in this study. There are however very few studies which have looked at the association between reproductive characteristics and poor glycemic control among diabetic women. In Bangladesh, Tasira et.al in 2015 found that contraceptive use was not associated with poor glycemic control among women who became pregnant and developed gestational diabetes mellitus (22).

# 9.0 CONCLUSION AND RECOMMENDATION

## 9.1 Conclusion

In conclusion we demonstrate that there is high prevalence of poor glycemic control among diabetic women of reproductive age at Kenyatta National Hospital. Older patients aged 35 years and above are two and a half times as likely to have poor glycemic control compared to those below the age of 35. Additionally diabetic women of reproductive age who don't test their blood sugar levels are less likely to have good glycemic control.

## 9.2 Strengths and Limitations

A key strength of this study was the fact that it was the first study in this setting and region to determine the quality of glycemic control among diabetic women of reproductive age. The fact that the sample size was adequate and we had access to patient medical records is another strength. The main limitation, however was the inability to determine temporal association between exposure and outcome, being a cross-sectional study.

## 9.3 Recommendations

There is great need to optimize glycemic control in diabetic women of reproductive age, particularly those above 35 years of age. This can be done through programmatic and policy interventions such as training of more healthcare workers, having appropriate diabetes infrastructure and equipment as well as ensuring there is constant supplies for diabetes care. Additionally there is need to address barriers to regular blood sugar testing. This could mean placing a lot emphasis on factors such as patient education, availability and affordability of blood sugar testing kits among other factors.

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## 11.0 ANNEXES

### ANNEX 1: QUESTIONNAIRE (ENGLISH VERSION)

Quality of glycemic control among diabetic women of reproductive age.

Fill in the blank spaces and tick in the appropriate response given.

1. Age of patient in years…….
2. Weight of patient in Kg…….
3. Height of patient in cm……..
4. Highest level of education……

| | |
|---|---|
| Primary | ☐ |
| Secondary | ☐ |
| Post-secondary | ☐ |
| Other (specify) | ☐ |

5. Religion/faith

| | |
|---|---|
| Christian | ☐ |
| Muslim | ☐ |
| Hindu | ☐ |
| Other (specify) | ☐ |

6. Marital status

| | |
|---|---|
| Married | ☐ |
| Single | ☐ |
| Divorce | ☐ |
| Window | ☐ |
| | ☐ |

Separated
Other (Specify) ☐

7. Duration of diabetes

   For how long have you had Diabetes?

   Days…….

   Weeks……..

   Months…….

   Years……

8. Diabetes and co-morbidities

   Do you have any history of

| | | |
|---|---|---|
| a) Hypertension | Yes ☐ | No ☐ |
| b) Asthma | Yes ☐ | No ☐ |
| C) Stroke | Yes ☐ | No ☐ |
| d) HIV | Yes ☐ | No ☐ |
| e) Sickle cell disease | Yes ☐ | No ☐ |

9. Current Treatment/Advice /Mode of glycemic control

   Which of the following regimens are you using?

a) Insulin only, specify types ☐
b) OHA only, specify types ☐
c) Diet only ☐
d) Insulin+OHA, specify types ☐
e) Other (specify) ☐

10. How often do you need blood sugar test (RBs or FBs)?

Daily ☐

Weekly ☐

Don't test ☐

Others

11. Is the diabetic clinic easy to access?

Yes ☐

No ☐

12. Are diabetic drugs affordable to you?

Yes ☐

No ☐

13. Are diabetic drugs always available?

Yes (all drugs) ☐

Yes (some drugs) ☐

No ☐

Other (specify) ☐

## ANNEX 2: HOJAJI (SWAHILI)

Ubora wa hali kisasa ya kudhibiti kisukari miongoni mwa wanawake walio katika umri wa kupata watoto.

Jaza nafasi uliyopewa na pia kuweka mkwanju kwa jibu mwafaka.

9. Umri wa mgonjwa kwa miaka…….

10. Uzan wa mgonjwa kwa kilo…….

11. Urefu wa mgonjwa kwa sentmita……..

12. Kiwango cha juu cha elimu……

- Elimu ya msingi ☐
- Elimu ya sekondari ☐
- Zaidi ya elimu ya sekondari ☐
- Nyingine (bainisha) ☐

13. Dini/Imani

- Ukristo ☐
- Uislamu ☐
- Hindu ☐
- Nyingine (bainisha) ☐

14. Ndoa

- Nimeolewa ☐
- Bado kuolewa ☐
- Tumetarakiana ☐
- Mjane ☐
- Tumetengana ☐

Nyingine (bainisha) ☐

15. Muda wa kuishi na kisukari

Umekuwa na kisukari kwa muda gani?

Siku…….

Juma……..

Miezi…….

Miaka……

16. Hali nyingine za kiafya zinazoandamana na kisukari

Una historia ya hali zifuatazo

a) Mpumko wa damu Ndiyo ☐ La ☐

b) Pumu Ndiyo ☐ La ☐

C) Upoozaji Ndiyo ☐ La ☐

d) Virusi vya Ukimwi Ndiyo ☐ La ☐

e) Maradhi ya selimundu Ndiyo ☐ La ☐

9. Tiba ya sasa/Ushauri/Mtindo wa kisasa wa kudhibiti

Ni taratibu gani unaotumia kati ya zifuatazo?

f) Insulini pekee, bainisha aina ☐

g) OHA pekee, bainisha aina ☐

h) Lishe pekee ☐

i) Insulini+OHA, bainisha aina ☐

j) Nyingine (bainisha) ☐

10. Huhitaji upimaji damu mara ngapi (RBs au FBs)?

Kila siku ☐

Kila juma ☐

Sipimi ☐

Nyingine

11.Unaifikia kiliniki ya kisukari kwa wepesi?

Ndiyo ☐

La ☐

12. Unaweza kugharamia dawa za kisukari?

Ndiyo ☐

La ☐

13. Dawa za kisukari zinapatikana kwa wepesi?

Ndiyo (dawa za aina zote) ☐

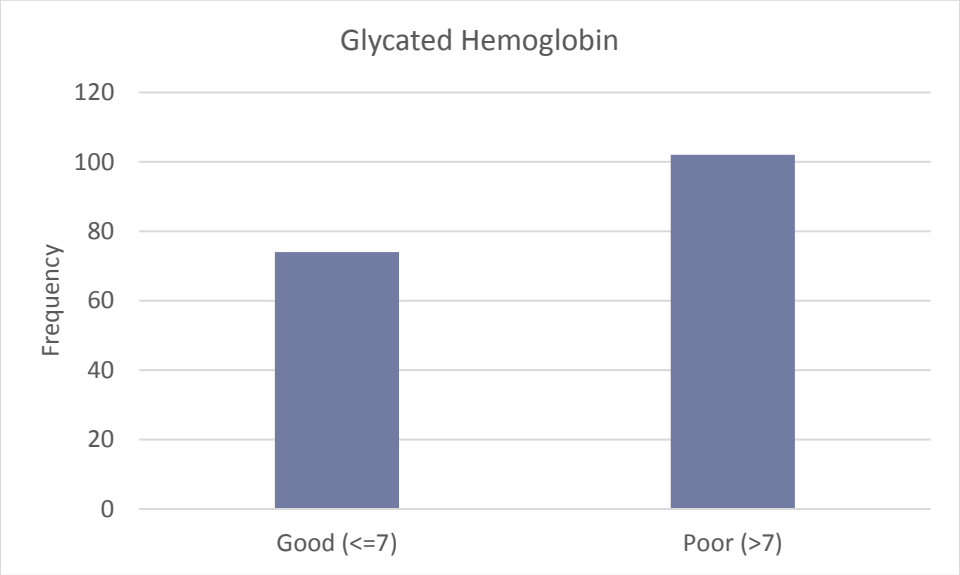
Ndiyo (baadhi) ☐

La ☐

Nyingine (bainisha) ☐

## ANNEX 3: DUMMY TABLES AND FIGURES

**Prevalence of poor glycemic control**



**Socio-Demographic characteristics by quality control**

| | Frequency n (%) | | Total n (%) | OR (95% CI) | p-value |
|---|---|---|---|---|---|
| | Good | Poor | | | |
| **Age** | | | | | |
| <35 | | | | | |
| ≥35 | | | | | |
| **BMI** | | | | | |
| Underweight + Normal (16.0-25.0) | | | | | |
| Overweight+ (25.1-35.0+) | | | | | |
| **Education** | | | | | |
| Primary and lower | | | | | |
| Secondary and above | | | | | |
| **Religion** | | | | | |
| Christian | | | | | |
| Other | | | | | |
| **Marital status** | | | | | |
| Married | | | | | |
| Single | | | | | |
| Divorced/Widowed/Separated | | | | | |

**Reproductive characteristics and clinical correlates of diabetic women of reproductive age**

| | Frequency n (%) | | Total n (%) | OR (95% CI) | p-value |
|---|---|---|---|---|---|
| | Good | Poor | | | |
| **Parity** | | | | | |
| Nulliparous | | | | | |
| Multiparous | | | | | |
| **Contraceptive use** | | | | | |
| Yes | | | | | |
| No | | | | | |
| **Menopausal** | | | | | |
| Pre-menopausal | | | | | |
| Post-menopausal | | | | | |
| **Frequency of blood sugar monitoring** | | | | | |
| Daily | | | | | |
| Weekly | | | | | |
| Monthly | | | | | |

**Clinical correlates of diabetic women of reproductive age**

| | Frequency n (%) | | Total n (%) | OR (95% CI) | p-value |
|---|---|---|---|---|---|
| | Good | Poor | | | |
| **Type of DM** | | | | | |
| 1 | | | | | |
| 2 | | | | | |
| **Family history of diabetes** | | | | | |
| Yes | | | | | |
| No | | | | | |
| **Hypertension** | | | | | |
| Yes | | | | | |
| No | | | | | |
| **Asthma** | | | | | |
| Yes | | | | | |
| No | | | | | |
| **HIV** | | | | | |
| Yes | | | | | |
| No | | | | | |

## ANNEX 4: STUDY TIME FRAME

| Task | 2018 | | | | | | | | 2019 | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | April | May | June | July | Aug | Sept | Oct | Nov | Dec | Jan | Feb |
| Concept Note | | | | | | | | | | | |
| Proposal writing | | | | | | | | | | | |
| Proposal Presentation | | | | | | | | | | | |
| Ethics Approval | | | | | | | | | | | |
| Data Collection | | | | | | | | | | | |
| Data Analysis and Presentation | | | | | | | | | | | |
| Report Writing | | | | | | | | | | | |
| Dissemination of Findings | | | | | | | | | | | |

## ANNEX 5: BUDGET

| ITEM | QUANTITY | UNIT COST(Ksh) | TOTAL (Ksh) |
|---|---|---|---|
| Proposal printing | 35 | 10 | 350 |
| Photocopy of proposal | 35x3 | 3 | 315 |
| Proposal binding | 3 Copies | 100 | 300 |
| HBA1C Test | 185 Patients | 1000 | 185,000 |
| Printing of questionnaire | 3 | 10 | 30 |
| Photocopy of questionnaire | 3x185 | 3 | 1,665 |
| Printing of results | 3 Copies | 200 | 600 |
| Binding of results | 3 Copies | 100 | 300 |

**CONTRACTED SERVICES**

| | | | |
|---|---|---|---|
| Statistician | 1 | 30,000 | 30,000 |
| Research Assistants | 3 | 15,000 | 45,000 |

**COMMUNICATION**

| | | | |
|---|---|---|---|
| Email and phone calls | | 5,000 | 5,000 |
| Publication | | 50,000 | 50,000 |
| Contingency, (15%) | | | 47,784 |
| TOTAL | | | 366,784 |

## ANNEX 6: CONSENT INFORMATION (English version)

I am Dr. Justus Nondi, a postgraduate student in the department of Obsterics and Gynecology at the University of Nairobi. I am carrying out a study as part of the requirement of Masters of medicine degree in Obsterics and Gynecology.

Study Title: Quality of glycemic control among diabetic women of reproductive age at Kenyatta National Hospital, a cross-sectional study.

**Principal Investigator**: Dr.Justus Nondi Tel: 0720252041

**Supervisors:** 1- Dr. Kizito Lubano

2-Dr. Alfred Osoti

**Purpose of study**: To determine the quality of and factors influencing glycemic control among diabetic women of reproductive age at Kenyatta national hospital

**Study procedure**: A standardized structured questionnaire will be administered. Blood samples will then be obtained from the patients for HbA1c determination.

The data will then be analyzed to realize the objectives of the study.

Study approval has been given by the Kenyatta National Hospital/University of Nairobi ethics committee {KNH/UON-ERC}

I am requesting your participation in this study. I would like to bring to your attention the following ethical considerations which will guide your participation.

1. Participation in this study is purely voluntary.
2. This study carries no risk or cost to you.
3. You may withdraw at any point of the study there won't be any consequences for your decision to withdraw.
4. Any information you provide including details on your demographic characteristics will be treated as confidential.
5. There is no compensation for participation in this study; you will receive the same standard of care as any other person attending this hospital.
6. The benefits of this study is in the fact that more information is likely to be generated to assist in comprehensive management of diabetic women of reproductive age

Signing the consent form indicates that you have read the consent form, that your question have been answered to your satisfaction, and that you voluntarily agree to participate in this research study. You will receive a copy of the signed consent form.

**For further information please contact:**

Dr. Justus Nondi

Tel: 0720252041

Email: jmnondi@gmail.com

Kenyatta University Hospital/UoN Ethics Committee

P.O Box 20,732-00,202

Tel: (254) 020 7263 00 EXT 44102, 44,355

E-mail: uonknh_erc@uonbi.ac.ke

I, the undersigned, do hereby consent to participate in this study whose nature, purpose and objectives have been fully explained to me. I am aware that participation is voluntary and that there are no consequences to withdrawal from the study. I have been informed that all data provided will be used for the purposes of study only.

Signed……..
Date……

**DECLARATION STATEMENT**

I,……
……declare that I have adequately explained to participant the purpose of the study and the procedures. I have given the participant time to ask questions and seek clarification regarding the study.

Signed……
Date…….

**CONTACTS**

Dr. Justus Nondi- Principal investigator

0720252041

Jmnondi@gmail.com

Dr Alfred Osoti- supervisor

0733886664

alredos@uw.edu

Dr. Kizito Lubano

0722737293

lubanokizito@yahoo.com

## ANNEX 7: HABARI KUHUSU UKUBALIFU (SWAHILI)

Mimi ni Daktari Justus Nondi, mwanafunzi wa Shahada ya pili katika Idara ya Ukunga na Ginakolojia, Chuo Kikuu Cha Nairobi. Ninafanya utafiti kama mojawapo ya mahitaji ya Shahada ya Uzamili katika tiba ya Ukunga na Ginakolojia.

Anwani ya Utafiti: **Ubora wa hali za kisasa za kudhibiti kisukari miongoni mwa wanawake walio katika umri wa kupata watoto katika Hospitali ya Kitaifa ya Kenyatta, utafiti unaotanda Nyanja mbalimbali.**

**Mtafiti Mkuu**: Dkt.JustusNondi. Nambari ya Simu: 0720252041

**Wasimamizi:** 1- Dkt. KizitoLubano

2-Dkt. Alfred Osoti

**Lengo la Utafiti**: Kubainsha hadhi ya  na mambo ambayo huathiri ubora wa hali za kisasa za kudhibiti kisukari miongoni mwa wanawake walio katika umri wa kupata watoto  katika Hospitali ya Kitaifa ya Kenyatta.

**Utaratibu wa Utafiti**: Hojaji yenye maswali yaliyosawasishwa itatolewa kwa walengwa. Sampuli za damu zitatolewa kwa wagonjwa ili kubainisha HbA1c.

Data itachanganuliwa kwa muujibu wa shabaha za utafiti.

Idhini ya utafiti  imetolewa na Hospitali Ya Kitaifa ya Kenyatta / Kamati Ya Maadili ya Chuo Kikuu Cha  Nairobi {KNH/UON-ERC}

Ninaomba ushiriki katika uchunguzi huu. Ningependa kukufahamisha kuhusu maadili yatakaoongoza kushiriki kwako katika uchunguzi huu.

1. Kushiriki katika uchunguzi huu ni kwa  hiari.
2. Uchunguzi huu hauna hatari au gharama kwako.
3. Unaweza kuondoka kushiriki kwako katika hatua yoyote ya utafiti na hamna matokeo yoyote kutokana na uamuzi wako wa kuondoka.
4. Habari yoyote utakayotoa ikijumuisha habari kukuhusu kidemografia zitakuwa ni siri na hazitatolewa kwa yoyote.
5. Hakuna malipo kwa kushiriki katika utafiti; Utapata matibabu kama mtu mwingine anayetafuta matibabu katika hospitali hii.
6. Manufaa ya utafiti huu ni kuwa kuna uwezekano wa kuchangia nyongeza ya habari katika udhibiti na usimamizi kamili wa kisukari miongoni mwa wanawake walio katika umri wa kupata watoto.

Kutia sahihi fomu ya ukubalifu ni ishara kuwa umesoma fomu hii na kuelewa, swali lako katika ushiriki limeweza kujibiwa kwa utoshelevu, na kuwa unakubali kwa hiari kushriki katika utafiti huu. Utapokea nakala ya fomu iliyotiwa sahihi.

**Kwa maelezo zaidi, wasiliana na:**

Daktari. Justus Nondi

Namba ya simu: 0720252041

Anwani ya mdahilishi: jmnondi@gmail.com

Hospitali ya Kitaifa ya Kenyatta /Kamati ya Maadili ya Chuo kikuu cha Nairobi.

S.L. Posta 20,732-00,202

Namba ya simu: (254) 020 7263 00 Mkondo 44102, 44,355

Anwani ya mdahilishi: uonknh_erc@uonbi.ac.ke

Mimi, niliyetia sahihi, nakubali kushiriki katika utafiti huu ambao utaratibu azima na malengo yake yamefafanuliwa kikamilifu kwangu. Ninafahamu kuwa kushiriki kwangu ni kwa hiari na kuwa hamna matokeo yoyote kwa kujitoa kwangu kushiriki katika utafiti. Nimefahamishwa kuwa data itakayopatikana itatumika kwa ajili ya azma ya utafiti pekee.

Sahihi……..
Tarehe……

**KAULI YA UKUBALIFU**

Mimi,…….
…….nakubali kuwa nimetoa maelezo kikamilifu kwa mshiriki kuhusu azima ya utafiti huu na taratibu zake. Nimempa mshiriki muda wa kuuliza maswali na kusaka ufafanuzi kuhusu utafiti huu.

Sahihi……
Tarehe…….

Wakuwasiliana nao

Dkt. Justus Nondi-  Mtafiti Mkuu

0720252041

Jmnondi@gmail.com

Dkt Alfred Osoti-  Msimamizi

0733886664

alredos@uw.edu

Dkt. KizitoLubano

0722737293

lubanokizito@yahoo.com

## ANNEX 8: ETHICAL APPROVAL LETTER

UNIVERSITY OF NAIROBI
COLLEGE OF HEALTH SCIENCES
P O BOX 19676 Code 00202
Telegrams: varsity
Tel:(254-020) 2726300 Ext 44355

KENYATTA NATIONAL HOSPITAL APPROVED 16 OCT 2018 KNH/UoN-ERC P.O. Box 20723-00202 NAIROBI

KNH-UON ERC
Email: uonknh_erc@uonbi.ac.ke
Website: http://www.erc.uonbi.ac.ke
Facebook: https://www.facebook.com/uonknh.erc
Twitter: @UONKNH_ERC https://twitter.com/UONKNH_ERC

KENYATTA NATIONAL HOSPITAL
P O BOX 20723 Code 00202
Tel: 726300-9
Fax: 725272
Telegrams: MEDSUP, Nairobi

Ref: KNH-ERC/A/372

16th October 2018

Dr. Justus Malowa Nondi
Reg. No.H58/74123/2014
Dept.of Obs/Gynae
School of Medicine
College of Health Sciences
University of Nairobi

Dear Dr. Nondi

**RESEARCH PROPOSAL – QUALITY OF GLYCEMIC CONTROL AMONG DIABETIC WOMEN OF REPRODUCTIVE AGE AT KENYATTA NATIONAL HOSPITAL, A CROSS-SECTIONAL STUDY (P533/07/2018)**

This is to inform you that the KNH- UoN Ethics & Research Committee (KNH- UoN ERC) has reviewed and **approved** your above research proposal. The approval period is 16th October 2018 – 15th October 2019.

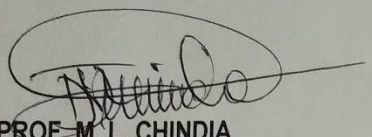
This approval is subject to compliance with the following requirements:

a) Only approved documents (informed consents, study instruments, advertising materials etc) will be used.
b) All changes (amendments, deviations, violations etc) are submitted for review and approval by KNH-UoN ERC before implementation.
c) Death and life threatening problems and serious adverse events (SAEs) or unexpected adverse events whether related or unrelated to the study must be reported to the KNH-UoN ERC within 72 hours of notification.
d) Any changes, anticipated or otherwise that may increase the risks or affect safety or welfare of study participants and others or affect the integrity of the research must be reported to KNH- UoN ERC within 72 hours.
e) Clearance for export of biological specimens must be obtained from KNH- UoN ERC for each batch of shipment.
f) Submission of a request for renewal of approval at least 60 days prior to expiry of the approval period. (*Attach a comprehensive progress report to support the renewal*).
g) Submission of an *executive summary* report within 90 days upon completion of the study. This information will form part of the data base that will be consulted in future when processing related research studies so as to minimize chances of study duplication and/ or plagiarism.

For more details consult the KNH- UoN ERC website **http://www.erc.uonbi.ac.ke**

Protect to discover

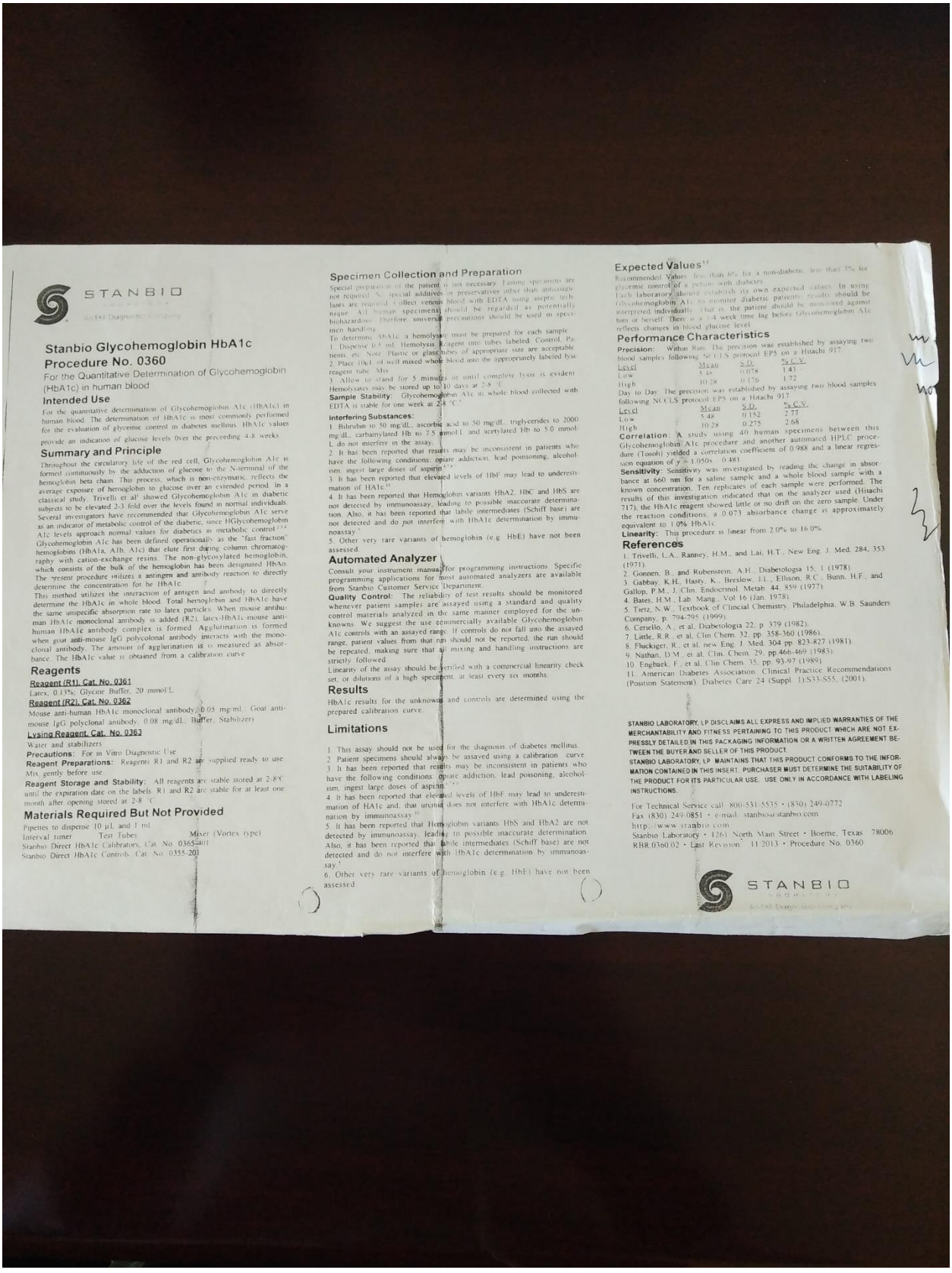
Yours sincerely,



**PROF. M. L. CHINDIA**
**SECRETARY, KNH-UoN ERC**

c.c. The Principal, College of Health Sciences, UoN
The Director, CS, KNH
The Chairperson, KNH-UON ERC
The Assistant Director, Health Information, KNH
The Dean, School of Medicine, UoN
The Chairperson, Dept. of Obstetrics and Gynaecology, UoN
Supervisors: Dr. Alfred Osoti, Dr. Kizito Lubano

## ANNEX 9: HBA1C MACHINE LITERATURE



STANBIO

### Stanbio Glycohemoglobin HbA1c
### Procedure No. 0360

For the Quantitative Determination of Glycohemoglobin (HbA1c) in human blood

#### Intended Use

For the quantitative determination of Glycohemoglobin A1c (HbA1c) in human blood. The determination of HbA1c is most commonly performed for the evaluation of glycemic control in diabetes mellitus. HbA1c values provide an indication of glucose levels over the preceeding 4-8 weeks.

#### Summary and Principle

Throughout the circulatory life of the red cell, Glycohemoglobin A1c is formed continuously by the adduction of glucose to the N-terminal of the hemoglobin beta chain. This process, which is non-enzymatic, reflects the average exposure of hemoglobin to glucose over an extended period. In a classical study, Trivelli et al[1] showed Glycohemoglobin A1c in diabetic subjects to be elevated 2-3 fold over the levels found in normal individuals. Several investigators have recommended that Glycohemoglobin A1c serve as an indicator of metabolic control of the diabetic, since HGlycohemoglobin A1c levels approach normal values for diabetics in metabolic control[2,3,4]. Glycohemoglobin A1c has been defined operationally as the "fast fraction" hemoglobins (HbA1a, A1b, A1c) that elute first during column chromatography with cation-exchange resins. The non-glycosylated hemoglobin, which consists of the bulk of the hemoglobin has been designated HbA0. The present procedure utilizes a antingen and antibody reaction to directly determine the concentration fot he HbA1c.

This method utilizes the interaction of antigen and antibody to directly determine the HbA1c in whole blood. Total hemoglobin and HbA1c have the same unspecific absorption rate to latex particles. When mouse antihuman HbA1c monoclonal antibody is added (R2), latex-HbA1c-mouse anti-human HbA1c antibody complex is formed. Agglutination is formed when goat anti-mouse IgG polyclonal antibody interacts with the monoclonal antibody. The amount of agglutination is is measured as absorbance. The HbA1c value is obtained from a calibration curve.

#### Reagents

**Reagent (R1), Cat. No. 0361**
Latex, 0.13%, Glycine Buffer, 20 mmol/L.

**Reagent (R2), Cat. No. 0362**
Mouse anti-human HbA1c monoclonal antibody, 0.05 mg/mL. Goat anti-mouse IgG polyclonal antibody, 0.08 mg/dL. Buffer, Stabilizers.

**Lysing Reagent, Cat. No. 0363**
Water and stabilizers

**Precautions:** For in Vitro Diagnostic Use.

**Reagent Preparations:** Reagents R1 and R2 are supplied ready to use. Mix gently before use.

**Reagent Storage and Stability:** All reagents are stable stored at 2-8°C until the expiration date on the labels. R1 and R2 are stable for at least one month after opening stored at 2-8 °C.

#### Materials Required But Not Provided

Pipettes to dispense 10 µL and 1 ml.
Interval timer. Test Tubes. Mixer (Vortex type)
Stanbio Direct HbA1c Calibrators, Cat. No. 0365-201
Stanbio Direct HbA1c Controls, Cat. No. 0355-201

#### Specimen Collection and Preparation

Special preparation of the patient is not necessary. Fasting specimens are not required. No special additives or preservatives other than anticoagulants are required. Collect venous blood with EDTA using aseptic technique. All human specimens should be regarded as potentially biohazardous. Therfore, universal precautions should be used in specimen handling.

To determine HbA1c a hemolysate must be prepared for each sample.
1. Dispense 0.5 ml. Hemolysis Reagent into tubes labeled: Control, Patients, etc. Note: Plastic or glass tubes of appropriate size are acceptable.
2. Place 10µl of well mixed whole blood into the appropriately labeled lysis reagent tube. Mix.
3. Allow to stand for 5 minutes or until complete lysis is evident.

Hemolysates may be stored up to 10 days at 2-8 °C.

**Sample Stability:** Glycohemoglobin A1c in whole blood collected with EDTA is stable for one week at 2-8 °C.[5]

**Interfering Substances:**
1. Bilirubin to 50 mg/dL, ascorbic acid to 50 mg/dL, triglycerides to 2000 mg/dL, carbamylated Hb to 7.5 mmol/L and acetylated Hb to 5.0 mmol/L do not interfere in the assay.
2. It has been reported that results may be inconsistent in patients who have the following conditions: opiate addiction, lead poisoning, alcoholism, ingest large doses of aspirin.[6,7]
3. It has been reported that elevated levels of HbF may lead to underestimation of HA1c.[8]
4. It has been reported that Hemoglobin variants HbA2, HbC and HbS are not detected by immunoassay, leading to possible inaccurate determination. Also, it has been reported that labile intermediates (Schiff base) are not detected and do not interfere with HbA1c determination by immunoassay.[9]
5. Other very rare variants of hemoglobin (e.g. HbE) have not been assessed.

#### Automated Analyzer

Consult your instrument manual for programming instructions. Specific programming applications for most automated analyzers are available from Stanbio Customer Service Department.

**Quality Control:** The reliability of test results should be monitored whenever patient samples are assayed using a standard and quality control materials analyzed in the same manner employed for the unknowns. We suggest the use commercially available Glycohemoglobin A1c controls with an assayed range. If controls do not fall into the assayed range, patient values from that run should not be reported; the run should be repeated, making sure that all mixing and handling instructions are strictly followed.

Linearity of the assay should be verified with a commercial linearity check set, or dilutions of a high specimen, at least every six months.

#### Results

HbA1c results for the unknowns and controls are determined using the prepared calibration curve.

#### Limitations

1. This assay should not be used for the diagnosis of diabetes mellitus.
2. Patient specimens should always be assayed using a calibration curve.
3. It has been reported that results may be inconsistent in patients who have the following conditions: opiate addiction, lead poisoning, alcoholism, ingest large doses of aspirin.[6,7]
4. It has been reported that elevated levels of HbF may lead to underestimation of HA1c and, that uremia does not interfere with HbA1c determination by immunoassay.[8]
5. It has been reported that Hemoglobin variants HbS and HbA2 are not detected by immunoassay, leading to possible inaccurate determination. Also, it has been reported that labile intermediates (Schiff base) are not detected and do not interfere with HbA1c determination by immunoassay.[9]
6. Other very rare variants of hemoglobin (e.g. HbE) have not been assessed.

#### Expected Values[11]

Recommended Values: less than 6% for a non-diabetic, less than 7% for glycemic control of a person with diabetes.

Each laboratory should establish its own expected values. In using Glycohemoglobin A1c to monitor diabetic patients, results should be interpreted individually. That is, the patient should be monitored against him or herself. There is a 3-4 week time lag before Glycohemoglobin A1c reflects changes in blood glucose level.

#### Performance Characteristics

**Precision:** Within Run: The precision was established by assaying two blood samples following NCCLS protocol EP5 on a Hitachi 917.

| Level | Mean | S.D. | % C.V. |
|---|---|---|---|
| Low | 5.48 | 0.078 | 1.43 |
| High | 10.28 | 0.176 | 1.72 |

Day to Day: The precision was established by assaying two blood samples following NCCLS protocol EP5 on a Hitachi 917.

| Level | Mean | S.D. | % C.V. |
|---|---|---|---|
| Low | 5.48 | 0.152 | 2.77 |
| High | 10.28 | 0.275 | 2.68 |

**Correlation:** A study using 40 human specimens between this Glycohemoglobin A1c procedure and another automated HPLC procedure (Tosoh) yielded a correlation coefficient of 0.988 and a linear regression equation of y = 1.050x - 0.481.

**Sensitivity:** Sensitivity was investigated by reading the change in absorbance at 660 nm for a saline sample and a whole blood sample with a known concentration. Ten replicates of each sample were performed. The results of this investigation indicated that on the analyzer used (Hitachi 717), the HbA1c reagent showed little or no drift on the zero sample. Under the reaction conditions, a 0.073 absorbance change is approximately equivalent to 1.0% HbA1c.

**Linearity:** This procedure is linear from 2.0% to 16.0%.

#### References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11. American Diabetes Association. Clinical Practice Recommendations (Position Statement). Diabetes Care 24 (Suppl. 1):S33-S55, (2001).





For Technical Service call: 800-531-5535 • (830) 249-0772
Fax (830) 249-0851 • e-mail: stanbio@stanbio.com
http://www.stanbio.com
Stanbio Laboratory • 1261 North Main Street • Boerne, Texas 78006



RRR 0360.02 • Last Revision: 11/2013 • Procedure No. 0360


STANBIO