



**Diabetes Mellitus in Kirehe District Hospital: Assessment of determinants
of good clinical outcomes**

**Findings from the Electronic Medical Record data for Non Communicable
Diseases recorded since 2010-2015.**

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School of Public Health

Master of Science in Epidemiology

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A dissertation submitted in partial fulfillment of the requirements for the degree
of MASTER OF SCIENCE IN EPIDEMIOLOGY

In the College of Medical and Health Sciences

By

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LIST OF ACRONYMS

| | |
|-----------|--|
| ARD: | Association Rwandaise des Diabetiques |
| BMI: | Body Mass Index |
| DM: | Diabetes Mellitus |
| DMEXP: | Health expenditure for Diabetes Mellitus |
| EMR: | Electronic medical records |
| Hba1c: | Gylucatedhemoglobin |
| HIV/AIDS: | Human Immunodeficiency Virus/Acquired Immune Deficiency Syndrome |
| IDF: | International Diabetes Federation |
| LFAC: | International Diabetes Federation's Life For a Child |
| LMIC: | Low- and middle-income countries |
| MESH: | Mentorship and Enhanced Supervision for Health Care |
| NCD: | Non-Communicable Diseases |
| RMOH: | Rwanda Ministry of Health |
| SPPS: | Statistical Package for Social Sciences |
| T1/2D: | Type 1or 2 diabetes |
| TB: | Tuberculosis |
| USD: | United States Dollar |
| WHO: | World Health Organization |

SUMMARY

Aims: Nowadays, diabetes mellitus is continuing to be an increasing international health burden. But, there was made international settings and guidelines to combat this epidemic crisis. This thesis attempts to assess the factors associated with good outcomes of diabetes program provided by KIREHE district hospital to stabilize the level of glycemia of patients and delay diabetes complications.

Methods: Data were cross-sectionally collected from routine Electronic Medical Records of patients treated for diabetes from January 2010 to December 2015 at KIREHE Hospital. Two hundred and one diabetic patients were enrolled into the study. Socio-demographic and clinical characteristics were collected from the records. Descriptive statistics on baseline demographic and clinical characteristics were performed. Bivariate analysis was conducted to identify variables that were statistically significant and were subsequently considered into the multivariate analysis. Finally, logistic multivariate analysis was used to assess the relationship of independent variables of interest and program outcome defined as Hba1c level. Good diabetic outcome was defined as having Hba1c value ≤ 7 and bad outcome was Hba1c >7 .

Results: The descriptive analysis revealed that among 201 sampled patients, 70.2% had Hba1c >7 at the date of enroll into the program. It was further indicated that more than 65% aged above 45 years and 18% used alcohol. The bivariate analysis revealed that BMI, age, number of visit and treatment status are statistically associated with the clinical and programmatic outcome whereas the reduced model of binary logistic regression revealed that only having a BMI ranged between 18.5 and 25(OR: 2.357), being on either oral therapy or insulin therapy (OR: 1.972 and 1.231 respectively) and regularly visits to DM professionals (OR: 3.239) contributes to better outcome of diabetes management.

Conclusions: Our findings indicate that diabetes can be effectively managed with reasonable outcomes by strengthening the education of patients as well as regularly treatment of patients. We also found relatively high risk of early developing complications among adult patients.

Key word: Diabetes Mellitus, Diabetes management, Good clinical outcome, Kirehe

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I. INTRODUCTION

I.1. Context.

Diabetes Mellitus (DM) is non-communicable diseases NCDs, commonly referred to as Diabetes, is a group of metabolic diseases in which there are high blood sugar levels over a prolonged period [1]. Presently, it ranks as the fourth most common cause of mortality with coronary artery disease. Diabetes either occurs when the pancreas does not produce enough insulin or when the body cannot effectively use the insulin it produces. As a result, the concentration of glucose in the blood increases, a situation described as hyperglycemia. Three types of diabetes exist, namely: type 1 diabetes, type 2 diabetes, and gestational diabetes [10, 11].

Non-communicable diseases are increasingly becoming a serious burden worldwide particularly in low- and middle-income countries (LMICs), where 80% of NCD-related deaths occurs. In 2008, an estimate of 382 million people had diabetes worldwide and accounted for 1.3 million deaths [2]. And in 2015, an estimate of 415 million people had diabetes worldwide where more than 14 million people are in Africa region and it had been seen that from 2012 to 2015, approximately 1.5 to 5.0 million deaths each year resulting from diabetes [3]. In sub-Saharan Africa, diabetes is predicted to rise rapidly, increasing by 80% over 20 years and will be affecting 18.7 million by the year 2025 [4]. In 2013, although only 8.6% of all deaths in sub-Saharan Africa were attributed to diabetes, 76.4% of these deaths occurred in people under the age of 60 years, compared to the 50% or less among diabetes-related deaths world-wide [5].

In 2015, there were estimates of 194300 cases diabetes in Rwanda.

Diabetes burden on community is significant and can cause significant morbidity, increasing the risk of non-traumatic lower limb amputations by ten-fold, as a leading cause of renal failure and visual impairment and as a major risk factor for cardiovascular disease around the world [2]. Despite this, access to services for diabetes care in sub-Saharan Africa is limited and there are significant disparities in patient outcomes when compared with global statistics. Access to services for rural patients is particularly lacking [6]. Contributing factors include few trained personnel, expensive medications and equipment [7], late presentation, delayed diagnosis, as well as treatment complications related to food in security such as hypoglycemia [5].

Recent discussions about the burden of diabetes in sub-Saharan Africa have focused on the growing epidemic in urban centers, where prevalence has reached as high as 8% in adult populations. The International Diabetes Federation (IDF) has outlined excellent practice guidelines for the African region, and the IDF's Life for a Child program has begun to make medications and supplies freely available to children and young adults around the world [8, 9].

I.2. Problem statement and gap of the study

According to a declaration made early 2010 by the United Nations Secretary-General Ban Ki-moon, diabetes and other non-communicable diseases are described as “a public health emergency in slow motion” [12]. Furthermore, from statistics, it seems like the world is on the cusp of losing the battle to contain diabetes [12]. The world prevalence of diabetes in 2010 among adults (aged 20-79 years) was estimated to 6.4% affecting 285 million adults. By 2030 it is expected to increase to 7.7% and affecting 438 million adults. This shows how the prevalence of diabetes is increasing. In Rwanda, 194300 diabetes cases around 2% of all populations. It seems low but there is a high probability that many people do not know their current situation of diabetes, they did not make a diabetes test. And it looks like that in Rwanda there is not more information and data on diabetes for long ago; so it is difficult to measure the increase of diabetes mellitus status in Rwandan people and its future estimation can perfectly be predicted. This study will evaluate the management and assessment of determinants of good clinical outcomes of diabetes in public facilities of KIREHE district hospital from 2010-2015 and analysis of the diabetes cases based on both case characteristics and demographic characteristics of diabetes patients of KIREHE hospital.

I.3. Research Objectives

A. General objective

To identify determinants of the good clinical outcome of diabetes management in NCD clinic, at Kirehe District Hospital.

B. Specific Objectives

Describes socio demographic characteristics of Diabetic patients in NCD clinic, Kirehe District Hospital.

To assess the association of clinical characteristics with diabetes management outcomes

To find out the impact of treatment in the control of hyperglycemia

To find out the impact of follow up in the stabilization of diabetes

I.4. Research Questions

This study-research is based on the following research questions:

- What could be the relationship between glycemia level and treatment of diabetes performed?
- What is the effect of visits on diabetes stabilization?
- What are the determinants of the adherence to diabetes among peoples of Kirehe district?
- Which are critical areas of intervention to improve the control of diabetes in Kirehe district?

I.4. Hypothesis of the study

Given that the diabetes epidemic and the continues increases in the disease's prevalence worldwide, this study lays forward the hypothesis that good outcomes of diabetes stability depends on effective management of clinical determinants and adherence to treatment, as implemented in NCD program in Kirehe District Hospital.

I.5.Study Area Description

I.5.1. Location of Kirehe hospital

Kirehe Hospital is located in Kirehe District, the Eastern Province at 131km from Kigali. The present area known as Kirehe District unites the ex-districts of Rusumo, Nyarubuye and Rukira. Kirehe district lies in the far south-eastern corner of Rwanda bordering Tanzania and Burundi.

In the East: The Akagera River constitutes the natural limit between KIREHE District and Tanzania.

In the South: The District of KIREHE is also frontier Republic of Burundi and the United Republic of Tanzania.

In the West: The District divides its border with the District of Ngoma and the District of Kayonza

In North: its border with the District of Kayonza divides such as shows it the administrative chart

The district of KIREHE, has 12 Sectors that constitute 60 Cells. It has a population of 299.468 and occupies an area of 1,225.4 km

I.5.2. Services of Kirehe Hospital

Kirehe District Hospital has different services with their particular functioning including the non-medical staff(Administration) and clinical staff.

The Kirehe Hospital has the various services that are complementary such as:

1. Department of Pediatrics
2. Department of Internal Medicine
3. Maternity ward
4. Infectious Disease Clinic (ID Clinic)
5. Operation room
6. Emergency
7. Out patients department
8. Social department
9. Support services: logistics, maintenance.

10. Medical Services:

- Technical radiology,
- Laboratory,
- Physiotherapy,
- Dentistry,
- Pharmacy,
- Sterilization,
- Hygiene and sanitation.

11. Mental Health service

12. Non Communicable Diseases

I.5.2. History of NCD Clinic in Kirehe Hospital and its functionality

Kirehe NCD clinic has been opened in October 2007 and was created to serve the patients from Kirehe district; the core activities carried out in this clinic include:

- Prevention, diagnosis, treatment and long term follow up for major diseases
 - HTN, HF, Diabetes, Asthma
 - NCDs at different levels (RF, health center/MESH and Palliative care)
- Comprehensive management of NCDs
- Task-shifting (nurse-led, protocol based, structured mentorship and outreach)
- Integration within MOH
- Socioeconomic supports
- Point-of-care testing
- Structured clinical forms, EMR
- Defaulter tracing mechanisms

I.5.3. Patient management

Patient management is led by nurses, who receive training and longitudinal mentorship from physicians, and reference standardized treatment protocols. Services are comprehensive spanning multiple types of NCDs, with nurses cross-trained in these and patients following up on disease-specific clinic days. Point-of-care diagnostics are employed including portable spirometer for asthma, hemoglobinA1c for diabetes and INR for post-valve repair surgery patients on warfarin.

Nurses are also able to perform echocardiography to provide preliminary diagnosis and inform initial management of heart failure patients (which is followed by confirmatory echocardiogram by cardiologist). Supportive services available include patient group education sessions delivered before each clinic and socioeconomic supports for vulnerable patients. District hospital nurses also serve as mentors for health center nurses in managing NCDs.

For diabetes, nurses receive didactic and practical training on diagnosis and long-term management of diabetic patients that is complemented by long-term mentorship from physicians and specialist nurses. At the district hospitals, each NCD clinic is staffed with at least two trained MOH nurses who cover the diabetes-specific clinic held once a week. Patients requiring admission are cared for by physicians and nurses in the pediatrics or internal medicine wards with consultation by NCD clinic team. At each of the seven health centers with NCD clinics, two trained MOH nurses take turns covering weekly the NCD clinic that includes diabetes but is not disease-specific. Health center NCD clinics receive visits from district hospital NCD nurse at least once a month for continued mentorship employing a structured mentorship model that has been established for womens' health, HIV and other clinical spheres

Diagnosis and monitoring employs point-of-care testing for urine glucose, urine ketones, blood glucose and, for the district hospitals only, hemoglobin A1c (HbA1c). Additionally, tests routinely available at the facility's laboratory, such as renal function tests, are performed to support diagnosis and monitoring. Treatment includes lifestyle risk factor modification and individual counseling, group patient education sessions, oral hypoglycemic agents (glibenclamide, or metformin if BMI >25.0), insulin (routinely available at the district hospital but only available for emergencies at the health center level) and socioeconomic supports such as food, transport voucher and community health worker follow-up for vulnerable patients. Frequency of patient visits for clinical consultation ranges from weekly to every two months, depending on acuity of patient illness.

II. LITERATURE REVIEW

Non-communicable diseases, such as diabetes mellitus, cardiovascular disease, stroke, cancer and chronic respiratory diseases are currently the leading cause of mortality in the world, representing 60% of all deaths (World Health Organization, 2008). Diabetes mellitus, long considered of minor significance to world health, is now taking its place as one of the main threats to human health in the 21st century (Zimmet, Alberti& Shaw, 2001).

WHO further estimates that deaths from noncommunicable diseases (NCDs) are likely to increase globally by 17% over the next 10 years, and the Region will experience a 27% increase, that is 28 million additional deaths from these conditions which are projected to exceed deaths due to communicable, maternal, perinatal and nutritional diseases combined by 2030. This rise is highly noticed in the region for instance Rwanda is highly ranked in implementation of homegrown health policies and strategies such as Mutuelle de sante (communal health insurance), but the lack of using such an advantage to do a comprehensive medical check-up on NCDs has been very low according to the ministry of health.

A Steps survey conducted in Rwanda in 2012/13 revealed that the prevalence of main risk factors was generally high in the country.

The report found alcohol consumption harmful at 23.5 per cent heavy episodic drinking, 41.3 per cent currently drinking.

In addition, tobacco use was estimated at 12.9 per cent, unhealthy diet only 0.3 per cent of fruit consumption per day, 0.9 per cent eat vegetables while 99.1 per cent had less than five 5 servings of fruits and/or vegetables). Physical inactivity was high, only 21.4 per cent were engaged in low level of activity.

As declared by WHO (1994), general objectives of diabetes management programs are;

- ❖ To relieve symptoms
- ❖ To correct associated health problems and to reduce morbidity, mortality and economic costs of diabetes

- ❖ To prevent as much as possible acute and long-term complications; to monitor the development of such complications and to provide timely intervention
- ❖ To improve the quality of life and productivity of the individual with diabetes

2.1. Types of diabetes

The type of diabetes is based on the presumed etiology. This chapter provides information about the two most common types of diabetes: type 1 and type 2 diabetes

2.1.1 Type 1 diabetes

In type 1 diabetes, the body does not produce insulin, and daily insulin injections are required. Type 1 diabetes is usually diagnosed during childhood or early adolescence and it affects about 1 in every 600 children.

2.1.2 Type 2 diabetes

Type 2 diabetes is the result of failure to produce sufficient insulin and insulin resistance. Elevated blood glucose levels are managed with reduced food intake, increased physical activity, and eventually oral medications or insulin. It is typically diagnosed during adulthood.

However, with the increasing incidence of childhood obesity and concurrent insulin resistance, the number of children diagnosed with type 2 diabetes has also increased worldwide [18]. This increase is greatest among individuals from certain ethnic/racial groups (African Americans, Native Americans, Hispanics and Asians/Pacific Islanders) and for those with a family history of type 2 diabetes [19].

2.2. DM Screening

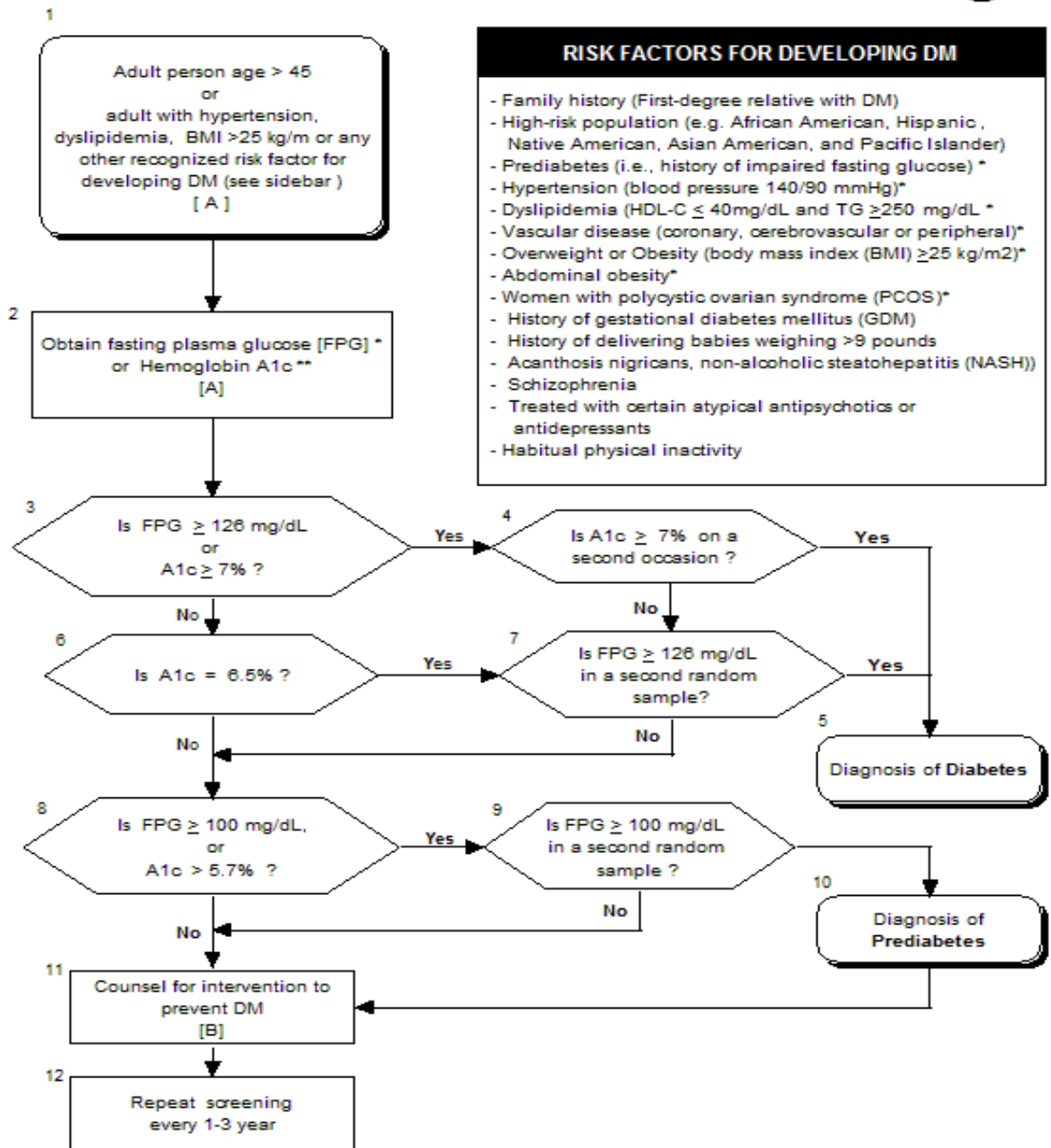
According to WHO and IDF, the following criteria are recommended for the diagnosis of diabetes mellitus: fasting plasma glucose ≥ 7.0 mmol/l (126 mg/dl) or 2-h plasma glucose (venous plasma glucose 2 hours after ingestion of 75g oral glucose load) ≥ 11.1 mmol/l (200 mg/dl). They further recommend that the oral glucose tolerance test is the most preferred diagnostic test for diabetes mellitus. The test should be performed in the morning after an overnight fast of between 8 and 14

hours and after at least 3 days of unrestricted diet (≥ 150 g carbohydrate per day) and unlimited physical activity. More so, the subject should remain seated and not smoke throughout the test. In recent times, glycated hemoglobin (HbA_{1c}) has also been recommended for the diagnosis of diabetes, with a threshold of $\geq 7\%$. See the detail in figure 1

Figure 1: Diabetes mellitus screening from clinical practice guideline

Management of Diabetes Mellitus Module S - Screening for DM

S



RISK FACTORS FOR DEVELOPING DM

- Family history (First-degree relative with DM)
- High-risk population (e.g. African American, Hispanic, Native American, Asian American, and Pacific Islander)
- Prediabetes (i.e., history of impaired fasting glucose) *
- Hypertension (blood pressure 140/90 mmHg)*
- Dyslipidemia (HDL-C ≤ 40mg/dL and TG ≥250 mg/dL *
- Vascular disease (coronary, cerebrovascular or peripheral)*
- Overweight or Obesity (body mass index (BMI) ≥25 kg/m2)*
- Abdominal obesity*
- Women with polycystic ovarian syndrome (PCOS)*
- History of gestational diabetes mellitus (GDM)
- History of delivering babies weighing >9 pounds
- Acanthosis nigricans, non-alcoholic steatohepatitis (NASH))
- Schizophrenia
- Treated with certain atypical antipsychotics or antidepressants
- Habitual physical inactivity

Note:
 * Fasting plasma glucose (FPG) is the preferred test. Random non-fasting plasma glucose is not recommended as a first line screening. Non-fasting plasma glucose ≥200 mg/dl (on at least two occasions) is sufficient to diagnose DM, and <110 mg/dl is sufficient to exclude it. Random non-fasting plasma glucose in the range 111-199 mg/dl should be followed up with FPG test.
 ** A1c should be measured using a clinical laboratory methodology (but NOT point of care) standardized to the National Glycohemoglobin Standardization Program [NGSP]

9/2/2010

2.2 Diabetes treatment and control as declared by HWO

The major components of the treatment of diabetes are:

1. *Diet (combined with exercise if possible)* Diet is a basic part of management in every case. Treatment cannot be effective unless adequate attention is given to ensuring appropriate nutrition. Physical activity promotes weight reduction and improves insulin sensitivity, thus lowering blood glucose levels. Together with dietary treatment, a program of regular physical activity and exercise should be considered for each person. Such a program must be tailored to the individual's health status and fitness. People should, however, be educated about the potential risk of hypoglycemia and how to avoid it.

2. *Oral hypoglycemic therapy drugs:* are considered only after a regimen of dietary treatment combined with exercise has failed to achieve the therapy targets set. There are two major groups of OHD: sulphonylureas (SUs) and biguanides (BGs). SU act by stimulating insulin release from the beta cells and also by promoting its action through extra pancreatic mechanisms. BG exerts their action by decreasing gluconeogenesis and by increasing the peripheral utilization of glucose. Methods and frequency of monitoring depend on the type of treatment, the local facilities available, and therapy targets set. Methods include:

- ✓ Urine glucose testing;
- ✓ Blood glucose measurements;
- ✓ Hemoglobin testing (HbA1c)
- ✓ Urine ketenes testing

3. *Insulin treatment:* People with diabetes should be taught self-monitoring techniques and be assisted in acquiring knowledge and developing skills that enable them to modify treatment according to the results of self-monitoring.

Education of the person with diabetes is an essential component of management in every case. To ensure appropriate management, the basic knowledge and skills should be acquired by the patient and his family and the health care team should work closely with the patient to achieve this objective and to promote self-care. The person with diabetes should also be involved in setting therapeutic targets for weight, blood pressure and blood sugar control.

2.3 Diabetes control in youth (Rwanda)

In order to address this problem, outside support has been necessary. One program providing such help is the International Diabetes Federation's Life for a Child (LFAC) program, which is managed in conjunction with the Australian Diabetes Council and HOPE worldwide. LFAC's mission is to support the provision of the best possible healthcare, given local circumstances, for children and youth with diabetes (>25 years) in developing countries. This is achieved by strengthening diabetes services through the provision of insulin, glucose monitoring supplies, HbA1c testing, diabetes education and expert advice and training. One organization receiving assistance from LFAC is the Association Rwandaise des Diabetiques (ARD) in Kigali, Rwanda—the major specialized care provider for diabetic patients in Rwanda. The Rwanda LFAC program at the ARD was initiated in 2004 with 25 children receiving support and annual clinic visits. The program has expanded since then, and as of the end of 2011, 634 children and young adults were enrolled.

According to Sara L. Marshall a, Deborah V. Edidin .Et Al. (2014) Glucose control in Rwanda youth reported showed that there were 286 children and youth with type 1 diabetes (T1D) in the LFAC Rwanda program, who had their first HbA1c test between June 2009–November 2010 [16]. The overall level of glucose control was poor with a mean HbA1c of $11.1 \pm 2.8\%$ (99 ± 30 mmol/mol), and 30.9% ($n = 88$) having HbA1c above 14%. Complications were also already present in this population, despite the mean diabetes duration of only 3.4 ± 3.1 years.

2.4 Clinical patterns and complications of diabetic patients

G J Rudasingwa,Et. Al described the prospective cross-sectional study carried out in Kigali University Teaching Hospital, Rwanda, between October 2008 and May 2010, to investigate the clinical patterns and complications profile of diabetic patients attending the Department of Internal Medicine. The study involved 294 patients (65% females, 40% of patients aged below 45 years). Co-morbidity with hypertension, overweight and dyslipidemia was found in 31%, 33%, and 28%, respectively. The mean diabetes duration was 6 ± 6 years (mean \pm SD).

Micro-vascular complications were common: neuropathy (53%), retinopathy (23%), and nephropathy (20%). Macro-vascular complications were less frequent: cerebrovascular disease (4%), coronary artery disease (3%), and peripheral vascular disease (15%). More efforts focused

on education programs, and early diagnosis through mass population screening, as well as the improvement of case management may help to reduce the burden of complications.

In Rwanda, the affordability of treatment and accessibility of health facilities are still limited, for multiple reasons, including geographical, financial, and cultural beliefs. Thus, diabetic complications are likely to occur in many patients and at an early stage. Yet, there have been no prior published data on diabetes-related complications in Rwanda.

2.4 Patient management

The model of comprehensive chronic care integration employed at PIH-supported public facilities in Rwanda is described in detail elsewhere [20, 21, and 22]. For diabetes, nurses receive didactic and practical training on diagnosis and long-term management of diabetic patients that is complemented by long-term mentorship from physicians and specialist nurses. At the district hospitals, each NCD clinic is staffed with at least two trained RMOH nurses who cover the diabetes-specific clinic held once a week. Patients requiring admission are cared for by physicians and nurses in the pediatrics or internal medicine wards, in consultation by NCD clinic team. At each of the seven health centers with NCD clinics, two trained RMOH nurses take turns covering the weekly NCD clinic that includes diabetes but is not disease-specific.

Diagnosis and monitoring employs point-of-care testing for urine glucose, urine ketones, blood glucose and hemoglobin (HbA1c) for the district hospitals only. Additionally, tests routinely available at the facility's laboratory, such as renal function tests, are performed to support diagnosis and monitoring. Treatment includes individual counseling on lifestyle risk factor modification and group patient education sessions, oral hypoglycemic agents (glibenclamide, or metformin if BMI > 25.0), insulin (routinely available at the district hospital but only available for emergencies at the health center level) and socioeconomic supports such as food, transport vouchers and community health worker follow-up for vulnerable patients. Frequency of patient visits for clinical consultation ranges from weekly to every two months, depending on acuity of a patient's illness.

2.5. The complications of diabetes

The complications of diabetes can be classified as:

1. **Acute problems:** (Otherwise termed the diabetic medical emergencies) *Diabetic ketoacidosis.

*Hypoglycaemia.

2. **The chronic complications of diabetes:** *Microvascular complications.

2.5.1. The acute complications of diabetes.

There is sometimes confusion about how to deal with a diabetic patient who becomes unwell in the clinic setting we have included a short description of the two most important acute emergencies, diabetic ketoacidosis and hypoglycaemia.

2.5.2. The chronic complications of diabetes.

These are the complications that occur because of the chronic exposure of the body's tissues to hyperglycaemia, hypoinsulinaemia or their associated metabolic disturbances. The potential chronic complications of diabetes are those that most people with diabetes fear; however over 40% of patients with type 1 diabetes survive for over 40 years after the disease has been diagnosed, half of them without developing significant complications.

The chronic complications of diabetes are classified as follows:

1. Micro-vascular (microangiopathic)

- ✓ **Diabetic Retinopathy:** A diabetes complication that affects eyes. It's caused by damage to the blood vessels of the light-sensitive tissue at the back of the eye (retina). At first, diabetic retinopathy may cause no symptoms or only mild vision problems.
- ✓ **Diabetic Neuropathy:** A family of nerve disorders caused by diabetes
- ✓ **Diabetic Nephropathy:** A progressive kidney disease caused by damage to the capillaries in the kidneys' glomeruli.
- ✓ **Diabetic skin problems (the “Diabetic foot”):** Blisters that can occur on the fingers, hands, toes, feet, legs, or forearms

2. Macro-vascular.

- ❖ Accelerated propensity to atherosclerosis/atheroma
- Peripheral vascular disease/ coronary heart disease.
- Myocardial infarction.
 - ❖ Arteriosclerosis.
- Hypertension and cerebrovascular disease.

3. Other associated metabolic abnormalities.

Hypercholesterolemia

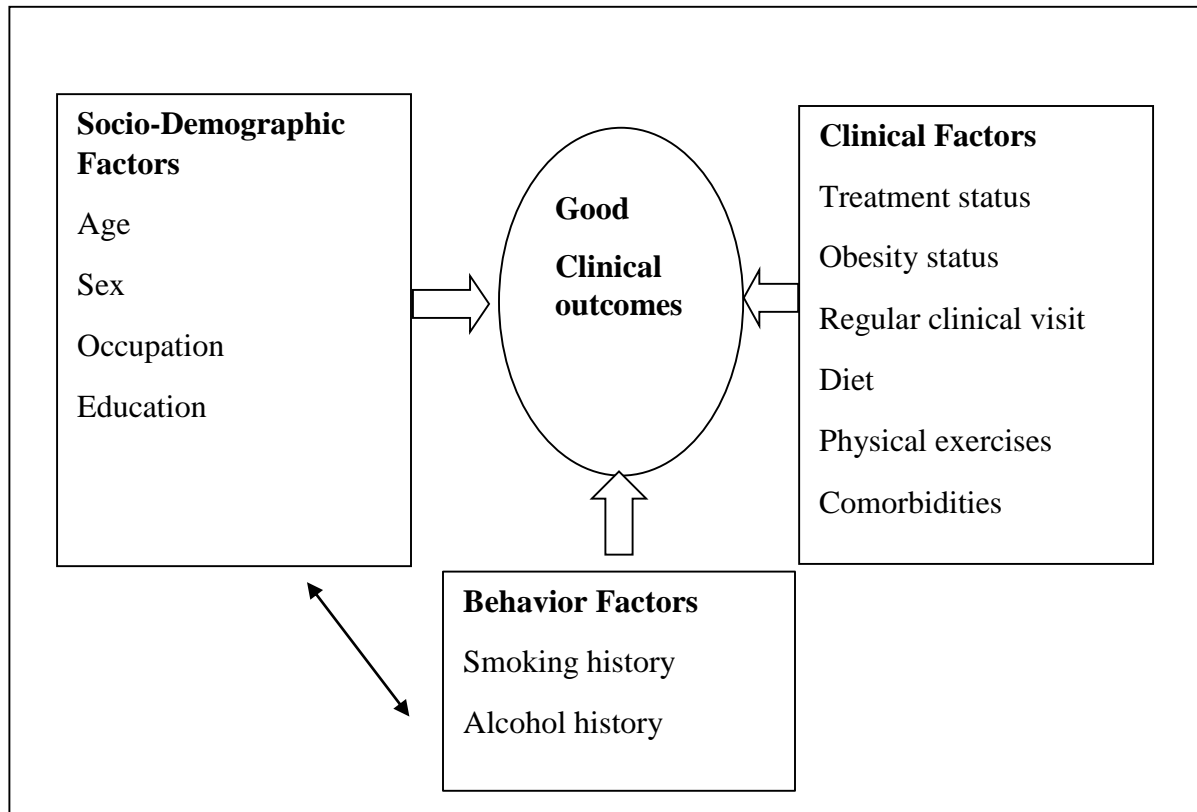
4. Increased susceptibility to infection.

For reasons not totally understood people with diabetes have an increased susceptibility to bacterial infection. This is an important factor in the development of diabetic foot ulceration and explains why people with diabetes have a much higher risk of limb amputation compared to the normal population.

2.6. Conceptual framework

Below is the conceptual framework for this study:

Figure 2: Conceptual framework



The figure2 illustrate the interaction between factors that would affect a diabetic patient towards a stable status (good clinical outcome). For better analysis the researcher divided those factors into socio-demographic factors, clinical factors and behavior factors.

Socio-demographic factors regroup variables which do not affect directly the stabilization of glycemia for a diabetic patient but amplify the effect of clinical factors and behavior factors on good clinical outcomes. Contrary, clinical factors and behavior factors regroup variables which directly control the health of a diabetic patient. However, none of the three factors is to be neglected though their degree of effect is not the same, they all have impact on clinical outcome and they should be managed at fully for better success.

III. METHODS

3.1. Study design

It is a Cross-sectional study which is a type of observational study that analyses data collected from a population at a specific point in time.

In this research, a cross-sectional study design was used to assess the good outcomes of diabetes management and treatments provided at KIREHE district hospital. It used secondary data analysis of EMR database, and patient files treated for Non-Communicable Diseases (NCD) collected since 2010-to-2015. The study inclusive criteria focused on diabetes, therefore diabetes patient data was used and diabetes program factors and determinants of good outcome which can help to stabilize glycaemia were the basic selection criteria. For selected patients, socio-demographic characteristics and clinical characteristics information were useful in analysis and in diabetes program evaluation in favor of good clinical outcomes.

3.2 Research Locations

This study has been conducted at KIREHE District Hospital, providing health services to the people of Eastern province, KIREHE District; where all used data were taken from Electronic Medical Records of patients treated in Non-Communicable Diseases Clinic at the Hospital.

3.3 Population and sample selection

The study target population is all diabetic patients treated at KIREHE hospital since January 2010-to-December 2015 which are 291 patients as indicated by electronic medical records of EMR database for KIREHE hospital diabetes program. Where recorded patient treatment given during follow up and how glycaemia level varies after a given period of time from there, impact of the program on diabetes especially in controlling their glycaemia level can be studied. The study sample size is 201 because individual cases with missing of HbA1c data have been removed or excluded in the analysis.

Inclusion criteria: All active¹diabetic patients enrolled from January 2010 to June 2015 at Kirehe district hospitals whose fully records on at least 2 Hba1c test results.

¹at least 6 months in program

Exclusion criteria: All inactive diabetic patients enrolled from January 2010 to December 2015 at Kirehe district hospital whose incomplete records on 2 HbA1c test results.

3.4 Variables definitions

3.4.1 Dependent variables

The dependent variable of this study should be linked with good outcomes of diabetes control which can be influenced by diabetes treatment program of the hospital. So, glycaemia level (good: $HbA1c \leq 7\%$ or bad: $HbA1c > 7\%$) would be the study binary dependent variable. There are so many tests for glycemia level, but we can use data of HbA1c test. For a diabetes patient if $HbA1c \leq 7\%$, it means that the glucose level is stable to delay complications. If $HbA1c > 7\%$, patient at risk of developing diabetes complications.

HbA1c (Glycated hemoglobin): is a hemoglobin test for measuring or identifying three-month average plasma glucose concentration.

3.4.2 Independent variables

Independent variables are the set of characteristics and factors in which the dependent variable can be directly or indirectly influenced.

- 1) **Direct factors:** Those are the main determinants of diabetes treatment program which can bring good or bad outcomes in short term period. Those factors are:

Visits: This variable was grouped into two categories: regularly (those who meet all required visits) and irregularly (those who skip at least one visit)

Drugs given to diabetes patient: This variable was grouped into three categories: Oral therapy, insulin therapy and education.

- 2) **Indirect factors:** Those are socio-demographic and clinical characteristic of patients which cannot directly influence outcome of diabetes program. Those factors are:

Sex: This is a dichotomous variable that takes value of 0 if a participant is a male and 1 otherwise.

Age: This is the age at which a patient enrolled into the program and it was categorized into five categories: <18; 18-30; 30-45; 45-60; >60.

Occupation: This variable was grouped into four categories: Farmer (related to agriculture); Professional (engaged in paid works); Unemployed (not yet get a job) and Student (still at school)

Obesity status: This variable was divided into four groups: $MI < 18.5$ (Underweight); $18.5 \leq BMI < 25$ (Normal weight); $25 \leq BMI < 30$ (Over weight) and $BMI \geq 30$ (Obese)

Smoking history: This variable was grouped into three categories: never (he/she never smoke; in the past (he/she used to smoke) and currently (he/she is a smoker).

Diabetes Type: This variable was grouped into two categories: type1 and type 2

Chronic disease comorbidities: This variable was grouped into four categories: diabetes (if a patient had no other NCD); Diabetes+HIV (if a patient has also HIV); Diabetes+CRD (if a patient has also a chronic disease) and Diabetes+ HTA (if a patient has also HTA)

Alcohol history: This variable was grouped into three categories: never (he/she never consumes alcohol), in the past (he/she used to drink alcohol) and currently (he/she is an alcohol consumer).

3.5 Data management and analysis

Secondary data analysis of routine electronic medical records (EMR) of patients managed for diabetes at KIREHE hospital that meet the inclusion criteria was performed. Data were cleared and variables were computed to easier the detection of impact using descriptive statistics for generating proportions of characteristic of interest and discovering if there is any statistical association at the level of significant $\alpha=0.05$ with the help of chi-square test of independent and binary logistic regression for detecting the degree of association of one covariate on the outcome variable (Clinical outcome).

In the logistic regression analysis of all independent variables that was found to be statistically associated with outcome variable, we used stepwise method to control possible bias that could be manifested once ENTER method is used. Predictors of good outcome among diabetic patients at Kirehe district Hospital were estimated using OR with their 95% CI in the multivariate analysis. Omnibus and Hosmer-Lemeshow tests was respectively used to check for the significance of model coefficients and goodness fit of the final model. All analyses were done using SPSS 16.1 and all resulted presented here are weighted.

3.6. Glycemic target ranges

The target range for glycemic control should be individualized, based on the provider's appraisal of the risk-benefit ratio and discussion of the target with the individual patient.

The patient with either none or very mild micro-vascular complications of diabetes, who is free of major concurrent illnesses, and who has a life expectancy of at least 10-15 years, should have an HbA1c target of <7 percent, if it can be achieved without risk.

Any patient with diabetes should have a HbA1c target of <9 percent to reduce symptoms of hyperglycemia.

The patient with longer duration diabetes (more than 10 years) or with co-morbid conditions, and who require combination medication regimen including insulin, should have an HbA1c target of < 8 percent.

The patient with advanced micro-vascular complications and/or major co-morbid illness, and or a life expectancy of less than 5 years is unlikely to benefit from aggressive glucose lowering management and should have a HbA1c target of 8-9 percent.

IV.RESULTS

4.1. Descriptive analysis

Descriptive analysis gives the summary of the data in a simple and easy way using frequencies tables, cross-tabulation tables between two variables, graphs, and chart to represent data.

4.1.1. Socio-demographic characteristics of patients

The table1 shows descriptive statistics of socio-demographic variables where diabetes program at KIREHE hospital treats 291 diabetes patients and 201 patients met the criteria to be in our study, the prevalence of diabetes in females is more significant than in men with 54.7% in female and 45.3 % per men. The distribution of age group of diabetes patients was mainly high in the ages between 45 and 60 years old with proportion of 40.8% of the total patient, patient with ages above 60 also occupied the second proportion of diabetes prevalence with 24.4%, as well as 30 - 45 age group, and the age group with a very low diabetic patient frequencies is less than 18 years old with only 3.5% the total of patients. Economic status and occupation of patients showed that 55.7% of all patients were farmers may because of the location of the hospital; the second occupation of the patient is professional with 13.4% and the proportion of unemployed proportion of 1.5%.

Table 1: Descriptive statistics of socio-demographic characteristics of diabetic patients managed at KIREHE hospital.

| Socio-demographic characteristics | Frequency | Percentage |
|--|------------------|-------------------|
| Gender | 201 | 100 |
| Male | 91 | 45.3 |
| Female | 110 | 54.7 |
| Age group | 201 | 100 |
| <18 | 7 | 3.5 |
| 18-30 | 14 | 7.0 |
| 30-45 | 49 | 24.4 |
| 45-60 | 82 | 40.8 |
| >60 | 49 | 24.4 |
| Occupation | 149 | 74.1 |
| Farmer | 112 | 55.7 |
| Professional | 27 | 13.4 |
| Unemployed | 3 | 1.5 |
| Student | 7 | 3.5 |

4.1.2. Clinical characteristics of patients

Descriptive statistics of clinical characteristics of diabetic patients in the table 2 shows 2 type of diabetes one with insulin dependent type 1 and type 2 non-insulin dependent. Comorbidities of patients were mostly only diabetes with around 95.5% of patients and 3% of patients with diabetes + HIV. The proportion of number of HbA1c test received by the patient were recorded and at least 55% of patients in the follow up diabetes program received 3 HbA1c test and only 8.5% of patients received 1 test. In obesity status of patients, we can see that more patients had normal wait at diabetes enrollment date, and only 6.5% of patients with the problem of obesity. Unfortunately, the data on patient height and weight were not recorded in the database; more than 37% of patients were not categorized for their obesity status because of missing data. In the alcohol and smoking

history of patients, we can see that most of them were did neither smoke nor drink alcohol. The table showed that only 3% currently smoke 7.5% currently drink and respectively 5.5% and 11.9% in the past. In general, descriptive statistics in tables above can show clearly the picture of the study variables in the dataset.

Table 2: Descriptive statistics of clinical characteristics of diabetic patients managed at KIREHE District Hospital.

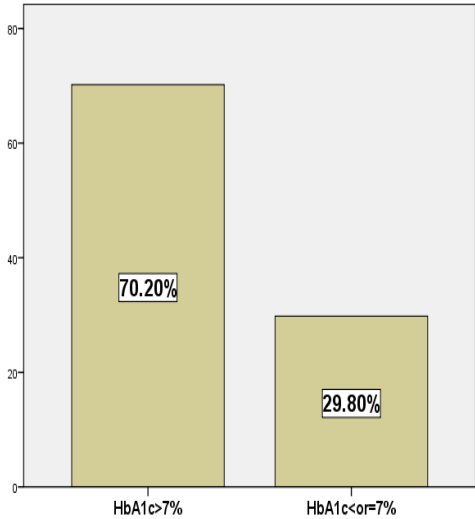
| Clinical characteristics | Frequency | Percentage |
|---------------------------------------|------------------|-------------------|
| Diabetes type | 201 | 100 |
| TYPE 1 | 98 | 48.8 |
| TYPE 2 | 103 | 51.2 |
| Obesity status | 126 | 62.7 |
| Under weight (BMI<18.5) | 19 | 9.5 |
| Normal weight (18.5>or=BMI<25) | 76 | 37.8 |
| Over weight (25>or=BMI<30) | 18 | 9.0 |
| Obesity BMI> or =30 | 13 | 6.5 |
| SMOKING HISTORY | 157 | 78.1 |
| NEVER | 140 | 69.7 |
| IN THE PAST | 11 | 5.5 |
| CURRENTLY | 6 | 3.0 |
| ALCOHOL HISTORY | 155 | 77.1 |
| NEVER | 116 | 57.7 |
| IN THE PAST | 24 | 11.9 |
| CURRENTLY | 15 | 7.5 |
| Number of test done by patient | 201 | 100 |
| One test | 51 | 25.4 |
| Two tests | 44 | 21.9 |
| Tree tests | 42 | 20.9 |
| Four tests | 23 | 11.4 |
| Five tests | 24 | 11.9 |
| Six tests | 17 | 8.5 |

| | | |
|----------------------|------------|------------|
| Comorbidities | 201 | 100 |
| DIABETES | 192 | 95.5 |
| DIABETES+HIV | 6 | 3.0 |
| DIABETES+CRD | 1 | .5 |
| DIABETES+ HTA | 2 | 1.0 |

4.1.3. Glycated hemoglobin level among patients

Diabetes patient, HbA1c test is an important measure, HbA1c is widely used as an index of mean glycaemia in diabetes, as a measure of risk for the development of diabetes complications, as a measure quality of diabetes care. The goal is to keep the HbA1c levels of diabetes patients less than 7%, since keeping levels below 7% has been shown to delay complications. Diabetes program at enrollment HbA1c test of patient showed that 70.2% of patients were at risk of developing diabetes complications with HbA1c>7%, and 29.8% of patients were likely to delay complications with HbA1c≤7%.

Figure 3: Hemoglobin test HbA1c of patient at enrollment



4.2. Analysis of Clinical outcome

4.2.1. Bivariate analysis

The bivariate analysis will allow us to explain the association existing between each independent variable and the outcome variable. This association will allow a sound selection of variables having a significant effect on clinical outcome at Kirehe District hospital. Once those variables are selected, they will be analyzed using multivariate regression to depict the net effect of each variable on the outcome variable.

Both social-demographic and clinical factors will be analyzed and hence, at the end of the analysis the statistical association between good outcome and each independent variable will be depicted with the help of chi-square test of independent.

Table 3: Bivariate logistic regression analysis for all independent variables, social and clinical characteristics among diabetic patients in NCD clinic Kirehe Hospital

| Variables | N | Clinical outcome | | P-value | O.R ² (95% C.I) ² |
|-----------------------------|-----|-------------------------------|------------------------------|---------|---|
| | | Good outcome: HbA1c≤7% (%) | Bad outcome: HbA1c>7% (%) | | |
| Gender | 201 | | | | |
| Male | 91 | 42 (46.2) | 49 (53.8) | | 1.00 |
| Female | 110 | 60 (54.5) | 50 (45.5) | 0.133 | 0.873[0.733,1.358] |
| Age | 201 | | | | |
| <18 | 7 | 2 (28.6) | 5 (71.4) | | 1.00 |
| 18-30 | 14 | 9 (64.3) | 5 (35.7) | 0.999 | 1.291 [0.933,3.309] |
| 30-45 | 49 | 24 (49) | 25 (51) | 0.099 | 1.783 [0.839,3.841] |
| 45-60 | 82 | 29 (35.4) | 53 (64.6) | 0.067 | 1.037 [0.738,2.205] |
| >60 | 49 | 13 (26.5) | 36 (73.5) | 0.051 | 0.851 [0.601,1.304] |
| Occupation | 149 | | | | |
| Farmer | 112 | 77 (68.7) | 35 (31.3) | | 1.00 |
| Professional | 27 | 13 (48.1) | 14 (57.9) | 0.071 | 3.772 [0.995,4.418] |
| Unemployed | 3 | 3 (100) | 0 (0) | 0.734 | 1.002 [0.993,1.735] |
| Student | 7 | 5 (71.4) | 2 (28.6) | 0.096 | 1.429 [0.839,3.685] |
| Obesity status(BMI) | 126 | | | | |
| Under weight (BMI≤18.5) | 19 | 8 (42.1) | 11(57.9) | | 1.00 |
| Normal weight (18.5<BMI≤25) | 76 | 62 (81.6) | 14 (18.4) | 0.000 | 4.273 [1.943,9.538] |

² Crude Odd Ratio

| | | | | | |
|----------------------------------|-----|-----------|-----------|--------------|-------------------------------|
| Over weight (25<BMI≤30) | 18 | 11 (61.1) | 7 (38.9) | 0.843 | 0.989 [0.639,2.941] |
| Obesity (BMI> 30) | 13 | 3 (23) | 10 (77) | 0.001 | 0.482[0.203,0.918] |
| Smoking history | 157 | | | | |
| Never | 140 | 94 (67.1) | 46 (32.9) | | 1.00 |
| In the past | 11 | 4 (36.4) | 7 (63.6) | 0.704 | 0.911[0.871, 2.093] |
| Currently | 6 | 1 (16.7) | 5 (83.3) | 0.0770 | 0.673 [0.615,1.847] |
| Alcohol history | 155 | | | | |
| Never | 116 | 65(56) | 51(44) | | 1.00 |
| In the past | 24 | 10 (41.7) | 14 (58.3) | 0.853 | 0.992 [0.730, 1.944] |
| Currently | 15 | 9 (60) | 6 (40) | 0.733 | 0.885 [0.655, 3.035] |
| Diabetes treatment status | 201 | | | | |
| Life style ³ | 4 | 2 (50) | 2 (50) | | 1.00 |
| Insulin therapy | 95 | 55 (58.1) | 40 (41.9) | 0.037 | 2.993 [1.285, 7.505] |
| Oral therapy | 102 | 68 (66.7) | 34 (33.3) | 0.040 | 1.904 [1.236,4.531] |
| Visits | 201 | | | | |
| Regularly | 175 | 113(64.6) | 62(35.4) | 0.003 | 4.887 [2.015, 9.325] |
| Irregularly | 26 | 3 (11.5) | 23 (88.5) | | 1.00 |

The bivariate analysis revealed that only BMI, Regularity of visits and Treatment status are statistical associated with clinical outcome at the level of significant $\alpha = 0.05$ as indicated by their probability under null hypothesis which are less than 0.05.

³ Follow up of patient by educating or cancelling only to adopt better behavior that favor the good health of a diabetic patient.

4.2.2. Multivariate analysis

In order to assess the factors associated with showing good outcome, a multivariable regression model was preferred. The model is capable of accounting for the net effect of each independent variable when the others are present. A dichotomous response is typically modeled with a binary logistic regression model.

Table 4: Multivariate analyses between identified statistically significant independent variables and good programmatic outcomes

| Variables | Model coefficients(B) | P_value | Adjusted OR ⁴ (95%C.I) ² |
|------------------------------------|-----------------------|--------------|--|
| BMI/Ref: ≤25 (Normal weight) | | 0.000 | |
| 25-30 (Over weight) | -1.912 | 1.033 | 0.302 [0.710, 2.315] |
| >30 (Obese) | -2.042 | 0.004 | 0.816[0.371, 0.953] |
| DM treatment status/Ref: education | | 0.033 | |
| Insulin | 1.917 | 0.000 | 1.991[1.961,5.510] |
| oral | 1.563 | 0.031 | 1.208[1.226,4.007] |
| Visits/Ref: irregular | | 0.000 | |
| Regularly | 2.291 | 0.000 | 3.904[1.219, 8.277] |
| Constant | 5.713 | 0.000 | 29.064 |

The table 4 indicated that a patient who are on treatment and regularly visit to DM professionals, increases the probability of delaying complications while an obese one accelerate complications.

However, each variable has its own degree of influence; starting from BMI, by holding other independent variables a constant value, a patient whose BMI greater than 30 is about 1.22 times less likely to present good outcome (OR: 0.816, p=0.004) compared to the one whose BMI less than 25 at $\alpha = 0.05$.

⁴ Adjusted Odd Ratio

As far as Treatment status is concerned, a patient on both oral therapy and insulin therapy are more likely to show better outcomes (OR: 1.991 and 1.208 respectively) compared to the one received education only.

Lastly, a patient who regularly visits DM professionals, is about 4 times more likely (3.904) to show better outcomes compared to a lost follow up patient.

4.3. Discussion

The main finding of this study is that the prevalence of diabetes mellitus is associated with the diabetes program provided to patient at hospital. The Clinical good outcomes of Diabetes Management are associated with implementation of IFD guidelines or WHO global guidelines of Diabetes mellitus treatment. For instance oral therapy, insulin therapy and education. Furthermore, for patients who are enrolled and have regular visits to DM professionals, reasonably their glycemic good control has been achieved. The baseline HbA1c level seen among diabetic patients at Kirehe district hospital are varying around the stability compared to patients of other countries in the region [10, 23].

In this study we didn't look at the prevalence of different types of Diabetes, and further studies are needed in this area to compare different factors related to each type of Diabetes and their contribution, in Rwanda. Lohse N (2011) and Enoru ST (2010), found that Type 2 diabetes is estimated to comprise well over 90% of cases in Africa [25, 26].

The World Health Organization (WHO) attributes NCD burden to four main lifestyle risk factors: unhealthy diet, lack of physical activity, tobacco use, and harmful alcohol use [1, 27]. Our patient population, predominantly rural based, does not have high proportions of the typical lifestyle risk factors of smoking, harmful alcohol use, sedentary lifestyle or obesity. The very low proportion of overweight and obese individuals (15.5%) is consistent with findings of rural communities in other settings [28] but contrasts with 68% prevalence observed in the United States' general population in 2007-8 [29] and 94% prevalence observed among type 2 diabetics followed at secondary care clinics in the United Kingdom [30].

This study revealed also that increased longevity is a major contributor to the high and steadily rising prevalence of chronic diseases especially diabetes and as patient getting old correspond to an increase in likeliness of developing diabetes complication because when people live longer,

many diseases and conditions have time to manifest. We find the same thing with other literatures on the treatment given to the diabetes patient, if the patient is very symptomatic or has a very high blood glucose level, diet and lifestyle changes are unlikely to achieve target values. In this instance, pharmacological therapy should be started without delay [31].

However, there is a need of health diet and regularly receiving treatment as recommended by WHO to ensure an earlier better outcome of the program.

4.4. Limitations and strength of the study

The main strength of this study is that is used data from EMR which uphold the reliableness of data. But on the other side the use of EMR brings also problems of miss data as it can't work offline.

Moreover, the use of cross sectional study design would not allow us to track the behaviors change in Hba1c over time as patients got treated for effective tracking the impact of each treatment received. However, a cohort study design is needed to minimize the bias.

CONCLUSION

In conclusion, our study demonstrates that relatively low rates of death in patients enrolled in the diabetes program can be achieved, and that for patients who remain enrolled diabetes can be effectively managed with reasonable and sustained glycemic control in a rural resource-limited and multi-center setting. We believe that enabling factors include task-shifting to nurses, embedding services within the rural setting so that they are closer to the homes of patients in need, decentralizing services to more facilities with the support of structured training and strong mentorship, employing point-of-care testing to minimize wait times and frequency of visits, and addressing socioeconomic needs for patients who are particularly vulnerable.

However, contributions of these program features both combined and individually, should be studied more in the future. Further, we found that our diabetes patients in rural Rwanda especially treated at KIREHE hospital had low levels of lifestyle risk factors and comorbidities compared with patients in the developed countries. These findings may have implications for context-specific prevention and control strategies for diabetes in similar settings and should be further studied with population-level NCD risk factors studies.

Good diet, physical exercises, and education should be the core of patient treatment to help to control and stabilize their level of diabetes. Patients should be aware of diabetes control importance and consequences which he/she can face in the future, so that all required steps of follow up are on the timetable of patient. And hence, the whole community should be informed the basic knowledge about diabetes mellitus enrollment and treatment as provided by the clinic or national guideline. Clinical test should be done as proposed by diabetes program guidelines. Diabetes program database should be updated and all needed variables should be recorded in the follow up period to help to made further research based on very high quality of data.

Further research can be conducted to evaluate the application of diabetes general guideline of international diabetes forum. The study findings suggest that attention should be paid to considering the determinants such as health expenditure for DM, urban population, adults aged ≥ 20 years who are obese, and alcohol consumption among adults ≥ 15 years, in further investigations of diabetes mellitus among the population with different economic status which can help to assess the burden of diabetes mellitus on poor population.

RECOMMENDATIONS

Following the outcome of this research, the following recommendations were proposed to control the hyperglycemia and early complications:

1. Information sources (e.g., books, pamphlets and web sites) and points of contact for organizations and other relevant resources should be provided to all patients in order to minimize the incidence rate.
2. Education in core competencies should be provided to all patients newly diagnosed with diabetes to ensure timely success.

Core competency education includes: response to acute complications (hyperglycemia and hypoglycemia); how and when to take medication(s); self- monitoring of blood glucose, basic diet guidelines; sick day management; and guidance on when and how to seek further treatment or medical advice.

3. The healthcare team should always be ready to respond to the patient's ad hoc inquiries about new treatments, problems, or concerns.
4. Assessment of the following factors should be completed to determine the extent of the patient's educational and skills deficit and his/her ability for self-management: knowledge of the diabetes disease process, treatment goals, management skills, cultural influences, health beliefs/behavior, attitudes, and socioeconomic factors and barriers to ensure regular visit.

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