IMPACT OF INSULIN STORAGE AND ADMINISTRATION TECHNIQUE ON GLYCATED HEAMOGLOBIN AMONG ADULT DIABETIC PATIENTS AT KENYATTA NATIONAL HOSPITAL

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DECLARATION

This research dissertation is my original work and has not been presented to any other academic institution for evaluation for research and examination.

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This research proposal has been submitted for evaluation for research and examination with our approval as university supervisors.

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DEDICATION

I dedicate this work to God Almighty for gracing me to do this.

To all Diabetes Mellitus patients who believe that nothing is impossible.

To my late Father, Kedogo Jimmy for giving me the foundations of which I'm today and impacting in me to believe with my heart in everything I do.

To my Mother, Hon. Kedogo Dorcas for her constant prayers and patience but also being my example of a dream comes true.

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LIST OF ABBREVIATIONS AND ACRONYMS

ADA- American Diabetic Association.

BDA-British Diabetes Association

BMI-Body mass index=Kg/M^2

BS-Blood sugar

CGM- Continuous Glucose monitoring

CSII-Continuous subcutaneous infusion injection

DCCT-Diabetes Control and Complications Trial

DM-Diabetes Mellitus

FBS-Fasting Blood Sugar

GDP-Gross Domestic Product

GIT- Gastro intestinal tract

HbA1c-Glycated hemoglobin 1 A

HDL-High Density Lipoproteins

HIV-Human Immunodeficiency Virus

HPLC-High performance liquid chromatography

IDF-International Diabetes Forum

IRCP- Immune reactive C peptide

KNH-Kenyatta National Hospital

PI-Principal investigator

RBS-Random Blood sugar

SD-Standard deviation

SCI- Subcutaneous injection

T1DM-Type 1 diabetes Mellitus

T2DM-Type 2 Diabetes Mellitus

UON-University of Nairobi

USA- United States of America

WDF-World Diabetes Forum

OPERATIONAL DEFINITION OF TERMS

Controlled blood sugar:	Absence of clinical symptoms of hypoglycemia or hyperglycemia and random blood sugar (RBS) ranging 4mMols/l to 10.9mMols/l or fasting blood sugar (FBS) ranging 3.9mMols/l to 5.5mMols/l or Glycated hemoglobin A1 concentration (HbA1c) of5% to 7% within 2 or 3 months.
Uncontrolled blood sugar:	Presence of clinical symptoms of hypoglycemia or hyperglycemia and RBS below 4mMols/l and above 10.9mMols/l or FBS below 3.9mMols/l and above 5.5mMols/l or HbA1c below 5% and above 7%.
Correct handling &Storage of insulin:	Use of insulin according to the manufacturer's advice on storage conditions or guidelines on handling insulin.
Incorrect handling & storage of insulin:	Not using insulin according to the manufacturers' advice on storage conditions and guidelines on handling the insulin.
Correct injection Technique	performing the complete process of the injection steps correctly according to the American diabetes association guidelines.
Incorrect injection technique:	Inability to correctly perform all the Injection technique steps according to the American diabetes association guidelines.

Pharmacy 15:	Kenyatta National Hospital Out-Patient pharmacy serving patients seen at the clinics. It operates between 8am and 5pm.
Diabetic outpatient clinic days:	The clinic days of diabetes are everyday of the weekdays except holidays and weekends. Patients are seen in the outpatient medical clinic.
Glycated hemoglobin (HbA1c) test:	Test indicating average blood sugar level for the past 2 to 3 months. Measures the amount of sugar glycated to the red blood cells in percentages. Normal range is from 5% and 7% (97-185) mg/dl
Diabetic-related complications:	Complications which arise after chronic uncontrolled blood sugar levels in DM. They include: Neuropathies, Heart, Macro vascular complications, Micro vascular complications, Foot ulcers & amputations, compromised immunity, Kidneys and Eyes.

ABSTRACT

Background: Insulin therapy is the mainstay of treatment for type I diabetes and also adjunct therapy for some type 2 diabetic patients. Proper storage and self-administration of insulin play an important role in long term optimal blood sugar control. There is scant published literature on diabetes self-care practices on insulin administration, handling and storage, and their impact on the overall glycemic control as measured by glycated hemoglobin.

Study objective: To assess the impact of insulin administration techniques and handling on the levels of glycated hemoglobin among diabetic patients at Kenyatta National Hospital.

Study population: Diabetes mellitus patients of aged 18 years and above refilling monthly insulin prescriptions in Kenyatta National Hospital.

Methodology: A tertiary hospital based cross-sectional study was used to consecutively sample 73 diabetic patients on insulin. Insulin storage and administration techniques were assessed using a pre-designed questionnaire. Overall control of blood glucose was determined by measurement of serum concentrations of glycated haemoglobin. Association between insulin storage methods, insulin administration technique and level of diabetes control was determined using Pearson's Chi square test at p-value of 0.05.

Results: The mean age of the participants was 53.6 (±11.0) years. The median age was 52.0 years (range 25-75). Majority of the participants were female at 63.0%. Slightly over 90 % had been on insulin for over 6 months. Almost all patients had been trained on insulin storage and injection techniques but only 30 % had been assessed on them. None of the patients was able to perform all the steps of injection technique. In addition, none of the patients knew that insulin should be discarded after 28 days of opening. Correct performance of the critical injection steps was associated with good glycemic control (p=0.013). However, refrigeration of insulin was not statistically associated with good glycemic control (p= 0.062).

Conclusion and Recommendation

Assessment of insulin use by patients in the hospital is inadequate. Good insulin injection technique is associated with optimal glycemic control unlike storage by refrigeration. We recommend regular and continuous patient training and assessment on insulin injection technique to improve glycemic control at Kenyatta National Hospital.

CHAPTER ONE: INTRODUCTION

1.1Background

Diabetes mellitus is a chronic disease of metabolic abnormalities. The disease manifests as chronic hyperglycemia due to absence/ defective secretion of insulin or action of insulin or both. There are 3 major types of diabetes mellitus (DM): DM Type 1, DM Type 2 and gestational DM (1–5).

The global epidemiology of diabetes for all age groups worldwide is estimated to be 4.4%. The total number of people with diabetes is projected to rise to 366 million by 2030 globally if nothing is done. DM type 2 constitutes 85% of the overall diabetes cases in the world.DM type 1 constitutes 10 % and gestational DM constitutes 5 % (4).

Estimates in 2011 showed that 14 million people had diabetes in Africa. According to the International Diabetes Federation (IDF) the prevalence rate of diabetes in sub-Saharan was estimated to be 2.4% in 2003 (4). This is expected to rise to 2.8% by 2025. In Kenya, the prevalence estimate was 4.5%. This is expected to double by 2025 due to lifestyle changes and rural to urban migration. DM type 1 is estimated to be 10% of the overall DM prevalence in Kenya(6).

Management of DM goal is to keep daytime blood sugar (BS) levels pre-prandial between 3.9 to 7.2mMol/L and< 10mMol/L two hours post-prandial (7). Management of DM type1 and gestation DM involves primarily insulin therapy.DM type 2 involves insulin therapy or oral hypoglycemic agents or both. Insulin currently in use should be kept at room temperature. This is not only comfortable to inject but also stable and potent for 28 days. Unless exposed to temperatures above 30^0C or below 2^0C. If the room temperature is outside that range, insulin should be stored in the refrigerator, at a temperature ranging 2^0C - 8^0C. Below 2^0C insulin will freeze and become unusable. Insulin should be disposed 28 days later from the start date of opening a new cartridge/vial (8,9).

In UK, about 30% of the DM patients use injectable therapies (10). In Kenya, it is estimated that 40% of DM patients access medicines (6). About two -fifths of DM patients in Kenya are using insulin. Studies have revealed that poor injection technique can result in unpredictable pattern of insulin absorption leading to hypoglycemia or hyperglycemia in patients (10). This may result in poor control of blood glucose (10,11).

Glycated hemoglobin (HbA1c) testing is a better surrogate marker of how well DM therapy and care plan has been working over 2-3 months. Findings of the Diabetes Control and Complications Trial (DCCT) indicate that DM patients with HbA1c levels <7% can prevent DM-related complications (7,12). Elevated HbA1c level may signal the need for a change in insulin regimen, meal plan or both. Levels of HbA1c may be associated with insulin administration technique as well as insulin handling (10,13).

The impact of storage and administration technique of insulin has an impetus in the overall control of blood sugar in DM patients. Storage and administration technique are the variables of effective utilization of insulin. Effectiveness of use directly correlates to maintaining the HbA1c value within 7%.Hence we sought to find out the clinical significance of storage and administration of insulin in keeping the blood sugar (BS) within required physiological limits.

1.2 Problem statement

The mainstay for the management of type one diabetic patients is insulin, requiring not only stringent storage requirements to avoid degradation but also good administration techniques (8,10). In low resource settings, storage requirements of insulin may be compromised due to unavailability of storage equipment and the harsh climatic conditions. This may compromise the overall quality of insulin and consequently the control of blood glucose. In addition, parenteral administration technique for insulin requires patients training. Improperly measured and poorly administered insulin may result in poor control of blood glucose. Local studies have shown that patients are not adequately trained on insulin usage (14). A study done in UK revealed that poor technique results in erratic absorption of insulin and hence poor blood sugar control (12). Prolonged poor control results in early onset of DM-related complications (12,15). The DM complications increase the financial, psychological and emotional cost of treatment. This lowers the quality of life in patients and life expectancy as well compared to the general population

(16,17). The patient, family, society and national economy, Gross Domestic product (GDP), at large are all affected.

1.3 Rationale/Justification

In DM patients on insulin therapy, blood sugar control is achieved by performing correct injection technique but also ensuring proper storage conditions of insulin (7,10,11). Standard management of DM includes training the patients on proper technique of administration and advice on proper storage conditions and also assessing these techniques and knowledge in every clinic visit. Poor blood sugar places economic burden on long term therapy plan and premature loss of life (6,16,17). Local data on prevalence of adult patients performing correct/incorrect injection technique and proper storage of insulin was lacking.

The aim of the study was to seek and find out the prevalence of insulin storage methods and the insulin injection techniques among diabetic adult patient and relates the two factors to the HbA1c levels in patients. The key beneficiaries are all the DM patients on insulin therapy to attain effective blood sugar control and the caregivers to enable their patients achieve successful insulin therapy. Proper storage methods and administration techniques of insulin shall help in increasing the effectiveness of insulin therapy. This study will strengthen management guidelines of DM, guide healthcare workers to intervene to reduce unscheduled clinic visits and improve blood glucose control especially through training of correct injection technique and proper storage conditions of insulin.

1.4 Study objective

1.4.1 General objective

To assess the relationship between insulin storage and it`s injection techniques and overall control of blood glucose among diabetic patients at Kenyatta National Hospital.

1.4.2 Specific objectives

1. To determine the proportion of DM patients with correct insulin injection technique.

2. To find out insulin storage and handling methods among diabetic patients at Kenyatta National Hospital.

3. To determine the level of control of blood glucose among diabetic patients attending KNH.

4. To determine the relationship between insulin storage and injection techniques and the overall control of blood glucose among diabetic patients at Kenyatta National Hospital.

1.5 Research questions

1. What is the proportion of DM patients who use the correct insulin injection technique at KNH?

2. Which methods of storage and handling of insulin are used by DM patients at KNH?

3. What is the level of blood glucose control among DM patients at KNH?

4. What is the relationship between storage of insulin, injection technique and overall control of blood glucose among DM patients at KNH?

1.6 Significance of the study

It will promote strategies to improve quality of counseling during initiation and continued use of insulin in KNH and local guidelines for insulin use. Inappropriate use of insulin through poor storage and administration techniques lead to typical use failure and reduced effectiveness of therapy. The development of diabetes mellitus complications and mortality can be averted if the patients are counseled on the correct methods of administration and storage. The findings of this study may serve as reference material and can be used to improve utilization of insulin.

CHAPTER TWO: LITERATURE REVIEW

2.1 Introduction

This chapter analyses relevant studies that have been carried out with focus to investigate the therapeutic aspects of patient knowledge and practices. The studies include administration, storage of insulin and their relationship to the HbA1c of DM patient`s using insulin.

2.1 Epidemiology of diabetes mellitus

Studies indicate Global prevalence of DM is approximately 4.4% (4). Regional prevalence of DM is approximately 2.8 % (1,2) and prevalence of diabetes in Kenya is estimated to be 4.5 % (6). Hence, a growing trend. The cost of accessing insulin in Kenya is equivalent to 4 working days of most low income earners who live on hand to mouth basis.

The cost of insulin locally is not only 20% more expensive than the average cost in Asia, Europe and South America but also 67% much higher in the private sector than the subsidized insulin in the public sector. Thus, the proportion of Kenyans capable of accessing insulin is less than 40% (6). Insulin needs to be used and stored appropriately in order for it to be effective among DM patients on insulin use.

2.2Insulin administration techniques

In the developing nations, generally, diabetes is a neglected area (1,2,4,6).The level of knowledge about diabetes among patients can be directly related to their adherence to recommendations of American Diabetes Association (7,18).

A study carried out by Nyamu *et al 2008* to assess the level of knowledge in KNH in diabetic patients observed that 49.5% of patients had sufficient knowledge on diabetes mellitus disease itself while 33.3% patients had sufficient knowledge on diabetes mellitus medications (14). This study also revealed that a pharmacist has an indispensable role in counseling the DM patients regarding medication use.

Self care is very significant in getting successful insulin therapy outcomes (19).The input of Health care providers and family support is significant in achieving the target of HbA1c of 7% and below. Patients with better self care practices have good blood sugar control.

Having diabetes knowledge alone does not equal to good blood sugar control (19). There is need to emphasize practical diabetic skills and self care activities to enhance problem solving and

improve self care in patients. Further studies need to be done to identify the barriers to self care and knowledge gap currently present in patient to help improve glycemic control in DM patients.

A meta analysis by Norris *et al in 2002* to evaluate the effect of self-management education on HbA1c recommended that self management improves HbA1c. But since learned behaviors change with time, it`s important to prolong contact time and sustain it to maintain long-term glycemic regulation (20).

Studies done on the injection technique in United kingdom (Uk) by Hicks *et al 2010* found that many DM patients on insulin do not remember receiving education on injection technique (10,11). Poor technique could result in an unpredictable pattern of insulin absorption. This results in hypo or hyper glycemia. They recommended that care givers not to presume that DM patients on insulin therapy are doing it correctly. The patient`s injection technique needs review on constant basis. Specifically, areas of DM patient`s knowledge and practice needs to be reviewed every year.

Attitudes may affect patient`s willingness to take insulin (21). Health care providers should take care to avoid promotion of negative sentiments toward insulin. They should actively respond to patient attitudes to reduce reluctance to take the medication.

A meta analysis on insulin pump therapy results indicated that continuous subcutaneous infusion injection (CSII) therapy is associated with significant improvements in glycemic control compared with traditional insulin therapies (22). Advanced technology and new studies have isolated significant issues related to injection technique (23).They include needle gauge, skin and subcutaneous tissue thickness, adequate re-suspension of cloudy insulin; leakage of the injection from the injection site, injection site rotation and choice, pinching a skin fold and lipohypertrophy identification. These not only affect insulin therapy but also cause bruising during injection at the injection site. The aspect of pain and bruising at the injection site is significant in causing fear and attitudes related to use of insulin injection therapy which affects compliance.

The risks in insulin administration may be life-threatening and safety in its use must be adhered to by all concerned in its use. Safe insulin administration requires partnership of medical and

nursing skills with a pharmacist and the patient. Knowledge of proper use of insulin is indispensable and essential to patient safety. Wrong route of administration and wrong timing of a dose plus omission of other doses were found to be common errors when administering insulin (24). Pharmacists should to be precise in storing, handling insulin products and meeting the patient`s required HbA1c as their dispensing objective through ensuring successful insulin administration technique (24). Correct disposal of sharps should be a central part of diabetic counseling (25).Doctors, nurses and pharmacists must be involved in reinforcing this education. Needle-prick injuries from poorly disposed needles of DM patients can be a risk for contracting various blood-borne diseases.

According to a study on insulin injection technique amongst the nursing staff in Pakistan (26).Over half (57.4%) knew that insulin should be injected 30 minutes before meal, 66.2% knew about injecting insulin in the subcutaneous tissue, 75% knew upper thigh as an injection site, 89% knew about the abdomen as a site of insulin administration, 64% knew well about the pinching technique and 72.8% gave correct 90^0 angle of injection (26). Blood sugar fluctuates as technique for insulin administration fluctuates (11,26,27).Insulin should be given by pinching skin fold between two fingers at an angle of 90^0 . Half an hour before meal (11,26,27).

According to the American Diabetic Association (ADA) disposal of syringes and needles should be done only after single use (11). Challenge in reusing syringe and needle is mainly the inability to guarantee sterility. They carry probable risk of infection for patients with poor basic hygiene and compromised immunity.

The 30 and 31 gauge needles tip tends to bend and form a hook after single injection. This can lead to needle- prick injuries. They either lacerate subcutaneous tissue or leave needle pieces in the skin and lipodystrophy is likely to occur (26,28). If a syringe should be reused, the patient`s skills in safe recapping of a syringe should be evaluated. Recapped syringe should be stored at a room temperature. Alcohol cleansing of the needle removes the silicon coat. Silicon coat makes the skin puncture less painful (26,28).

A study by Swetha Shettigar *et al 2013,* on improving the competency level on self – administration of insulin amongst type 2 Diabetes patients reported that diabetic patients on insulin injection have a phobia of self administration and miss out on correct steps of injecting

insulin (29).The DM patients need to be knowledgeable on disease and insulin. The refresher training is required for all. The patients need to also have positive attitude towards self-injection of insulin to deal with the challenges of insulin injection in bid to get good glycemic control. DM patients should have a fair knowledge on self-administration of insulin injection and improved after training. The DM patients who were fearful towards insulin injection become confident after teaching and could do it well.

2.2 Methods used to store insulin by patients

According to findings by Mjota in Kenya 2008, there is a small proportion of patients storing insulin by refrigerators due to poverty (6). The cultural practices, social economic and political challenges that unsettle people make most DM patients to live in very pathetic housing conditions, street families in particular. This makes correct home storage practice of insulin to be practically impossible for the low income earners and the poverty stricken class who constitutes about 70% of the urban population. The effect of storing insulin in suboptimal conditions is a commonplace for the majority of insulin using DM patients in urban Kenya which goes a long way in the effectiveness of therapy being suboptimal (6).

Most insulin users from a low economic class use pot with sand in water contraptions from a random survey on storage in sub-Saharan region medical outpatient clinics. Range of 26% to 77% DM patients have refrigerators for storing insulin (30).

Insulin outside the refrigerator should be kept cool within 12 ^{0}C- 30^{0}C; shouldn't be allowed to freeze. If stored between 2- 8 ^{0}C it will remain stable until the expiry date. According to Garry Gilles 2009 clinical review, insulin used daily should be kept at room temperature and remains potent and stable for 28 days also comfortable for injection (8). However, it`s good to have extra supply of insulin in the refrigerator as a buffer stock for any eventuality of loss of potency, damage, or loss.

Most physicians are not aware of the real effectiveness of insulin once it`s opened. Also three pharmaceutical companies that supply insulin reveal different storage indications for every type

of insulin they produce, depending on the particular formulation, method of manufacture, its container, and ambient storage conditions (31).

The storage of unopened vials, cartridges, or prefilled insulin delivery systems should be done at recommended temperatures, so that they can be used until the expiration date Insulin. In-use can be kept non refrigerated for up to 28 days away from direct heat and light, at controlled room temperature [<30°C]. For pens and cartridges the life span are shorter than those for vials, reflecting the reduced volumes and the environment to which these products might be exposed. Substantial discrepancies occur in cartridges and prefilled devices containing insulin NPH and fast-acting and long-acting mixtures (31). Insulin is very expensive in developing countries. It`s very hard to achieve the required 2^0C – 8^0C in warm tropical countries. Patients in Africa region live in warm climates that lack cooling facilities (31).

A study by Steel and Mngola 1974, found that four out of six batches of insulin to be less potent by 75% when the insulin concentrations were measured by radioimmunoassay prior to patient prescription (32). Lack of refrigeration and power supply in rural areas of tropics are major obstacles to insulin storage in the tropics. In Nigeria, 68% of the patients had access to a refrigerator (30) compared to 37% in Blantyre, (30) and 69% in Soweto, (33). In Tripoli , 77% had access (34). compared to 26% in Addis Ababa, (30,33) and 30% in Hlabisa (30). Lack of refrigeration facilities was high in the rural areas than urban areas. Most patients didn't own the refrigerators during the study but used proxy storage arrangements with Butchers, Shoppers, Bars, Friends, Relatives among others. Patients in this case survive as a result of traditional African Hospitality (1996) (30).

Non-refrigeration methods of insulin storage from the above studies include using shady corners of rooms or Huts; Holes in the ground; Boxes outside the House; Porous Clay pots with water and sand inside which is popular in sub Saharan Africa including Kenya. Evaporation of water through the porous clay pot lowers the temperature inside the pot. This popular method in practice is yet to be critically assessed and approved. More study still needs to be done on it (33).

According to the British Diabetic Association (BDA) 1996 recommended that insulin treated patients to only store their extra stock for later use in the refrigerator 2^0C - 8^0C (30). Insulin

currently in use should be stored at a room temperature and discarded after 28 days from the date of initiating its use. This is based on a study by Pingel &Volund 1972. Lente insulin looses 5% of biological activity after 2 weeks (35).

The viewpoint concluded that there is lack of good evidence about clinically significant deterioration in the bioactivity of insulin that is currently in use stored at ambient tropical temperatures. Refrigeration is a prerequisite for insulin stored for long periods beyond 28 days, as the case of hospital pharmacies, warehouses etc. Further research is still needed to critically appraise cooling methods such as clay pots, holes in the ground among others (30).

2.3. Concentration of HbA1C in patients using insulin

Glycated hemoglobin reflects long-term metabolic control of diabetes and was analyzed in 131 patients with juvenile-onset diabetes (36). HbA1c was inversely related to plasma immune reactive C-peptide concentration (IRCP). A low but significant, positive correlation was found between HbA1c and the duration of diabetes. HbA1c was also correlated with a subjective rating score of the metabolic control performed by the treating physician. Fasting plasma glucose was significantly related to HbA1c but not to any of the independent variables. Fasting 3-hydroxybutyrate showed an inverse correlation with age of the patient. The present study showed that in juvenile-onset diabetic patients, endogenous insulin secretion as reflected by IRCP was the factor best correlated with a low level of HbA1c. After the cessation of endogenous insulin secretion, there was a progressive deterioration of metabolic control and multiple injections of insulin rather than one or two per day needed to reach optimal control in the patients (36).

A previous study on quality of glycemic control among insulin treated ambulatory patients with diabetes mellitus at Kenyatta National Hospital shows that in spite of improved therapy and knowledge, glucose control is still not within optimum in many patients (37). This was to find the link between the disease, treatment factors and quality of glycemic control among insulin treated ambulatory patients. Two hundred and twelve patients (212) on insulin therapy for at least 3 months were recruited. The median duration of DM and duration of insulin use was 11.1 and 6.0 years respectively. Sixty four percent adhered to the insulin injections. Five point two percent monitored sugars at least once per day. Two hundred and one samples were analyzed for

HbA1c. Eighty six percent were found to have had HbA1c>=7% and were considered poorly controlled and 70% had their HBA1c>=8%. Forty two percent had their HBA1c>=10%.

The study concluded that glycemic control was significantly associated with age at disease onset. Disease onset at early age and longer duration of insulin use were associated with poor control. However, there is still scanty data and information on quality of control in Kenya particularly on insulin treated patients (37).

A study by Eric S Kilpatrick *et al 1994*, found that clinically significant variation exists between HbA1 and HbA1c in evaluating glycemic control in patients.HbA1c value could mean the patient is at a high risk of developing long term DM complications .HbA1 may not tell us on how risky the patient is capable of developing these complication(38).

According to Allan *et al 2013*, many patients on conventional insulin regimens do not get optimum control (39). The clinical benefits of CSII versus multiple daily injection therapy in patients with diabetes mellitus are quite evident in appropriately selected patients with greatest glycemic improvement associated with reduced baseline HbA1c levels.

Insulin therapy is the most preferred choice of management for both type 1 and type 2 diabetes mellitus, Mauli *et al 2009*.A study carried out in KNH diabetic clinic found out that 76.4% of the adolescents had poor glycemic control (HbA1c>=7%).The study revealed many variables like income of the parents, clinical attendance, insulin storage, foot care, encouragement in diabetic management, fostering independence by family members, teacher and peer to the adolescent in diabetic management and random blood sugar were found to be statistically significant (40).

According to study by David *et al 1980*, values of HbA1c were elevated in most patients despite aggressive treatment (41). The HbA1c level was elevated at diagnosis, fell to near normal after 60–90 days of insulin therapy, increased gradually, and reached a plateau after approximately 4 year duration. Mean insulin dose (U/kg/24 h) paralleled both HbA1c and duration of diabetes. In this study, the effectiveness of the endogenous insulin was twice more than the exogenous insulin (41).

Diabetes Mellitus patients with HbA1c levels <7% can prevent DM-related complications (16). The complications have been the largest factors of mortality in DM related deaths (17) Elevated HbA1c level may signal the effectiveness of the existing therapy of DM. Thus, HbA1c testing is better surrogate marker of how well DM therapy and care plan is working (12,15,38). Research done in 2010 found that poor blood sugar control is linked to early emergence and progression of complications in diabetes (42). Management of diabetes in a limited-resource setting, poor blood sugar control and high occurrence of complications are connected.

HbA1c is a marker in use for long term blood glucose control (43).Thus it`s diagnostic value in predicting cardiovascular risk. It was found that High density lipoproteins (HDL) was less in patients with HbA1c > 7%. The patients with HbA1c < 7% had elevated HDL while other lipid profiles were less as compared to those with HbA1c > 7%. It was concluded that HbA1c levels can provide reliable supporting information on the levels of circulating blood lipids. This is relative to blood sugar control.

Summary

The use of insulin in management of diabetes mellitus is increasingly becoming the most preferred choice of treatment due to not only reduced side effects compared to oral hypoglycemic drugs but also the only choice available for controlling blood sugar in type 1 DM. The role of storage of insulin, administration techniques are very essential in turning around the success of therapeutic plan in DM.

CHAPTER THREE: METHODOLOGY

3.1 Introduction

This chapter details the methods of data collection, analysis and presentation that were used in this study. It focuses on the methodology and steps that were taken to enhance validity and reliability of the data that were obtained from the study.

3.2 Research design

The study was a cross sectional survey. An interviewer administered questionnaire was used to collect the required information from the participants.

3.3. Target population

This included all adult diabetic patients of 18 years and older on insulin therapy in Kenyatta National Hospital. Patients recruited had been on treatment with insulin for at least last 3 months and refilling insulin prescriptions at KNH outpatient pharmacy 15.The life span of red blood cells is 120 days, approximately 3months.The HbA1c is an average measurement of glycated hemoglobin in the red blood cells (Rbc) of the last three months. The choice of pharmacy 15 was ideal on account of it being the point where insulin is dispensed to patients attending medical outpatient clinic. Also, it`s adjacent location to the medical outpatient clinic. This makes the ease of collecting data from the patient file.

3.3.1Inclusion criteria

- Diabetic patients on exclusive insulin therapy for at least three months.
- Ambulant diabetes patients who are able to demonstrate their insulin injection techniques and participate in the interview.
- Patients who consented.
- Patients of age 18 years and over
- Diabetic patients without other pathological chronic conditions other than those related to diabetic long-term complications.

3.3.2 Exclusion criteria

- Patients with other pathological states other than diabetes mellitus and related long-term complications. Other pathological states were potential modifiers of the disease and to overall blood glucose control.
- Patients on medications for other chronic conditions unrelated to diabetes and its long-term complications.
- Patients of aged less than 18 years.
- Critically ill patients, who were unable to demonstrate their insulin injection techniques.
- Patients who declined to consent.
- Patients who abandoned the study before completion.

3.4 Sample size

Studies indicate that the prevalence of DM in Kenya in 2014 was approximately 4.5% (6).

By use of Fischer`s formula (44), sample size is calculated as follows

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

$$n = \frac{1.96^2 \times P(1-P)}{d^2}$$

Where:

n is the sample size

Z is 1.96 which is the normal deviate corresponding to a confidence interval of 95%

P is 0.045 which is the estimated prevalence of DM patients in Kenya

D is 5% degree of precision/accuracy.

Thus:

p = 0.045

d = 0.05

$$n = \frac{1.96^2 \times 0.045 \times 0.955}{0.05^2} = 66$$

n=66.

To cater for data losses, we add an average of 3-10%, so to get the final sample size n=72.2.

Which is rounded off to the whole figure; n = 73

3.5 Sampling technique

The sampling technique that was employed was consecutive sampling where every patient was sampled as they come for refilling of prescriptions.

3.6 Data collection method.

3.6.1 The interview

The research instrument was a pre-tested interviewer administered questionnaire (Appendix II).Patients that met the inclusion/exclusion criteria were given an explanation about the purpose of the study and consent was sought before the interview. I interviewed the patients who consented and their responses entered in the questionnaire. I asked the patients to demonstrate insulin administration technique using an empty syringe with needle provided by me or their own syringe and needle. By use of insulin administration guidelines of American Diabetes Association, a check list was ticked as correct/ incorrect.

The demonstration was termed correct if all the critical steps were performed correctly. The demonstration was termed incorrect if any of the critical steps was missed or any of the critical steps was performed incorrectly.

The patient was also interviewed on how they stored and transported their insulin and the data obtained was entered into a questionnaire.

3.6.2 Laboratory procedure

After the questionnaire, I reviewed the patient`s file to identify if HbA1c had been done for the patient in the recent past one to two months .For those who had had HbA1c done, their results were recorded. For those who hadn't, HbA1c was determined.

Procedure for the determination of HbA1c.

This was be done for those patients who had not had their HbA1c done within the last 2 to 3 months and had signed informed consent. The patient was referred to a waiting laboratory assistant for blood collection into the sample tubes. Sterility was assured by: The surgical spirit and cotton wool/surgical swabs were used to sterilize the skin before puncturing the vein. The blood collection needles were from the sachet for each patient and discarded to the sharps

container after each use. This was to avoid cross contamination and biohazards caused by the sharps. After the blood was collected, a fresh surgical swab was used to press on the skin of the punctured vein to ensure that no more blood is lost. A cotton wool was used to plug the punctured wound and fasted by a tape to enhance the surface clot formation. The collected blood in the collecting sample tube was coded as per the patient code in the research tool then moved to the Clinical chemistry laboratory inside of KNH/UON, medical school , College of Health Sciences, University of Nairobi (UON). HbA1c determination was done in HbA1c analyzer. The results were received and recorded in the questionnaire of the study. HbA1C were said to be normal, borderline and high (poor control) if below 5.7 %, between 5.7 - 6.9 % and 7 % or more, respectively.

3.7. Data analysis

Data from completely filled questionnaires from the patients was entered into the computer software, excel spread sheet, to create a database which was cleaned with the help of a statistician. It was then exported to STATA version 10 for analysis. Demographic variables were presented as percentages, numbers, medians and ranges, bar charts and tables. Correct/incorrect insulin administration technique and storage methods were represented by use of percentages and bar charts. Association between demographic variables and administration technique and storage were assessed using Pearson's Chi square test. Student t-test was used for continuous variables and p- value less than or equal to 0.05 were considered statistically significant.

Adherence of patients to the therapy and other medications that were likely to affect blood sugar were the confounding factors in this study and stratification method of analysis was used to factor in these two confounding factors during the analysis.

3.8 Data quality control

Data collection form was pre-tested before use by randomly interviewing ten patients at KNH Pharmacy 15. The data collection tool was adjusted and reformatted where needed. Data was entered into the database routinely checked for accuracy and completeness. Errors and omissions were corrected. On completing data entry, data cleaning was done to correct mistakes that occurred.

3.9 Ethical considerations

3.9.1 Approval to carry out the study

Permission to carry out the study was sought from the Kenyatta National Hospital/ University of Nairobi Ethical and Research Committee and a letter ref no: KNH-ERC/A/242 dated 29/May/2015 was given.

3.9.2 Recruitment and consenting procedures

I routinely reported daily to the diabetic clinic, as first thing, during the study period. I went through the files of the patients` clinic day bookings and I noted the patients who met inclusion/exclusion criteria. I waited for them in pharmacy 15 immediately they were through with the doctor`s consultation and ready to get their monthly insulin refill. Patients received an explanation about the study in either English or Kiswahili. Initial salutations and introductions were done in either of the two languages. This was done before they got their medications. This was to allow room for dispensing and teaching while conducting the study thus using patient`s time effectively. Consent was sought from patients after the explanation on the purpose of the study. Information on the risks and their prevention involved in the study was discussed with the patient. The patient was further advised on the right to decline or abandon the process at any moment if they felt uncomfortable. Information to participate in the study was on voluntary basis.

3.9.3 Informed consent

Each patient was requested to sign a consent form before inclusion into the study. This was after the patient had been explained about the risks involved in the study, benefits and ethical considerations that applied. I requested the patients to paraphrase their understanding of what was in the consent form as a way of ensuring that the patient is fully aware and informed about the study benefits, risks and their rights before signing the consent form.

3.9.4 Confidentiality

The patient was interviewed privately and demonstrations on how they administer insulin were done in a private room. All the information obtained was treated with confidentiality. Serial numbers on their questionnaires were used instead of the patient’s name to protect their identity.

CHAPTER FOUR: RESULTS

4.0 Introduction

This chapter presents the findings of the analysis of a total of 73 adult diabetes mellitus patients attending KNH for refilling of monthly insulin.

4.1 Demographic characteristics

Table 1: Demographic characteristics of Study Participants

Characteristics	n	%
Age category (years)		
0-35	4	5.5
36-65	57	**78.1**
Above 65	12	16.4
Marital status		
Married	65	**89.0**
Single	8	11.0
Gender		
Male	27	37.0
Female	46	**63.0**
Occupation		
Employed	47	**64.4**
Unemployed	14	19.2
Retired	11	15.1
Student	1	1.4
Highest education level		
No formal education	4	5.5
Primary	17	23.3
Secondary	20	27.4
Tertiary	32	**43.8**
Residence		
Urban	65	**89.0**
Rural	8	11.0
Alcohol status		
Former	24	32.9
Current	3	4.1
Never taken	46	63.0

Females comprised 63.0% of participants with most (64.4%) patients being employed and 89.0% married. Over ninety per cent reported to have had formal education.

The age range with the highest number of the participants (78.0%) was 36-65 years. Patients aged less than 35 years were the minority at 5.5%. Almost 90% participants lived in urban areas (Table 1).

4.2 Insulin Injection Technique Assessment

Table 2: Overall performance of the injection technique by patients on insulin in KNH.

Injection technique	**n**	**%**
Correct	39	53.4
Incorrect	34	46.6

On average 53.4% of the patients performed overall steps of the injection technique correctly (Table 2), with most patients (94.5%) performing step 1(fixing the syringe to the needle and step 10 (loading insulin at room temperature) correctly. Loading the insulin with equal amounts of air, step 2, was the worst performed by 47.9% of the patients. They loaded less or more air unequal to the units they were taking.

Only 60% of the patients performed one of the key critical steps well which included, checking for clarity and detecting any precipitation, frosting and crystallization (step 5).

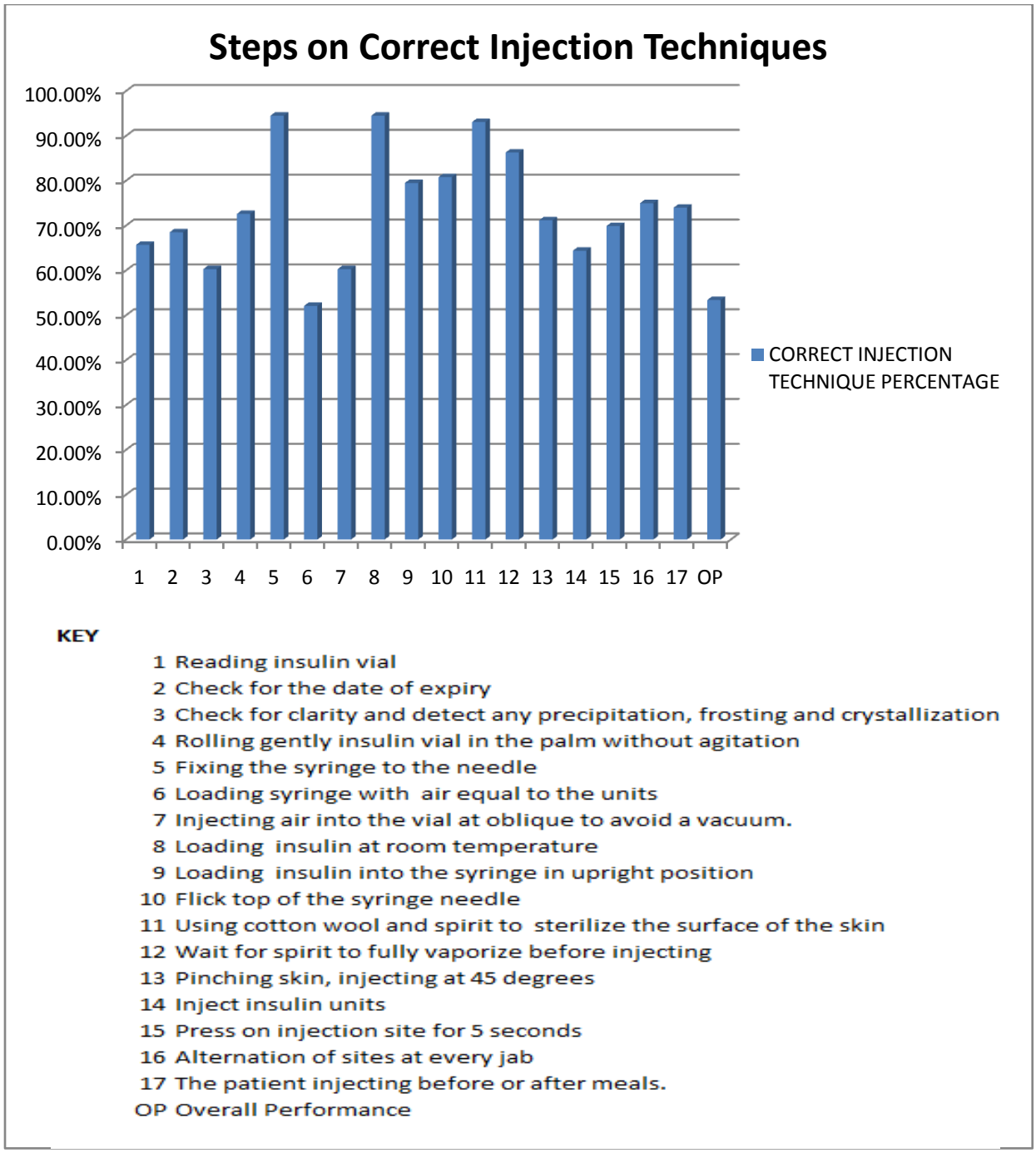

Fig 1: Participants' performance on Steps for Insulin Injection Techniques

4.3.1 Details on Insulin Injection Technique

As illustrated in tables 3 and 4, training patients on the injection technique and their regular assessment of the technique varied with the personnel involved and the frequency of training.

Table 3: Training on insulin injection

Variable		n	%
Participants trained on insulin Use			
	Yes	72	98.6
	No	1	1.4
Duration since the last assessment on Insulin use	<6months	17	23.3
	>6months	7	9.6
	Never Assessed	49	67.1

Most of the patients (98.6%) on insulin therapy in KNH reported having been previously trained on insulin use and only 32.9% of them reported recent being trained in the recent 6 or more month's period.

Table 4: Details of training on insulin use

Characteristic		n	%
Trainers	Clinician	16	21.9
	Pharmacist	1	**1.4**
	Nurse	56	**76.7**
Patients trained on first insulin use	Yes	70	**95.9**
	No	3	4.1
Type of training instruction	Oral instruction	3	4.1
	Practical demonstration	5	6.9
	Both	65	**89.0**

The highest number of health practitioners, 76.7%, offering the training were the nurses and training was least offered by Pharmacists, 1.4%, in KNH. Most of the patients, 95.9%, were trained on their first insulin prescription. Combined practical demonstrations with orals constituted 89.0% of the training methods.

4.3.2 Storage and handling of insulin among patients

Table 5: Storage and handling of insulin

Variable		**n**	**%**
Home storage	Refrigeration	22	30.1
	Cotton dipped in tin	51	69.9
Handling on travelling	Bag	5	6.9
	Container(tin/thermos)	68	93.1
Labeling a newly opened vial	Yes	1	1.4
	No	72	98.6
Period upon which the newly opened vial should be discarded	After 28 days	0	0.0
	Until empty	73	100.0
Overall storage performance	Correct	3	4.1
	Incorrect	70	95.9

There are only two methods of storage revealed in our study. The most popular (69.9%) home storage method was spirit cotton dipped in tin. Refrigeration method of storage was used in

30.1% of the study participants. Only 1.4% of the patients labeled a newly opened vial. All (100%) the patients discarded the opened vial after it was empty. The overall storage performance had most patients, 95.9%, as incorrect.

Table 6. Critical steps in insulin storage

Characteristic		**n**	**%**
Labeling a newly opened vial and indicating the date of discarding	Correct	1	1.4
	incorrect	72	98.6
Home storage refrigeration/tin thermos	Correct	73	100.0
	incorrect	0	0.0
Discard after 28 days from date of opening	Correct	0	0.0
	incorrect	73	100.0
Insulin storage assessment done after 6 months to 1 year.	Correct	17	23.3
	incorrect	56	76.7

Almost all patients performed 1 out of the 4 steps in the storage and handling methods correctly (Table 6 above). Home storage was done correctly for the insulin in use.

4.4 The level of blood glucose control among patients attending KNH outpatient DM clinic.

Table 7: Glycemic control among the study participants

Characteristic	**n**	**%**
RBS Category		
High (>10.9 mMol/L)	27	37.0
Normal (4.0-10.9 mMol/L)	43	58.9
Low (<4 mMol/L)	3	4.1
Mean RBS [SD]	10.4 [5.9]	
HbA1c category		
High (>7%)	39	53.4
Normal (<7%)	34	46.6
Mean % [SD]	8.1[3.6]	

Key: HbA1c**:** Glycated Hemoglobin; RBS- Random Blood Sugar; SD-Standard deviation

Over half of the patients (53.4%) had supratherapeutic level of HbA1c and a similar proportion (58.9 %) were euglycaemic at the time of study (Table 7). The mean RBS and HbA1c was 10.mMol/L (SD 5.9) and 8.1% [3.6] respectively.

Table 8: Adherence to insulin therapy

Variable	Status	n	%
Frequency of injecting insulin	Twice	70	95.9
	Thrice	3	4.1
Adherence to dosing frequency	Yes	41	56.2
	No	32	43.8
Reasons for non-adherence	Pain on injection	17	53.1
	Lack of interest	15	46.9
Daily dosing adherence	Yes	64	87.7
	No	9	12.3
Reasons for non-adherence	Pain on injection	3	33.3
	Lack of interest	6	66.7

Most of the patients , 95.9%, were reported to be on twice a day dosing frequency, as in table 8 above. Slightly over half, 56.2%, were unable to adhere to the dosing frequency. Out of the proportion of the patients reported to be non-adherent, 46.9% of them reported lack interest in the treatment, while the rest reported painful injection as a reason of failing to adhere to dosing frequency. Eighty seven point seven percent ,87.7%, of the patients at least injected insulin on daily basis, regardless of missing a single dose or not. Twelve point three percent, 12.3%, reported to have missed injecting insulin some days of the treatment, out of this 66.7% reported lack of interest while 33.3% reported pain on injection. Overall assessments of frequency and daily non adherence, 46.9% - 66.7% were reported to not adhere due to lack of interest. Thirty three point three percent 33.3% – 53.1% reported not to adhere due to pain on injection. Averagely, lack of interest in treatment was reported to be a slightly major reason for non adherence over pain on injection.

4.5. Bivariate Analysis on factors associated RBS levels

Table 9: Relationship between blood sugar and patients characteristics

	Random blood sugar			
Variable	**High**	**Normal**	**Low**	**P value**
	n (%)	**n (%)**	**n(%)**	
Age				
<35	0 (0.0)	4 (5.5)	0 (0.0)	
36-65	23 (31.5)	32 (43.8)	2(2.7)	0.394
>65	4 (5.5)	7 (9.6)	1 (1.3)	
Marital status				
Married	24 (33.0)	38 (52.0)	3 (4.0)	1.00
Single	3 (4.0)	7 (7.0)	0 (0.0)	
Highest education level				
Informal	0 (0.0)	4 (6.0)	0 (0.0)	
Primary	5 (7.0)	10 (14.0)	2 (3)	0.386
Secondary	8 (11.0)	12 (16.0)	0 (0.0)	
Tertiary	14 (19.0)	17 (23.0)	1 (1.0)	
Alcohol status				
Former	10(14.0)	12 (16.0)	2 (3)	
Current	1(1.0)	2 (3.0)	0 (0.0)	0.613
Never taken	16(22.0)	29 (40.0)	1 (1.0)	
Duration of insulin use				
< 6 Months	3(4.0)	3 (4.0)	0(0.0)	
> 6 Months	24 (33.0)	40(55.0)	3 (4.0)	0.746
Training status				
Yes	37 (37.0)	42 (58.0)	3 (4.0)	1.00
No	0 (0.0)	1 (1.0)	0(0.0)	
Refrigeration				
Yes	11(15.0)	9 (12.0)	2(3.0)	0.062
No	16 (22.0)	34(47.0)	1(1.0)	
Injection technique				
Correct	15 (21.0)	37 (51.0)	2 (3.0)	**0.013**
Incorrect	12 (16.0)	6 (8.0)	1(1.5)	
Storage				
Correct	0 (0.0)	3 (4.1)	0(0.0)	0.365
Incorrect	27 (37.0)	40(54.8)	3(4.1)	

After exploring for factors which may be associated with blood sugar control, we found that insulin injection technique was statistically significantly associated with optimal blood sugar control ($p=0.013$)(Table 9). Other factors such as demographics, duration of use, insulin storage technique, training on insulin administration and use of alcohol among the participants were not statistically significantly associated with adequate glucose control ($p>0.05$). (Table 9)

Table 10: Factors associated with Glycated Haemoglobin

Variable	Glycated hemoglobin(HbA1c) High		Normal		P-value
	n	%	n	%	
Random blood sugar					
High	31	31.5%	11	15.1%	**0.0001**
Normal	7	9.5%	22	30.3%	
Low	0	0%	2	2.7%	
Overall performance in injection technique					
Correct	4	5.5%	34	46.5%	**0.0001**
Incorrect	34	46.5%	1	1.5%	
Age					
<35	0	0%	4	5.5%	0.077
35-65	30	41.2%	27	36.9%	
65>	8	10.9%	4	5.5%	
Smoking status					
Former	9	12.3%	6	8.2%	0.693
Current	2	2.7%	1	1.5%	
Never taken	27	37.0%	28	38.36	
Highest education level					
Informal	4	5.5%	0	0%	0.272
primary	8	10.9%	9	12.3%	
Secondary	11	15.1%	9	12.3%	
Tertiary	15	20.5%	17	23.4%	
Residence					
Urban	33	45.2%	32	43.9%	1.000
Rural	5	6.8%	3	4.1%	
Gender					
Male	14	19.2%	12	16.5%	1.000
Female	24	32.8%	23	31.5%	
Occupation					
Employed	20	27.4%	27	37.0%	0.059
Unemployed	10	13.7%	4	5.5%	
Retired	8	10.9%	3	4.1%	
Student	0	0.0%	1	1.4%	
Marital status					
Married	32	43.8%	6	8.2%	0.264
Single	33	45.2%	2	2.8%	

Injection technique and random blood sugar were statistically significantly associated with optimal control of HbA1c ($p<0.0001$).

Table11: Independent predictors of glycaemic control among the study participants

HbA1c	Corr. Coef.	Std. Err.	t	P-value	95% C. I	
Age (Years)	0 .0755711	0.0294917	2.56	0.013	0.0167519	0.1343903
RBS	0.3647045	0 .0546973	6.67	0.0001	0.2556141	0.4737948

Key: Age-Age of the participant in years; C.I-Confidence interval ; Coef.- Correlation coefficient (r) ; HbA1c-Glycated haemoglobin; Std. Err-Standard error of the Mean; T- t-test; RBS-Random Blood Sugar;

Using stepwise backward binomial logistic regression to determine independent predictors of optimal control of blood sugar, the participant's age ($p=0.013$) and RBS ($p<0.0001$) were statistically significantly associated with optimal glycemic control among the study participants (Table 11).

CHAPTER FIVE: DISCUSSION, CONCLUSIONS AND RECOMMENDATIONS

5.0 Introduction

This chapter discusses the study results and compares them with other similar studies done elsewhere. It also tries to offer scientific explanation for the study findings and explain the disparities between study findings and other findings in a bid to draw conclusions and make recommendations for policy and practice.

5.1 Discussion

Our study was predominantly females at 63.0% and the mean age [SD] was 53.6(±11.0) years. A similar study done by Nyamu *et al* (14) in 2008 revealed slightly more males than females. The same diabetic clinic being the common source of study participants in both studies. The differences in the proportions on gender could have been attributed to more awareness and knowledge in women as result of that study done same hospital, including the response of the hospital management in implementing the recommendations of the same study.

Despite the fact that 98.6% of the patients were trained on their first insulin prescription, sixty seven percent of participants were not assessed during their continued outpatient visits. This suggests that most of the patients may have forgotten on what they were trained earlier and that is why our study revealed the correct injection technique to be low at 53.4%. Hicks *et al*, in their study on the insulin injection technique revealed the proportion of patients who demonstrated correct technique were about 15% (10,26). The difference in these proportions could be attributed to differences in methodologies and populations studied.

The steps adapted as in the American Diabetes Association were hard for 100% of the patients to follow as enumerated in the protocol chronologically. All the patients performed naturally steps 1, 2, 3,4,5,6 then 7 and on till 17 as in fig.1.This chronology the patients adopted was the most natural way of handling insulin in our local circumstances before injecting it. The steps followed by participants in this study couldn't conform to the chronology as per in the American Diabetes Association as in appendix 2 table 12. This could be attributed to the differences between American setting where these guidelines were drawn and gross assumptions made that could be

obvious to their patients. Unlike in our setting, the circumstances of our patients and product (insulin) quality must be assessed before drawing insulin from the vial.

Insulin injection technique step 5(fixing the syringe to the needle) and step 8(loading insulin at room temperature) were the highly correctly performed steps. Perhaps these were the most obvious for patients to remember. Step 6 (loading the insulin with equal amounts of air) was the worst performed by 47.9% of the patients as they loaded less or more air unequal to the units they were taking suggesting that patients never knew the importance of this step or require to be adequately trained. A study done in Pakistan by Mushtaq *et al* (26) on knowledge on injection techniques amongst nurses in a public hospital revealed that most of them never knew that they should load the syringe with air before drawing the drug. Similarly a previous study done in the KNH showed that patients don not differentiate between units and milliliters during insulin measurements (14).

Only 60% of the patients performed one of the key critical steps (step 5) correctly which included, checking for clarity and detecting any precipitation, frosting and crystallization. This indicates that almost half of the patients lacked of knowledge in verifying the pharmaceutical characteristics of insulin before use. Forty percent who did it wrongly assumed that the product is good for use regardless of its pharmaceutical state. A similar study done in Pakistan by mushtaq *et al* (26) amongst 252 nurses revealed that none of them knew the need to check for clarity and detecting any precipitation, frosting and crystallization. On the other hand, a third of the participants did not know the right technique of pinching the *skin* before injecting (step 13), suggesting that they do not know that this is crucial and may affect the absorption levels of insulin. Elsewhere in KNH, a study was carried by Omari et al 2013 (19) supporting lack of knowledge as a barrier to self-care in DM patients. Thus, a key factors in the control of Blood sugar.

About 90% of the mode of training was oral with practical demonstrations. Perhaps this was an important method of training because a correlated study to assess the effectiveness of training on improving competencies among DM patients in 2013 (29) revealed that a combination of oral and practical demonstrations were effective in enhancing self-administration skills and practices in DM patients.

Nurses took the major share of the role (77%) in training patients while pharmacists took the least role (1.4%).This is attributed to probably the traditional assumption that a nurse is the dominant health practitioner interacting most with the patient as demonstrated by studies by done by Mushtaq *et al* (26) and Swetha *et al* (29) which recommend that nurses take a central role in patient care. However, this may not be true because pharmacists form the interface between the patient and the drug when dispensing thereby creating an enabling opportunity to counsel the patient. It is unclear why pharmacists were not mostly involved in patient education. Most of the critical steps involved in the injection technique can be effectively taught by the pharmacist as part of their dispensing obligations. A study carried out (14) revealed the indispensable role of a pharmacist to impacting knowledge and practice of self-care in patients. Similar inputs were made in clinical review (24) on the indispensable role of a pharmacist in counseling the DM patients regarding insulin use including being precise in handling insulin products and promoting the achievement of the required HbA1c as the objective of a successful insulin administration technique.

Home Storage by refrigeration was a challenge to 69.9% of the patients in our study and the same proportion used spirit/water in cotton for home storage. In fact over 80% of patients in our study do not own refrigerators. This closely relates to findings by Mjota (6) 2008 which estimated that 70% of the urban population in Kenya lacks refrigeration facilities. A previous survey (30) had indicated that 26%-77% DM patients have no refrigerators for storing insulin. A similar study carried out in 1996 showed that lack of refrigeration facilities was high in most parts of Africa (30). Popularly used in storing insulin in our study included use of containers with liquid absorbent material that can evaporate to keep cool temperatures. However, the effectiveness of these methods is unclear as similar study by Gill *et al* (33) has recommended that this method is yet to be critically assessed and appraised.

The ignorance of all our patients on discarding the insulin after 28 days of opening a new vial was observed in our study. Patients refilled insulin on monthly basis and not extra for their buffer stock therefore, all refills came before lapse of 28 days period during the monthly clinic appointments. Hence, the significance of discarding insulin after 28 days was unnoticed. Nevertheless, knowledge should be imparted on all patients because some may decide to buy

insulin stocks to last them a few months from other channels. However, clinical review by Dan *et al* 2014(31) and Garry *et al* (8) revealed that insulin still remains potent and stable for 28 days within $(12\text{-}30)^0$c suggesting that the insulin used by was stable before the next clinic appointment.

The level of blood sugar control in our study patients showed a high measure of dispersion in their RBS and HbA1c values. This pattern of dispersion may have been a result of variations in injection techniques among our study patients, which may cause unpredictable pattern of insulin absorption. The pattern observed correlates to studies by Hicks et al (10) and Strauss et al (11). Similar findings were showed in a study by Mushtaq *et al* (26) and scientific reports in (27,28) They concluded that blood sugar fluctuates with technique of insulin administration.

Fifty three percent of the patients performed correct injection technique. It was expected that at least a similar proportion of the study participants to have their HbA1c within normal values. Forty seven of the study participants had their HbA1c within normal values. There must have been other reasons to account for the short of 7% of the patients falling into the high category. Other confounder factors such as non-adherence to treatment were reported and could be the cause of high HbA1c in the 7%.

The proportion of non-adherence to insulin injection in the participants was 56.2%. Out of this, 58.5% reported lack of interest in the treatment as revealed in other similar studies (21,24) which showed that attitudes may affect patients' willingness to take insulin. These studies recommended that healthcare providers should take care to avoid promotion of negative sentiments towards insulin medication. Other factors impacting on adherence included fear of insulin treatment due to painful injection in slightly over 40 % of the participants. This finding correlates with the findings of Saltiel-Berzin *et al* (23). Studies have revealed that pain and bruising at the injection site is significant in causing fear and negative attitude insulin injection therapy which may affect compliance (23,30). They recommended refresher training is needed for all patients to have a positive attitude towards self-injection.

There was a statistically significant association between random blood sugar control and the injection technique (p=0.013) unlike findings from other studies (39). In addition, HbA1c levels were not only associated with random blood sugar but also with injection technique (p <0.0001). This could be due to improved knowledge and practice with our patients due to regular DM clinic training sessions conducted in the hospital every Mondays and Wednesdays. Other factors such as other drugs; level of income; level of highest education; marital status; alcohol use; duration of insulin use; training status were not statistically significant. The observed associations of RBS and HbA1c in our study are in support to the findings in similar work done by Hick D *et al* (10) and Norris *et al* (20).

Using student- t-test, age (t =2.56, p< 0.013) and random blood sugar (t = 6.67, p< 0.0001) were statistically significantly associated with HbA1c among diabetes patients. Logistic regression revealed that as the age of patients increased, their HbA1c was raised while as their random blood sugar increased, their HbA1c rises. Study by Allan *et al* (39) on the factors such as time of onset of diabetes in relation to control over time revealed that as the disease progressed optimal control reduces. I, however, observed that some aged patients beyond 70 years had well controlled HbA1c while some younger participants of age (<30 years) had elevated HbA1c.Therefore, relationship between HbA1c with age of onset of DM and duration of treatment may not apply to all circumstances. Other unexplored factors may be playing a role.

5.3: Study Limitations

The patients were unable to remember exactly what they do on routine basis as pertains to the administration technique of insulin. Therefore, relying fully on the information given by patients may have introduced recall and response bias .However, we used objective records from the patient file before interacting with the patient rather than relying on recall alone which kept patients blind of the associations under study. I also designed and pretested the questionnaire and also used objective measuring parameter of glucose control (HbA1c measurement).

5.3.2 Utility of this study.

The participants selected to this study were ambulant healthy diabetics on insulin therapy. This limited the study utility exclusively to the impact of insulin storage and insulin injection technique on HbA1c among the patients from colder regions ranging between $(20\text{-}30)^0$ C. Other factors as chronic pathological states that can exist in diabetics in our setting such as cancer, Human Immunodeficiency Virus (HIV), Psychiatric disorders and both chronic and acute infectious diseases among patients with diabetes using insulin and their HbA1c relationship were not investigated.

Over 99% of the participants in this study resided in Nairobi and its environs. Thus the room temperatures during the study period favored the stability of insulin in use. This study was limited to the stability of insulin in patients residing in cold areas. Patients residing in warm areas like Turkana, Coast and north eastern cannot benefit from the findings of insulin stability at room temperature for 28 days. The room temperature invariably exists above 30^0 C in these areas. A similar study if it were conducted in these warm areas could have found an association of insulin storage by refrigeration and HbA1c to be statistically significant.

5.4 : Conclusion

Proportion of our study population, 53%, had a high HbA1c suggesting poor overall blood sugar control. About half performed injection technique correctly .Most of the critical steps were not performed adequately. Lack of interest and painful injection during treatment due to attitudes and fears contributed to 58% of the reasons for non- adherence to dosing interval. Our study has revealed that there was a positive association between correct injection technique and the optimal control of the blood sugar levels in KNH. Pharmacists were not actively involved in patient education on insulin use and injection technique.

5.4 Recommendations

5.4.1Recommendation for research

Our study has revealed that 69.9% of the patients lack refrigeration. Their poor storage methods is a reason to doubt the potency of their insulin .In fact it has been suggested that there is 75%

and 5 % loss of potency and biological activity of insulin, respectively, when in the tropics due to invariably high temperatures which could accelerate degradation.

We suggest studies on assay of insulin that our patients use in tropical countries and correlate this with the glycaemic control.

5.4.2 Recommendations for Policy and practice

1. Continuous training on insulin injection techniques should be encouraged among the patients because this has a positive impact on the optimal control of the blood glucose.

2. Our study has shown that a very high proportion of patients performed incorrectly on the critical steps in storage methods. The hospital should emphasize training of DM patients on proper storage steps of insulin.

3. Our study has revealed that most of the patients who did not adhere to insulin therapy either lacked interest or experienced painful injection. Therefore, counseling patients should be done during regular clinic visits to support them psychologically in dealing with attitudes and fears to treatment by insulin injection.

4. Pharmacists should be encouraged to participate in counseling DM patients on insulin use especially at the dispensing point since they form an important interphase between the patient and the drug.

5. Patient's insulin use assessment should be included in the treatment chart/protocols. The content in the plan should include: review of the insulin injection techniques critical steps and review of the critical storage steps to act as a guide while counseling and assessing patients.

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APPENDICES

APPENDIX 1: Consent Form

Title of the study: **IMPACT OF INSULIN STORAGE AND INSULIN ADMINISTRATION TECHNIQUE ON GLYCATED HEMOGLOBIN AMONG DIABETIC PATIENTS AT KENYATTA NATIONAL HOSPITAL**

Institution: Department of Pharmaceutics and Pharmacy Practice, School of Pharmacy, University of Nairobi, P.O BOX 30197-00400, Nairobi.

Investigator: Dr. Evans Kituzi Kedogo, P.O BOX 55793, NAIROBI 00200. Tel 0732247305

Supervisors: Dr. P. N. Karimi, Department of Pharmaceutics and Pharmacy Practice;

Dr. D. G. Nyamu, Department of Pharmaceutics and Pharmacy Practice;

Ethical Approval: Kenyatta National Hospital/ University of Nairobi Ethical and Research Committee, P.O BOX 20723-00100, Nairobi. Tel 2726300/2716450 Ext 44102

Permission is requested from you to enroll in this medical research study. The following general principles which apply to all participants in a medical research:

1. Your agreement to participate in this study is voluntary.

2. You may withdraw from the study at any time without necessarily giving a reason for your withdrawal.

3. After you have read the explanation please feel free to ask any questions that will enable you to understand clearly the nature of the study.

Purpose of the study

Was to find out the proportion of patients on insulin only therapy who practice proper insulin storage methods and insulin administration techniques and their outcomes.

Procedure to be followed

With your permission I will ask you to demonstrate to me your insulin loading technique, your injection site and ask you to demonstrate your injection technique with a placebo I will provide to you. I will also inquire from you how you store your insulin at home and how you carry it when you are travelling.

Also I will ask you to allow me take a sample of your blood to do an investigation of HbA1c.HbA1c is a measure to determine if your treatment plan is working for you. This test shall be done here in KNH laboratory. I have a laboratory assistant who shall take your blood with your permission. He/she is trained to ensure that there shall be no contamination at all during the process and ensure sterility. But also has skills of collecting blood with minimum pain experienced. There shall be no cost incurred by the patient for this test. This procedure shall only be done In case your file doesn't indicate recent test of the same for the last 2 to 3 months. All information will be handled with confidentiality and will only be used for the purpose of this study.

Benefits

I will demonstrate to you the correct loading technique from the insulin vial, choice of injection site and injection technique at the end of this interview. You will be educated on the correct storage and transportation of insulin. All subjects interviewed will be taught the correct insulin administration technique, regardless of whether they perform correct or incorrect administration technique. Patients` who have not had their HbA1c done shall have their HbA1c done.

Risks

There will be pain on pricking but aseptic technique will be used to ensure that no infection will take place

Assurance of confidentiality

All information obtained from you will be kept in confidence. At no point will you or your name be mentioned or used during data handling or in any resulting publications. Codes will be used instead.

In case you need to contact me, my academic department or the Kenyatta National Hospital/ University of Nairobi Ethics and Research Committee concerning this study please feel free to use the contacts provided above.

I now request you to sign the consent form attached.

Investigator's statement

I am Dr Evans Kituzi Kedogo from the Department of Pharmaceutics and Pharmacy practice, School of Pharmacy. I am carrying out a study to find out the proportion of adult Diabetes Mellitus patients in Kenyatta National Hospital on insulin performing properstorage of insulin and administration technique and how it affects their glycated hemoglobin and outcomes.

With your permission, I will ask you some questions about your insulin storage methods, ask you to demonstrate your injection technique with an injection and a placebo vial I will provide to you and take your blood for glycated hemoglobin test in case you have not done it for the last three months. All information will be handled with confidentiality and will only be used for the purpose of this study.

Contacts

My contact is 0732247305. Feel free to contact me if you have any matter arising from this study. You can also get in touch with me through the Chairman, Department of Pharmaceutics and Pharmacy practice, school of Pharmacy, university of Nairobi.

I Mr/Mrs./Ms…… patient/parent/guardian of

…….. Agree to enroll him/her into the

Study as explained to me by Dr. …….

My signature is confirmation that I have understood the nature of the study and that whatever information that I give will remain confidential. I also confirm that no monetary or material gains have been promised or given to me for participating in the study.

Signed……(patient/patient/guardian) Relationship……

Date:……

Signature of principal investigator…… Date:…….

KISWAHILI TRANSLATION

FOMU YA IDHINI:

Title ya utafiti: ATHARI ZA UHIFADHI YA INSULINI na insulini ADMINISTRATION mbinu ILIYO GLYCATED damu miongoni mwa wagonjwa WA kisukari wa HOSPITALI Ya Taifa ya Kenyatta.

Taasisi Idara ya pharmaceutics Na Pharmacy Mazoezi, Shule ya Pharmacy, Chuo Kikuu cha Nairobi, PO BOX 30197-00400, Nairobi.

Mpelelezi:Dr. Evans KituziKedogo, PO BOX 55793, NAIROBI 00200. Tel: 0732247305

Wasimamizi:

Dr. PN Karimi, Idara ya pharmaceutics Na Pharmacy Mazoezi,

Dr. D.G. Nyamu, Idara ya pharmaceutics Na Pharmacy Mazoezi,

Idhini ya Maadili: Hospitalikuuya Kenyatta/Chuo kikuu cha Nairobi Kamati ya maadili Na utafiti S.L.P.20723-00100, Nairobi. Nambari ya simu 2726300/2716450 Ext 44102.

Idhini yahitajika kutoka kwako iliushiriki katikika utafiti huu wa masomo ya matibabu. Haya ndio mahitaji muhimu ambayo yanahitajika kwa kila mshiriki wa utafiti wamasomo ya matibabu:

1. Utakubali kushiriki kwa utafiti huu kwa hihari yako.
2. Unaweza Hama kutoka utafiti huu wakati wowote bila kupeana sababu yoyote.
3. Baada ya kusoma maelezo,Tafadhali jisikie huru kuuliza maswali yoyote ili uweze kuelewa vizuri utafiti utakaoshiriki.

Maana ya Utafiti huu

Kujua uwiano ya wagonjwa wenye hutumia dawa ya insulin wenye wanahifadhi dawa ya insulin kwa njia halisi na wenye wana ujuzi kamili wa kujidunga dawa ya insulin na matokeo yao.

Jinsi utafiti itakavyo tekelezwa

Na ruhusa yako nitahitaji unionyeshe vile huwa unaweka dawa Kwa sindano yako ya insulin Na dawa yake. Na vile unavyo dunga sindano ya dawa kwenye ngozi yako. Nitakupea dawa ya maji ya kutumia kwa mazoezi ya kuonyesha vile huwa unavyo jidunga kila wakati wakudunga dawa ya insulini. Pia nitahitaji kujua kutoka kwako vile huwa unahifadhi dawa yako ya insulin ukiwa nyumbani. Napia vile huwa unahifadhi wakati unapo safiri au ukiwa mbali Na nyumbani.

Nitakuomba uniruhusu nitoe damu yako Kwa utafiti WA HbA1c.HbA1c nikipimo kinachotumika kujua nakuelewa jinsi mpango wamatibatu ya sukari kwa damu kama inafaa.HbA1c ikiwa zaidi ya 7% inamaanisha mpango wako WA matibabu ya faa ibadilishwe. Kipimo cha HbA1c inafanyiwa hapa hospitali kuu ya Kenyatta. Katika Laboratory ya chuo cha Nairobi, shule ya masomo ya matibabu.

Hapa tuko na msaidizi mwenye amefuzu katika masomo ya laboratory ya matibabu na atatoa damu yako kwa mshipa kwa hisani na idhini yako.Yeye kulingana na masomo yake atahakikisha ya kwamba hautahisi uchungu kuzidi kiasi . Na pia kuhakikisha hakuna madhara au viinivyovyoteutahambukizwakufatanaNa utafitihuu. Kipimo cha HbA1c itafanywa kwako kama kitabu chako cha matibabu hakionyeshi kuwa hicho kipimo hakijafanywa kwa

muda wa miezi mitatu iliyopita. Habari hii itashugulikiwa kwa siri na itatumika kwa manufaa ya utafiti huu.

Manufaa.

Baada ya utafiti , Nitakuonyesha njia sahihi yakuweka dawa ya insulini kwa sindano, vile inavyofaa kuchagua sehemu ya mwili ya kudunga na ujuzi wa kudunga sindano katika hiyo sehemu ya mwili. Nitakuelimisha jinsi unafaa kuhifadhi dawa yako ya insulini wakati ukiwa nyumbani na ukisafiri mbali na nyumbani . Washiriki wote katika utafiti huu wataelimishwa jinsi na ujuzi wakuweka dawa ya insulini kwa sindano nakudunga kwa ngozi na sehemu ya mwili inayo faa na jinsi ya kuhifadhi insulini ukiwa nyumbani na ukiwa safarini. Wote watapata mafunzo bila ubaguzi wa kuwa kama ulidhihirisha kwamba ulifanya vyema kwa maonyesho au vibaya. Washiriki ambao hawajafanya kipimo cha HbA1c kwa muda zaidi ya miezi mitatu iliyopita watapata fursa yakufanyiwa katika utafiti huu bila malipo. .

Tahadhari

Mshiriki atahisi uchungu wakati wa kudunga sindano pia kinga itatumika kuhakikisha ya kwamba hakuna madhara au viini vya magonjwa vita ambukizwa

Hakikisho la siri

Habari yoyote nitakayo pokea kutoka kwako itawekwa siri. Hakuna wakati wowote wewe au jina lako litatajwa au kutumika wakati wa kutayarisha utafiti au wakati wa kuandika matokeo. Nambari za siri zitatumika badala ya jina lako.

Kuwasiliana

Ukitaka kuwasiliana nami, katika shule ya masomo au Hospitali kuu ya Kenyatta/Chuo Kikuu cha Nairobi kamati ya maadili na utafiti .Jisikie huru kutumia njia hizo zote kuwasiliana jambo lolote kuhusu utafiti huu.

Sasa kwa idhini yako ningependa ujaze na utie sahihi katika kibali cha utafiti:

KIBALI CHA UTAFITI

Taharifa ya mtafiti.

Mimi Dkt. Evans Kituzi Kedogo kutoka idara ya Pharmaceutics na Pharmacy Practice, Shule ya Pharmacy. Ninafanya utafiti juu ya uhifadhi wa insulini ,ujuzi wa kudunga sindano ya insulini kwa usahihi na jinsi inavyo sababisha kipimo cha sukari kwa damu cha glycated hemoglobin (HbA1c) .

Naomba nikusajili katika utafiti huu, nikuulize maswali juu ya ugonjwa wa diabetes mellitus, jinsi unahifadhi insulini na jinsi unavyojidunga na nichukue damu nipime glycated hemoglobin (HbA1c).Mawasiliano yote yatakuwa kwa siri .

Mawasiliano.

Unaweza kuwasiliana nami wakati wowote kwa kupiga simu nambari 0732247305, kuniuliza jambo lolote linalotokana na utafiti huu. Pia unaweza kuwasiliana nami kupitia mweyekiti, Department of Pharmaceutics and Pharmacy practice, School of Pharmacy, University of Nairobi.

Mimi, Bi/Bwana ……..
Nimekubali kushiriki katika utafiti huu baada yakuelezwa na daktari…….
Sahihi yangu nithibitisho ya kwamba nimeelewa umuhimu wa utafiti huu na kwamba habari

Yoyote nitakayotoa itawekwa siri.

Pia nathibitisha ya kwamba sijapewa au kuahidiwa pesa au chochote kile, kukubali

Kushiriki kwenye utafiti huu.

Sahihi ……. Uhusiano …….

tarehe …….

Sahihi ya mtafiti ……. Tarehe …….

APPENDIX 2: Questionnaire

INTERVIEW QUESTIONNAIRE ON: IMPACT OF STORAGE AND INSULIN ADMINISTRATION TECHNIQUE ON GLYCATED HEMOGLOBINAMONG DIABETIC PATIENTS AT KENYATTA NATIONAL HOSPITAL.

Tick the correct answer.

BIODATA.

1)Date _____ Study serial number_____

2)Data Collector's initials_____Prescription Code number_____

3)Age (Years) _____

4)Residence: i)Urban ☐Rural ☐

5)Gender: i)Male ii)Female

6)Occupation: ii)Employed ii)Unemployed

iii)Retired iv)student

7)Marital status: i) Married ii) Single

8) Monthly income/guardian (Ksh) i) <2500 ii) >2500

9)Highest educational level:

i)No formal Education ii)Primary iii)Secondary iv)Tertiary

9)Alcohol status: i)Former ii)Current iii)Never taken

10)Smoking Hx i)Former ii)Current iii)Never taken

B. INSULIN ADMINISTRATION

1. How long have you used insulin?

i)< 6 months ii) > 6 months

2. Do you use a vial or a pen? i) pen ii) vial iii)Other (specify)……..

3. What type of insulin do you use?

i) mixtard ☐ ii)soluble ☐ iii)Both ☐

iv) Other (specify)…….

4. Have you ever been trained by a healthcare professional on how to administer insulin?

i) Yes ii) No

1. If YES to 4 above;

Who trained you how to use your insulin?

1. Clinician ☐
2. Pharmacist ☐
3. Nurse ☐
4. Others (specify) ☐

2. Were you trained during your first insulin prescription?

a) Yes b) No

3. How were you instructed on how to administer insulin?

1. Oral instructions ☐
2. Practical demonstrations ☐

3. Both ☐

4. others ☐

4. Did you demonstrate to the healthcare professional insulin administration technique during your first training?

a) Yes b) No

5. When was the last time your insulin administration technique was assessed by a healthcare professional?

a) < 6 months b) > 6 months

c) Never assessed

6.If NO to 4 above;

- i).How did you learn to use your insulin?
- ii).Literature insert
- iii).Internet
- iv).Relative
- v).Friend
- vi).Other

C .INSULIN STORAGE ASSESSMENT

1. Do you store your INSULIN in the refrigerator at home?

(i) YES

(ii) NO

2. If NO to 1 above, how do you store your INSULIN at home?

i) Pot

ii) Cotton with spirit in tin

iii) Dark corner of the room

iv)In a box.

v)Cupboard

vi)Other (specify)……..

3. Where do you keep your INSULIN when you are travelling/away from home?

i) Wallet (conventional leather wallet).

ii) Bag

iii) Container

iv) Other (specify)……

3. Do you label the date of opening new INSULIN vial?

(i)YES

(ii)NO

4. If YES to 3 above, do you discard the vial after **28**days?

(i)Yes

(ii)No

5. If NO to 3 above, when do you discard off the INSULIN after opening the vial?

(i)After 28 days

(ii)Less than 28 days

(iii)Until it's empty

6. When was the last time your INSULIN storage method was last assessed?

(i)Last year

(ii)Last month

(iii) Never assessed

Overall performance: 1) Correct storage **2) Incorrect storage**

D.INSULIN TREATMENT ADHERENCE ASSESMENT AND DRUGS THAT COULD AFFECT BLOOD SUGAR (For confounding)

1) How many times do you inject your insulin per day?

A) Once

B) 2x

C) 3x

D) 4 x

E) More than 4 x

2) Do you miss injection anytime of the day when you are required to take?

A) YES

B) NO

3) If YES to 2 above, why?

A) Lack of insulin

B) Lack of needle

C) Pain of injection

D) Lack of interest in treatment

E)

Other……

……..

4) Do you take insulin injection every day?

A) YES

B) NO

5) If No to above, Why?

A) Lack of insulin

B) Lack of needle

C) Pain of injection

D) Lack of interest in treatment

E).Other ……..

6) Do you take other drugs apart from insulin injection?

A) YES

B) NO

6). If YES to 6 above, can you remember and list the drugs are you taking?

Table 12: Proportion of patients performing correct/incorrect steps of insulin injection technique.

Steps		Frequency	Percent
1.fix the syringe to the needle*	**Correct**	**69**	**94.5**
	Incorrect	**4**	**5.5**
2.load the syringe with air equal to the units	**Correct**	**38**	**52.1**
	Incorrect	**35**	**47.9**
3. a. Read the insulin vial to be sure it`s the type of insulin you are to use.	**Correct**	**48**	**65.7**
	Incorrect	**25**	**34.3**
4.check for the date of expiry	**Correct**	**50**	**68.5**
	Incorrect	**23**	**31.5**
5. Check for clarity and detect any precipitation, frosting and crystallization.	**Correct**	**44**	**60.3**
	Incorrect	**29**	**39.7**
6. Roll gently the insulin vial in your palm. don't agitate	**Correct**	**53**	**72.6**
	Incorrect	**20**	**27.4**
7. Inject the air into the vial at oblique to avoid a vacuum.*	**Correct**	**44**	**60.3**
	Incorrect	**29**	**39.7**
8. Load the insulin into the syringe in upright position to ensure there is no air loaded.*	**Correct**	**58**	**79.5**
	Incorrect	**15**	**20.5**
9.Flick the syringe to get air out in case it was loaded with air.	**Correct**	**59**	**80.8**
	Incorrect	**14**	**19.2**
10*Always load insulin that is at room temperature.	**Correct**	**69**	**94.5**
	Incorrect	**4**	**5.5**
11. Using a cotton wool & spirit sterilize the surface of the skin where you intent to inject.*	**Correct**	**68**	**93.1**
	Incorrect	**5**	**6.9**
12. Wait for the spirit to fully vaporize before injecting.	**Correct**	**63**	**86.3**
	Incorrect	**10**	**13.7**
13. With a pinch of the skin, inject at 45^0 to the skin to avoid intramuscular injection.*	**Correct**	**52**	**71.2**
	Incorrect	**21**	**28.8**
14. Inject the insulin unit. Hold the injection for 5 seconds before withdrawal from the skin to allow the insulin to fully exit from the needle to the site.	**Correct**	**47**	**64.4**
	Incorrect	**26**	**35.6**
15. Withdraw the injection from the site .And discard the needle. Press on the injection site for 5 seconds. Rub or massage.	**Correct**	**51**	**69.9**
	Incorrect	**22**	**30.1**
16. Does the patient always alternate injection sites at every jab?	**Correct**	**55**	**75.0**
	Incorrect	**18**	**25.0**
17. Does the patient inject before or after meals.	**Correct**	**54**	**74.0**
	Incorrect	**19**	**26.0**

*Injection steps are an adaptation American Diabetes Association. (27-28)

Last RBS Reading……Date……..

HbA1c concentration_____

APPENDIX 3:

STEPS OF STORAGE

- 1.*Labeling a newly opened vial
- 2*Indicating the date of discarding
- *After 28 days from date of opening
- 3 Home storage
- *In refrigeration, for the buffer insulin.
- *In room temperature for insulin in use.
- *For the refrigerated, in use insulin, always roll in the palms to room temperature before use to avoid pain during injection.
- 4.* Always discard insulin in use vial after 28 days.
- *Always have insulin storage assessment done after 6 months to 1 year by a pharmacist. Advice on storage and assessment needed due to variations of weather conditions in various geographical environments of patients, change of formulation and stability requirements from manufacturer and change of distributor / change of geography of manufacture of insulin product.

Key

*critical errors to look out for. As per the recommendations in clinical review by Garry Gilles et al(8) and View point on stability of insulin by Dan kent et al (31).

APPENDIX 4: Steps in Injecting Insulin

Steps

- 1. Read the insulin vial to be sure it`s the type of insulin you are to use.
- 2.check for the date of expiry
- 3. Check for clarity and detect any precipitation, frosting and crystallization.
- 4. Roll gently the insulin vial in your palm. Don't agitate.
- 5.fix the syringe to the needle*
- 6.load the syringe with air equal to the units
- 7. Inject the air into the vial at oblique to avoid a vacuum.*
- 8. Load the insulin into the syringe in upright position to ensure there is no air loaded.*
- *Always load insulin that is at room temperature.
- *Insulin at room temperature for more than 30 days tends to reduce in potency.
- 9*Flick the top of the syringe needle to get the air out in case it was loaded in.
- 10. Using a cotton wool and spirit sterilize the surface of the skin where you intent to inject.*
- 11. Wait for the spirit to fully vaporize before injecting.
- 12. With a pinch of the skin, inject at 45^0 to the skin to avoid intramuscular injection.*
- 13.* Inject the insulin unit. Hold the injection for 5 seconds before withdrawal from the skin to allow the insulin to fully exit from the needle to the site.
- 14. Withdraw the injection from the site .And discard the needle.
- 15. Press on the injection site for 5 seconds. Rub or massage to enhance circulation for quick-absorption*.
- 16. Does the patient always alternate injection sites at every jab?*

  Recommended: The sites to be rotated about 1cm apart from the previous injection site to avoid scarring and lipodystrophy / lipohypertrophy (24).
- 17.Does the patient inject before or after meals*

  Key:*Critical steps to look out for. An adaptation from American Diabetes Association [30-32].

APPENDIX 5: Knh/Uon-Erc Approval

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29th May, 2015

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U56/69342/2013
Dept.of Pharmaceutics and Pharmacy practice
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Dear Evans

RESEARCH PROPOSAL: IMPACT OF STORAGE AND INSULIN ADMINISTRATION TECHNIQUE ON GLYCATED HEAMOGLOBIN LEVELS AMONG ADULT DIABETIC PATIENTS AT KENYATTA NATIONAL HOSPITAL (P249/04/2015)

This is to inform you that the KNH/UoN-Ethics & Research Committee (KNH/UoN-ERC) has reviewed and **approved** your above proposal. The approval periods are 29th May 2015 to 28th May 2016.

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 severe 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) 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*).
f) Clearance for export of biological specimens must be obtained from KNH/UoN-Ethics & Research Committee for each batch of shipment.
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 **www.erc.uonbi.ac.ke**

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