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PATIENT FACTORS AFFECTING UNWILLINGNESS TO USE INSULIN IN TYPE 2 DIABETICS AT THE CAPE COAST TEACHING HOSPITAL

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AWARD OF MASTER OF PUBLIC HEALTH DEGREE

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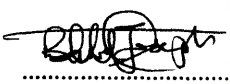
DECLARATION

I, Salifu Bawa, declare that this dissertation submitted for the degree of Masters in Public Health has been composed in its entirety by me and that it has not been submitted, in whole or in part, in any previous pursuit for a degree. Except otherwise indicated by reference or acknowledgment, the work presented here is my own.



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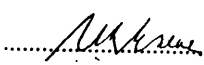

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(SUPERVISOR)

DEDICATION

My wife, Mary Ama Bawa, and my three sons: Zoe, Praise and Richard. Sacrificed a lot for me to get this far. I dedicate this work to them.

ACKNOWLEDGEMENTS

My sincere gratitude goes to Dr. Reuben Esena, my supervisor and Head of Department whose guidance made this work possible. My appreciation also goes to Prof. Francis Enu-kwesi, Mr Prince Asare, Dr. Maame Efua Enyin-Dadzie, Justice Owusu, Emmanuel manton, Paul Yankey Jnr and the nurses and doctors at the Cape Coast Teaching Hospital diabetic Clinic, who all contributed in diverse ways to my pursuance of the Master of Public Health degree.

ABSTRACT

Background: Some Type 2 diabetic patients require insulin therapy to control their blood sugar levels in order to prevent complications. A proportion of patients who meet the criteria to be put on insulin are unwilling to start. Patients already on insulin are unwilling to intensify insulin therapy as a result of various factors. This study looked at patient factors determining the acceptance or refusal of insulin therapy at the Cape Coast Teaching Hospital.

Objective: To assess patient factors affecting unwillingness to use insulin in type 2 diabetics at Cape Coast Teaching Hospital

Method: This is a cross-sectional analytical study of 302 diabetic patients using consecutive sampling method. Data was analyzed using stata 14 version. Chi squared test was done to compare categorical variables and student t test used to compare means. Multivariate logistic regression was used to determine predictors of responses with selected independent variables.

Findings: The level of unwillingness to use insulin in patients with type 2 diabetes was 39%. The fear of injection was the factor significantly affecting patients' unwillingness to accept insulin therapy. The knowledge of patients on insulin therapy was poor. And majority of patients would want more communication on insulin therapy with their doctors.

Conclusion: patients are unwilling to accept insulin therapy because of the fear of injections.

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LIST OF ABBREVIATIONS

ADA	America Diabetes Association
DCCT	Diabetes Control and Complications Study
DM	Diabetes Mellitus
HbA1c	Glycated Hemoglobin
PIR	Psychological Insulin Resistance
UKDPS	United Kingdom Diabetes Prospective Study

CHAPTER ONE

INTRODUCTION

1.1 Background

Carbohydrate metabolism disorder leads to a disease condition that manifest as hyperglycemia resulting from deficiency in insulin production, or action, or both in diabetes mellitus(Kelly, 2011). The chronic high blood sugar levels of diabetes presents in the long-term with injury, dysfunction, and failure of multiple organs such as the eyes, kidneys, nerves, heart, and blood vessels (Owens, 2013). The processes involved in the pathogenesis of diabetes are many. These include autoimmune destruction of pancreatic β-cells with resultant insulin deficiency to abnormalities that result in resistance to insulin action. "The basis of the abnormalities in carbohydrate, fat, and protein metabolism in diabetes is deficient action of insulin on target tissues" (Kelly, 2011).

Diabetes mellitus is a pandemic. Globally the prevalence of diabetes in 2010 was 285 million. And it is estimated that by 2030, 439 million people will be living with diabetes mellitus (Sicree, Shaw, & Zimmet, 2012). In sub-Saharan Africa, about one in twenty people has diabetes mellitus. "However, the estimated prevalence of undiagnosed diabetes is 62%, and an estimated 75% of deaths from diabetes happen in people aged younger than 60 years. Furthermore, the number of people affected is projected to rise from 21 million to 35 million during the next 20 years" (Lipsky, Apelqvist, Bakker, Netten, & Schaper, 2015).

In 2010, in the US, around 73,000 non-traumatic amputations of lower-limbs were performed among adults 20 years of age or older with confirmed diabetes. Also, after adjusting for

difference in population age, deaths due to carbohydrate diseases were about 1.7 times more in adults 18 years or older with confirmed diabetes than among adults without diabetes in 2003 to 2006 (C DC, 2014). In addition, from 2005 to 2008, among diabetic adults who are 40 years old or more, 4.2 million people had retinal disease. Adults with retinopathy were 4.4% (655,000) which could lead to marked blindness. Diabetes mellitus was the number one cause of new cases of renal failure with 40% incidence in 2011 alone. "In 2011, 49,677 people of all ages began treatment for kidney failure due to diabetes" (Centers for Disease Control and Prevention, 2014).

In the United States, an aggregate of 228,924 individuals of any age with kidney failure because of diabetes were living on perpetual dialysis or with a renal transplant. Around 60% lower limp amputations of individuals two decades or more happened in individuals confirmed to have diabetes mellitus (CDC, 2014).

The 2016 diabetes country profile put the prevalence of diabetes mellitus in Ghana at 4.8. The prevalence for males and females are 4.6 and 5.0 respectively (WHO, 2016). Diabetes mellitus, characterized by hyperglycemia, could lead to severe long term complications that reduce quality of life of people affected. However, tight blood sugar control with insulin has long term benefits of reducing these complications (National & Clearinghouse, 2008).

Eventually, some type 2 diabetics who are started on oral hypoglycemic medication will have to be put on insulin therapy as soon as the oral anti diabetic medications fail to maintain HbA1c levels below 7%. Not all patients on oral anti diabetic agents are willing to be put on insulin by their physicians even when it is indicated. And patients already on insulin who need upward adjustment of their regimen may resist or refuse it.

1.2 Problem statement

The unwillingness to use insulin is a percentage of patients who refuse insulin therapy recommended by the clinician for the long term control of their blood sugars. It varies from country to country. This unwillingness is affected by doctor factors, institutional factors and patient factors (Haque, Navsa, Emerson, Dennison, & Levitt, 2005). Myths about insulin, lack of understanding about diabetes, phobia of injections, poor social and economic status were some of the factors identified as barriers to starting insulin treatment in this study by Haque et. Al., (2005). Owens, (2013) noted that unwillingness to use insulin leads to hyperglycemia which results in chronic complications of diabetes such as blindness, kidney failure, non-traumatic amputations and many others.

Studies have been done on unwillingness to use insulin in many countries including China by Chen et al., (2011). Australia, E. Holmes-Truscott, Skinner, Pouwer, & Speight, (2016) and Singapore, (Khalili, Sabouhi, Abazari, & Aminorroaya, (2016). In Africa studies have been done in South Africa (Haque, Navsa, Emerson, Dennison, & Levitt, 2005) and Libya. Studies on resistance or unwillingness to use insulin among diabetics have not been done in Ghana. The 2015 annual report of the diabetes centre of the Cape Coast Teaching Hospital indicated that 255 out of 1,243 active clients of type 1 and 2 diabetes were on insulin. The report showed an increasing need for insulin therapy and refusal of some type 2 diabetics to start insulin therapy.

In Ghana, particularly at the Cape Coast Teaching Hospital, no study has been done to determine the level of unwillingness to insulin therapy. Also the factors affecting unwillingness are not known. This study provides information in this regard which is helpful for educational purposes

and to ensure glycaemic control among Type 2 diabetics at the Cape Coast Teaching Hospital and Ghana as a whole.

The study found answers to the questions: "what is the level of unwillingness to use insulin in type 2 diabetics?" and "what patient factors affect unwillingness to use insulin in type 2 diabetics?"

1.3 Conceptual framework

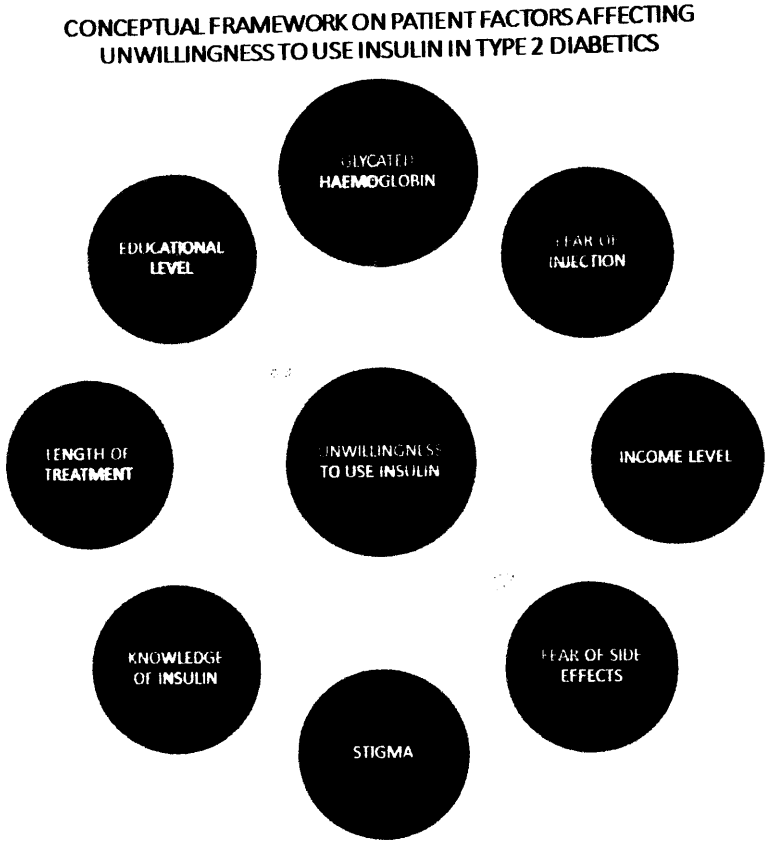

Figure 1.1 A Conceptual framework on patient factors affecting unwillingness to use insulin in type 2 diabetics.

1.3.1 Narrative of conceptual framework

As shown in figure 1, patients are put on insulin based on their HbA1c level. If patients' glycated hemoglobin level is not markedly high, patients may refuse insulin therapy. Patients may also refuse insulin therapy because of fear. This fear may be the fear of injections which is required to administer insulin or the fear of stigma of people when they see or know that they use insulin. The fear may also be due to hypoglycemia which is a side effect of insulin use. When patients have accurate knowledge of insulin therapy they are more inclined to accept to use insulin. Also patients who have been on treatment for diabetes for a long time have a higher likelihood of accepting the introduction of insulin into their treatment regimen than those who have been on treat for a short time. Low educational status and income levels are more likely to lead to increased unwillingness to use insulin than high educational and income status. Educational level when low may result in low level of knowledge on insulin because of inability or reduced interest to read. Knowledge of clients on insulin has a bearing on whether or not they will accept to even do a laboratory investigation such as HbA1C which is used to determine who should be on insulin. Patients who are better educated may be in a better position to handle stigma attached with the use of insulin as a result of the exposure.

1.4 Justification

This study provides data on the level of unwillingness to use insulin in type 2 diabetics at the Cape Coast Teaching Hospital and the factors that influence patients' unwillingness to use insulin. It assessed patients' knowledge on insulin therapy and how that affects their unwillingness.

The issues that emerged for exploration are the effect of fear of injection on the acceptance of insulin therapy in type 2 diabetics, the low level of knowledge of type 2 diabetics on insulin

therapy and the need for more communication on insulin therapy between the patient and health care professional.

1.5 Objectives

Based on preliminary readings and investigation in the study area, the following objectives would be accomplished;

1.5.1 General objectives

The general objective of this research is to assess patient factors affecting unwillingness to use insulin in type 2 diabetics

1.5.2 Specific objectives

The specific objectives of the study are to:

1. Determine the level of unwillingness to use insulin
2. Identify patient factors affecting unwillingness to use insulin
3. Assess patients' knowledge and perception about insulin therapy

CHAPTER TWO

LITERATURE REVIEW

2.1 Introduction

The review of related publications is essential in any research or study. The review of literature provides the theoretical framework on which the study is based. Also, it discusses other studies that have been done on the topic under study or related to the topic. By studying what others have done one is able to discover conventions on which to base his or her study. You are also able to discover questions for which solutions are yet to be provided on which a study can be based.

Diabetes management is multidisciplinary. It involves professionals from various aspects of the health sector including physicians, nurse educators, dieticians, surgeons, physiotherapist and others. This literature review provides theoretical information on diabetes mellitus, its diagnosis, and management. It will provide details about the different forms of treatment using oral hypoglycemic medications and insulin.

Also, a number of articles are reviewed on the unwillingness to use insulin in type 2 diabetics known technically as psychological insulin resistance.

2.2 Clinical Presentation

Symptoms of severe hyperglycemia are urinating large volumes of urine, polydipsia, weight reduction, frequent eating, and impaired sight. Growth impairment and compromised immunity to certain infections may also result from prolonged high blood sugars. Fatal effects of diabetes mellitus that is not controlled are diabetic ketoacidosis or hyperosmolar nonketosis. According to Stang J. (2015), chronic complications of diabetes include retinopathy with possibility of vision

loss: renal disease leading to renal failure; peripheral nerve disease may cause ulcers of the feet, amputations, and abnormalities of ankle joints; and autonomic nerve disease leading to genital, urinary, gastrointestinal, and cardiovascular symptoms and erectile dysfunction. Diabetes patients have an elevated incidence of macro-vascular diseases. Abnormalities of lipid and protein metabolism, and high blood pressure are common among persons with diabetes (Stang J, 2005).

2.3 Types of Diabetes mellitus

The majority of diabetes cases are grouped into two main types. In type 1 diabetes, the etiology is an overt lack of insulin secretion. It occurs as a result of damage to β cells of the pancreas. Persons with greater inclination of developing this particular form of diabetes are identified through serum analysis using genetic markers and immune pathologic response process of islet cells of the pancreatic. In the much more common type 2 diabetes, the cause is a combined effect of resistance to insulin activity and an insufficient compensatory insulin endocrine response.

The degree of hyperglycemia in type 2 diabetes is sufficient to cause disease and functional changes in various tissues, but without clinical symptoms. It abides for a prolonged period without being diagnosed. Amid this asymptomatic period, it is conceivable to show an irregularity in starch digestion by estimation of plasma glucose in the fasting state or after a test with an oral glucose stack. The level of hyperglycemia may change after some time, contingent upon the degree of the metabolic dysfunction.

An impairment of glucose metabolism might be present yet might not have advanced sufficiently to result in hyperglycemia (Kelly, 2011). A similar disease progression can lead to impaired

fasting glucose and/or impaired glucose tolerance without fulfilling the set standards for the determination of diabetes (Need, Diabetes, & Put, 2010). Between August 2007 and June 2008, in a study at the Komfo Anokye Teaching Hospital study, Kumasi, Ghana, 1466 people were enrolled from hypertensive and diabetic centers, outpatients, the community, and hospital staff. Fasting plasma glucose, serum lipids and urine albumin levels were determined. The majority of the 675 type 2 diabetic patients, 75%, were female between 40-60 years.

Type 2 diabetes was diagnosed in 97% of patients, and almost all were on treatment. Diabetic complications occurred in 20. Illiteracy was 46% and socioeconomic indicators were generally low (Danquah *et al.*, 2012).

The third type of diabetes is gestational diabetes which presents in pregnancy in women who had no diabetès. The blood sugar levels usually return to normal. However, gestational diabetes increases the risk of a woman developing diabetes later in life.

About 5–10% cases of diabetes are a contribution from type 1 diabetes Its etiology is a cell-mediated autoimmune destruction of the β-cells of the pancreas (Kelly, 2011). In this kind of diabetes, the rate of β-cell destruction varies, being fast in for the most part neonates and toddlers and moderate in for the most part adults. Some patients, particularly youngsters and teenagers, may give ketoacidosis as the primary clinical presentation of the condition. Others have mild fasting hyperglycemia that can change speedily into severe hyperglycemia as well as ketoacidosis in the presence of disease or anxiety. Still others, especially adults, may have β-cell activity adequate to counteract ketoacidosis for a long time; such people in the long run end up noticeably reliant on insulin to live and are at risk of ketoacidosis. At this phase of type 1 diabetes there is almost no insulin secretion. As a result there are undetectable or low

concentrations of C-peptide in plasma. Type 1 diabetes is can occur at any age though it is common in adolescence and childhood. Apart from autoimmune destruction of β-cells that has been attributed to type 1 diabetes, there are numerous hereditary and environmental elements that are still ineffectively characterized. In spite of the fact that patients are hardly obese when they get this type of diabetes, the presence of obesity does not exclude the diagnosis. These patients are additionally inclined to other immune system diseases such as, Addison's disease, Graves' disease. Hashimoto's thyroiditis, vitiligo, pernicious anaemia, and myasthenia gravis. Type 2 diabetic patients have resistance to insulin and would usually have relative (instead of outright) insulin insufficiency. In any event at first, and regularly all through their lifetime, these people needn't bother with insulin treatment to survive. Of the number of diabetes cases 90–95% of them are those with type 2 diabetes. It has been discussed as non–insulin dependent diabetes. Despite the fact that the particular causes are unknown, there is no immune system decimation of pancreatic β-cells. Majority of patients with type diabetes 2 are obese, and obesity itself causes some level of resistance to insulin. Patients who are not obese by conventional standards of weight measurements may have abdominal obesity. Ketoacidosis does not commonly occur spontaneously in type 2 diabetes. It may arise in association with the stress of another illness such as infection. Typically it goes undetected over a prolonged period of time for the reason that fact that the hyperglycemia progressives slowly and at prior stages is regularly not sufficiently serious for the patient to realize any of the signs and symptoms of diabetes. These patients are at a higher risk of developing macro-vascular and micro-vascular complications. The danger of developing this type of diabetes increases with age, weight, and sedentary lifestyle. It happens all the more as often as possible in ladies with earlier GDM and in people with hypertension or dyslipidemia, and its recurrence fluctuates in various racial and tribal

groups. The genetic inclination of type 1 diabetes compared to type 2 is less. Type diabetes is therefore more hereditary inclined than type1.

There are other more specific types of diabetes mellitus which may result from "genetic defects of β-cell function, genetic defects in insulin action, diseases of the exocrine pancreas, and endocrinopathies" (Balducci, Stefano, Sacchetti, Massimo, Haxhi, Jonida, Orlando, Giorgio, D'Errico, Valeria, Fallucca, Sara, Menini, Stefano, Pugliese, 2014).

2.4 Diagnosis

In 1997, as a team with the WHO, the ADA updated the rules for the diagnosis of diabetes mellitus into three criteria. In the event that one particular requirement is met, the determination of diabetes is made.

1. The presence of classical symptoms of high blood sugar, for example, urinating large volumes, frequent thirst, and weight reduction and a random plasma glucose concentration; 11.1 mmol/L or

2. A fasting plasma glucose; 7.0 mmol/L. Fasting is characterized as no caloric intake for not less than 8 hours before the test or

3. A blood glucose level; 11.1 mmol/L at the 2-hour point of a 75-g OGTT. The glycated hemoglobin (HbA1c) was not prescribed as a confirmatory test for diabetes since it is not thoroughly institutionalized far and wide and the typical range can differ in view of the reagents utilized. In any case, while a normal HbA1c does not preclude diabetes, an elevated value is very significant and indicates the diagnosis of diabetes or the need to do more tests (Leahy & Cefolu, 2002).

Hemoglobin is a biological substance in the red blood cells made up of protein and iron. It functions by transporting oxygen from the lungs to every one part of the body. When haemoglobin comes into contact with sugars in the blood, like different proteins, hemoglobin can join with them. This particularly happens with glucose in the blood. At the point when this happens, it transforms into glycated hemoglobin, alluded to as glycohemoglobin or in some cases as HbA1c. The higher the concentration of glucose in the blood, the more hemoglobin will be attached to it. When joined, hemoglobin and glucose remain as such for the life of the red blood cell—around 16 weeks (four months). The A1C test measures glycated hemoglobin levels in the red blood cells. The A1C test is generally done by a lab. An example of your blood is taken. The blood can be taken anytime of the day. It doesn't make a difference what meal you last ate. It doesn't make a difference what your blood glucose level is at the time of the test. A1C Test tells you about your average blood glucose level for the past 2 to 3 months. An A1C < 7% is good for most people, while an A1C > 7% indicates that your blood glucose level was high during the past 2–3 months requiring a change in your treatment regime.

Oral glucose tolerance test (OGTT) is performed to diagnose gestational diabetes mellitus (GDM). It is done in the morning after an overnight fast of at least 8h. In conducting a 75g OGTT, plasma glucose measurements are taken after the ingestion of 75g of glucose at one and two hours, at 24-28 of week's pregnancy not previously diagnosed with diabetes. Prior to ingestion of the glucose, the fasting blood sugar is measured.

According to ADA, when the following plasma glucose levelss are surpassed, Fasting: 92 mg/dl (5.1 mmol/l) 1h: 180 mg/dl (10.0 mmol/l) 2h: 153 mg/dl (8.5 mmol/l) the diagnosis of GDM is made.

2.5 Management

"Three central goals in the treatment of diabetes mellitus are the avoidance of hyperglycemia to prevent the development or progression of diabetes complications over time, the avoidance of hypoglycemia and the maintenance or achievement of good quality of life. Insulin is the most powerful agent that can be used to control blood glucose levels" (Araszkiewicz, Zozulinska-Ziolkiewicz, Trepinska, & Wierusz-Wysocka, 2008).

In some individuals with diabetes, satisfactory glycemic control can be accomplished with weight decrease, work out, or potentially oral glucose-lowering medications (Need et al., 2010).

"Treatment typically includes diet control, exercise, home blood glucose testing, and in some cases, oral medication and/or insulin. Approximately 40 percent of people with type 2 diabetes require insulin injections" (Kelly, 2011).

There are three types of medications for treating people with diabetes: tablets, insulin, and non-insulin injectables. Tablets can be used to treat people with type 2 diabetes. Insulin is absolutely essential for the treatment of type 1 diabetes but is also necessary to help control blood glucose levels in many people with type 2 diabetes. There are two non-insulin injectable medications available: pramlintide can be used in combination with insulin by people with type 1 and type 2 diabetes; incretins can be used by people with type 2 diabetes to help control blood glucose levels. Incretins require that insulin- producing cells are present in order to work. For blood sugar control, patients should take insulin or diabetes medicines as prescribed by their doctor

(Need et al., 2010). Currently diabetes self management is encouraged. It involves patients being equipped to actively participate in their management without having to depend on the health personnel all the time.

Diabetes self-management instruction is carried out by trained attendants, dieticians, pharmacists, and others to give patients the aptitudes, knowledge, and boldness to deal with their own diabetes on an everyday basis through examination of their lifestyle and blood glucose trends in order to make educated choices in their insulin doses or other treatment (Swinnen, Hoekstra, & DeVries, 2009).

The tablets for treating diabetes and their modes of action are shown in table 2.

Table 2.1 Oral agents used in treating type 2 diabetes mellitus (Swinnen, Hoekstra, & DeVries, 2009).

Glucose-Lowering Oral Agents Commonly Used for Treatment of Type 2 Diabetes.

Type of Agent	Mechanism of Action	Generic Names
Biguanides	Decrease hepatic glucose production, increase muscle insulin sensitivity	Metformin
Sulfonylureas	Increase insulin secretion	Glyburide Glipizide Glimepiride
Meglitinide	Short-term promotion of glucose-stimulated insulin secretion	Repaglinide
Glucosidase inhibitors	Decrease digestion and absorption of carbohydrate	Acarbose Miglitol
Thiazolidenediones	Increase insulin action in muscle, adipose tissue and probably the liver	Rosiglitazone Pioglitazone

2.6 Insulin

Insulin is the only medication that is effective in controlling blood glucose in type 1 diabetes. Factors that determine insulin dose include illness, food, stress and physical activity. Insulin requires regular monitoring of the factors that affect insulin (Cheekati, Osburne, Jameson, & Cook, 2009). There are different types of insulin. Fast acting insulin might be given some time before, in the midst of, or quickly after a supper. Postprandial insulin administration may help diminish the postprandial hyperglycemia related with high fatty foods (Balducci, Stefano, Sacchetti, Massimo, Haxhi, Jonida, Orlando, Giorgio, D'Errico, Valeria, Fallucca, Sara, Menini, Stefano, Pugliese, 2014). Mixed insulin is a blend of fast or short acting insulin and intermediate acting insulin. This regimen is utilized to assist lessen fasting hyperglycemia related with the long interval between supper and breakfast and the length of activity of the moderate acting insulin and to facilitate the management of dawn phenomenon (Gomes & Negrato, 2016). This is usually given twice daily before breakfast and evening meal. Multiple daily injections of rapid or short acting insulin before every meal may be used with once or twice daily injection of intermediate insulin. This is also called intensive insulin therapy. Intensive therapy is given through a continuous subcutaneous insulin infusion or insulin pump utilizing Rapid-acting insulin which is conveyed administered to meet the body's basal need to stifle hepatic glucose generation. A bolus dosage of insulin is given before dinners and snacks in light of the measure of starch eaten and the measured level of blood glucose (Haas, 2007). This regimen is for motivated patients who will test often (>4 times/day), monitor the intake of carbohydrates closely, change insulin dosage when necessary and resolve to contact diabetes team frequently. The frequency of injections of insulin per day varies. Insulin may be delivered with insulin syringes, insulin pens or external insulin pumps.

Needle phobias are common. This could be informed by patients' previous experience with injections. Unlike intramuscular injections which are painful, subcutaneous insulin injections with current syringes and pens are usually painless. The Diabetes Control and Complications Trial proved clearly that tight glycaemic control and the resulting benefits in the long-term can be achieved by intensified insulin therapy. However, the risk of severe hypoglycemia is three times higher with the intensification of insulin treatment compared with conventional treatment. The DCCT insulin dose adjustment was performed by clinicians during frequent outpatient visits, rather than by patients based on recent blood glucose readings.

2.7 Psychological insulin resistance

The unwillingness or refusal to use insulin is called psychological insulin resistance (PIR). PIR is defined as psychological barrier to initiating insulin therapy among diabetic patients and health workers.

A study done to identify factors associated with glucose control, as measured by HbA1c over 4 years, in people with type 2 diabetes starting insulin therapy in which data was collected semi-annually over a 4 year period on people with type 2 diabetes starting any insulin in 311 centers in 12 countries used multivariate regression analysis to select factors associated with glycaemic control from a limited number of candidate variables. On starting insulin HbA1c decreased to steadily in one year, and changed a bit after that. Poorer glycaemic control over the 4 years was predominantly determined by the HbA1c before starting treatment, after accounting for the other statistically significant associated variables in multivariable study: higher BMI, younger age, longer diabetes duration, more glucose-lowering drugs, using basal insulin alone, higher insulin dose and female sex. At 4 years, a higher current, insulin dose was the characteristic most strongly associated with a higher concurrent HbA1c. It was realized that HbA1c at the beginning

of insulin therapy was the parameter most predictive of later HbA1c, after accounting for other variables associated with HbA1c. This may provide sound reason improve glucose control through early introduction of insulin therapy. (Balkau et al., 2015)

A cross-sectional study carried out by (Batais & Schantter, 2016) among participants with Type 2 diabetes using a self-administered questionnaire in Saudi Arabia to investigate whether demographic characteristics such as age, gender, educational level and duration of diabetes are associated with unwillingness to use insulin among these participants using 408 insulin-naive respondents with Type 2 diabetes between May and August 2014 from the primary care outpatient centers at King Khalid University Hospital in Riyadh, Saudi Arabia found that unwillingness to start insulin use was common in around 33% of Saudi members with Type 2 diabetes. Negative perception raised by respondents towards starting insulin were keeping insulin as a last resort (57.1%), limitation of lifestyle (48.8%), problematic hypoglycemia (45.1%), and perception of failure to care for diabetes previously(44.6%), and worries about weight gain (40.7%). In a multivariable logistic regression analysis, after adjusting for respondent's age, sex, instructive level, area and span of diabetes, members with tertiary training were 48% less inclined to start insulin treatment when contrasted with the individuals who had just primary education. However, there were no significant associations between unwillingness to commence insulin and other study variables. In another cross-sectional survey of patients in the public health system of Trinidad, all diabetic patients who attended the chronic disease clinics at their local health centre formed the study population of patients. A target of 400 patients across all 4 of their Regional health Administration (RHA) was chosen. Within each RHA at least 4 health centers were randomly selected using a table of random numbers. At each health centre, convenience sampling of 30 diabetic patients was done based on selecting consecutive patients

who attended the chronic disease clinic for their usual appointment. All included patients were adults (>18 years) with a history of type 2 diabetes. Patients with blindness, deafness and disabilities of the upper limbs that may hinder administration of insulin therapy and pregnancy were excluded.

A de novo questionnaire was designed and pilot tested before face-to-face interviews were conducted. SPSS version 17 was used to analyze the data obtained using 95% confidence intervals. "Chi squared tests were used to compare independent groups of categorical variables. Means were compared with t tests or non-parametric equivalents where appropriate. Multivariate logistic regression was used to determine predictors of responses based on age, education status, gender, economic status, medication type and HbA1c. Study involved both insulin and non-insulin users" (Beneby et al., 2015). Out of the 405 patients, 275 (67.9%) were non-insulin users and 130 (32.1%) were insulin users. The mean duration of diabetes was 11.1 years (SD = 9.6). A recent HbA1c result (within the past 6 months) was available for 198 (48.9%) of the sample. Also, 392 (96.8%) did not know their last HbA1c value. Education level, age, RHA and ethnicity were not predictive of knowledge of last HbA1c value. The mean HbA1c was 7.65% (SD = 2.33%).In all half of participants had HbA1c values greater than 7%. The HbA1c value was significantly higher among Insulin users compared to non-users ($P < 0.001$). Also more insulin users compared to non-users had uncontrolled diabetes (HbA1c>7%, $P = 0.001$). Education, ethnicity and RHA were not predictive of glycaemic control. In a subgroup of patients with an HbA1c > 10%, 42% (14/33) were not on insulin. The insulin level could be higher in insulin users because of physicians' reluctance to adjust doses of insulin upwards as blood sugar levels are increasing.

Chen et al.,(2011) evaluated whether perception of insulin therapy differs between patients with type 2 diabetes treated with insulin and those treated with oral hypoglycemic agents (OHAs), and examined whether gender, education level, injection duration and mode of injection were associated with the patients' perception of insulin therapy.

"The validated Chinese version of the Insulin Treatment Appraisal Scale (ITAS) was used to evaluate the perception of insulin therapy among 100 insulin-treated patients and 100 OHA-treated patients. The higher the total score, the more negative is the appraisal".

The OHA-treated group had a higher mean total score (20 items), a higher mean total score for 16 negative items and a lower mean total score for four positive items than the insulin-treated group. The proportion of participants who rated the negative items as "agree" or "strongly agree" was significantly higher in the OHA-treated group than in the insulin-treated group. In addition, the proportion of participants who rated the four positive items as "agree" or "strongly agree" was lower in the OHA-treated group than in the insulin-treated group. Gender, education level, duration of insulin injection and mode of injection did not have a significant impact on perception of insulin therapy.

Chinese type 2 diabetic patients on tablets had more negative beliefs and attitudes with insulin therapy than patients on insulin. This difference was not associated with either sex or education status. Also, neither injection duration nor type of device was related to perception of insulin therapy.

From a sample included in Diabetes MILES–Australia cross-sectional survey, participants whose primary diabetes treatment was oral hypoglycemic agents were studied for the contribution of general and diabetes-specific emotional wellbeing and beliefs about medicines in the prediction

of insulin therapy appraisals in adults with non-insulin-treated type 2 diabetes. The study among other things looked at complete validated measures of beliefs about the 'harm' and 'overuse' of medications in general; 'concerns' about and 'necessity' of current diabetes medications; negative insulin therapy appraisals (ITAS); depression); anxiety, and diabetes distress using various validated tools. Factors associated with ITAS Negative scores were examined using hierarchical multiple regressions (E. Holmes-Truscott et al., 2016). Twenty-two percent of the difference in ITAS Negative score was explained by the number of complications, 'emotional burden', and 'concerns' about current diabetes treatment.

Elizabeth, Holmes-Truscott, Browne, & Speight, (2016) explored the impact of insulin treatment, both positive and negative, and attitudes associated with future insulin intensification. Twenty face-to-face interviews were done, and analyzed using thematic inductive analysis. Eligible participants were adults with type 2 diabetes, on insulin for 4 years. Five themes that emerged were "physical impact, personal control, emotional well-being, freedom/flexibility, (concerns about) others' reactions. Increased inconvenience and the perceived seriousness of using fast-acting insulin were both reported as barriers to future insulin intensification, despite most participants being receptive to the idea of administering additional injections" (Elizabeth, Holmes-Truscott, Browne, & Speight, 2016). These findings are useful to inform the interaction between patients and the diabetic physician in the process of educating the patient on insulin therapy.

In India, according to Jha et al., (2015), major factors contributing to psychological insulin resistance "were fear of injection or fear of pain during injection, fear of hypoglycemia, social stigma and lack of education". Effective interactions with healthcare providers could facilitate the reduction of PIR, especially in patients whose literacy level is low indicating the need for

skilled healthcare staffs in Indian health care centres.(Jha et al., 2015) The number validated scales used improves the quality of research but is too cumbersome for a study with a short time and little financial resource. The data of patients were collected by interacting face to face using 5 validated questionnaires- Diabetes Knowledge Test, Diabetes Attitude Scale, Interpersonal Processes of Care Survey-29, Diabetes Self-Efficacy Scale, and Barriers to Insulin Treatment scale. It was done to identify factors associated with resistance to insulin use in Indian type 2 diabetes population.. Patients with type 2 diabetes, on oral hypoglycemic medication and who provided written informed consent were qualified for the study. "Demographic variables, categories of patients based on their annual family income, education, glycated hemoglobin (HbA1c). occupation and type of healthcare setup were correlated with overall scores of validated questionnaires. Statistical analyses were performed using Pearson correlation coefficients, analysis of variance, two-group t-test and hierarchical multiple regression".

In the UKPDS, 27% of the patients randomized to insulin treatment at first denied insulin, contrasted with and 13% in the chlorpropamide team and 7% in the glibenclamide team. Polonsky et al., (2011) study had similar outcomes, demonstrating that around 28% of patients who have not received insulin treatment with diabetes answered to be unwilling to start insulin if recommended. Consequently, these outcomes suggest strongly that, negative evaluations with respect to insulin treatment exist in around 33% of the insulin-naive patients. Recent studies have demonstrated that the patients' reasons behind detesting insulin treatment obviously go beyond fear of injections alone. Different reasons, such as worry over putting on weight, the effect of insulin treatment on the social condition or emotions that insulin treatment connotes that one has neglected to oversee diabetes, additionally seem to play a part. Abu Hassan et al.,(2013), explored the factors that influence type 2 diabetic patients in Malaysia to accept insulin. In this

qualitative study in-depth interviews and focus group discussions were done among 21 people. Using Nvivo 7, three major thematic areas were arrived at. "Participants' feelings towards insulin, their perception about insulin and reasons for accepting insulin" were identified. Some of the reasons for which people would reject insulin were painful injection, lifestyle restriction and social stigma. However, they would accept insulin because they think it is effective for treating diabetes. They also think insulin is natural and that oral hypoglycemic agents are limited in their benefits(Abu Hassan et al., 2013).

In Africa, a study was done on patients who attended primary care community health centers (CHCs) to investigate resistance to starting insulin treatment in poorly controlled type 2 diabetes patients on highest dosage of oral glucose-lowering agents' therapy in community health centers in the Cape Town metropolis.

This is a qualitative study by Haque et al., (2005) using focus group discussions and in-depth semi-structured individual interviews done with 46 MOs who work at the health centers. Doctor, patient, and system barriers to initiating insulin therapy were determined. "Doctors' barriers include lack of knowledge, lack of experience with and use of guidelines related to insulin therapy, language barriers between doctor and patients, and fear of hypoglycemia. Patient barriers were mistaken beliefs about insulin, non- compliance, lack of understanding of diabetes, use of traditional herbs, fear of injections, and poor socioeconomic conditions. System barriers were inadequate time, lack of continuity of care and financial constraints".

Suggestions made for dealing with resistance were more training of medical officers on insulin initiation and the use of standardized protocols. Also, a patient-centered approach with better interaction between doctors and patients, may be achieved by reorganizing parts of the health

system, which could improve patient knowledge, address myths, improve compliance and help overcome barriers.(Haque et al., 2005) This is the only study done on the psychological resistance to insulin in Africa. As shown by literature, there are variations in the level of resistance and the factors influencing them from place to place. For effective education on insulin therapy one needs to understand the area specific factors.

In Ghana, there are many studies that have been done on diabetes. For example an analysis of the financial cost of diabetes mellitus was done in Four Cocoa Clinics of Ghana by P. Akweongo et al (2015). Also, K. Terpe et al. (2012), examined the characteristics and associated factors of Diabetes mellitus type 2 in urban Ghana. An investigation into Gestational diabetes mellitus among women attending prenatal care at Korle-Bu Teaching Hospital, Accra, Ghana was carried out by M Amoakoh Coleman et al. (2015).

However, no study has been done on the psychological insulin resistance.

CHAPTER THREE

METHODOLOGY

3.1 Study area

This study was done at the Cape Coast Teaching Hospital at the Central Region of Ghana (figure 2). The Cape coast Teaching hospital has Cape Coast town, the whole of the Central Region and some parts of the Western region as it coverage areas. The population of Cape Coast was 1,010,554 by the 2010 census. The people are mostly formal workers, farmers, fisher folks and students. Out patient records of newly reported cases of diabetes mellitus at the outpatient department were 19838 for the Central Region (GHS, 2016). Study was undertaken over three weeks period at the hospital diabetic clinic at the outpatient department which clinic days fall on Mondays, Wednesdays, and Fridays.

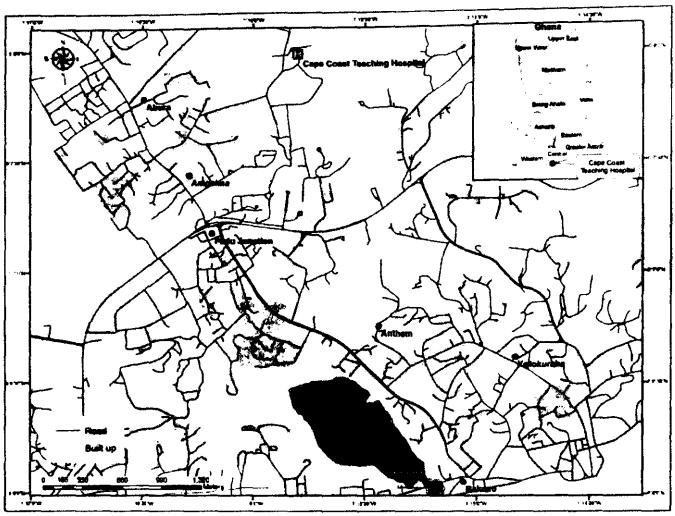

Figure 3.1: Map of Cape Coast showing the various suburbs. The Cape Coast Teaching Hospital is located in the Abura suburb. Inset: map of Ghana with the location of Cape Coast.

3.2 Study design

This research design is a cross sectional analytical study. All participants were selected at a given time and interested variables recorded. It sought to establish the association between independent and dependent variables quantitatively

3.3 Inclusion criteria

Participants were type 2 diabetic patients at the Cape Coast Teaching Hospital who were on medication. They were 18 years old and above.

3.4 Exclusion criteria

Type 2 diabetes patients who had any physical impediment to them using insulin were excluded from the study. For example the blind, those with amputated upper limbs, or mental retardation.

3.5 Sample size determination

Fisher's formula for sample size calculation, which is $n= z^2pq/d^2$, was used in determining the sample size for the participants of the study. The calculation for the participants is shown below. Three hundred (302) patients were recruited instead of the 320 anticipated participants determined using an estimated sample proportion of 75%, power of 80% alpha of 5% with a sample size of 288 and an addition of 30 for non-response. Patients were selected consecutively till 302 patients were selected from the 26th of June, 2017 to the 5th of July, 2017.

Where,

$z= 1.96$,

$p= 0.75$,

$q= 1-p = 0.25$ and

$d= 0.05$

$n= 288$

The proportion p=0.75 was used based on the proportion of insulin unwillingness in other African countries such as South Africa and Libya which had unwillingness levels between 56% and 94%. The 320 participants could not be interviewed because of time limitations.

3.6 Sampling method

The sampling approach was consecutive. Patients were talked to as and when they came to the diabetic clinic. Those who fit into the inclusion criteria were requested to participate in the study. Those who agreed were recruited. Recruitment was done in the order they came into the clinic until all 302 participants were recruited. Recruitment was carried out in the nurses' consulting room by the diabetic nurse and research assistants using the doctors' clinical diagnosis to determine type 2 diabetic patients as recorded in the patients' folders. They were interviewed as they waited to see their doctors and their HbA1c values were retrieved from their folders.

3.7 Data collection instrument:

Interviewer administered questionnaire from another study in Trinidad by Beneby et al., (2015) was adapted and modified for this study. Modified questionnaire was pretested at the University of Cape Coast Hospital for suitability and acceptability. Fifty (50) questionnaires were administered and the expected results were obtained.

3.8 Data processing

Data from questionnaires were first entered into Excel work sheet. It was then imported into Stata version 14, coded and cleaned.

3.9 Data analysis:

Stata version 14 has been used to analyze data obtained using significance level of 5% and 95% confidence intervals. Chi squared test was used to compare categorical variables and student t

test used to compare means. Multivariate logistic regression was employed to determine predictors of responses with selected independent variables.

3.10 Quality control

Three research assistants were recruited and trained to administer questionnaires. Data was edited to ensure accuracy as differences in handwritings and abbreviations were reconciled. Recoding was done for certain variables to suit the objective under investigation. Observations with missing values were left out of the analysis.

3.11 Study variables

The main dependent variable is the level of unwillingness to use insulin while the independent variables include age, sex, educational level, cost of insulin perception, monthly income level, knowledge of respondent, fearing of insulin side effects, fear of injection, pain with injections, duration of diabetes and HbA1c.

3.11.1 Dependent variables

Unwillingness to use insulin (Main)	Refusal to accept insulin therapy on recommendation by patient clinician when indicated
Usage of insulin	Being on insulin therapy with or without oral diabetic medication for the long term control diabetes

3.11.2 Independent variables

Variables	Descriptions
Age	number of completed years as of last birthday (numeric)
Sex	Male or female (categorically)
Monthly income (numeric)	Wages, salaries, remittances, personal earning from trade or other sources per month
HbA1c (numeric)	Value of glycated hemoglobin in the last six months
Duration of diabetes (numeric)	Period in years from the day diabetes mellitus Type 2 was diagnosed and treatment started
Fear of side-effects (categorical)	Being afraid of side effects or potential side effect of insulin therapy such as hypoglycemia, coma, weight gain, scarring at injection site
Embarrassments (categorical)	Feeling of discomfort of using insulin in public
Knowledge of insulin therapy (ordinal)	The perceive knowledge of patients on insulin therapy

3.12 Ethical consideration

Ethical approval was obtained from the Ghana Health Service Ethical Review Committee. Permission was sought from the management of the Cape Coast Teaching Hospital prior to data collection. Hospital administration and study participants were assured of confidentiality, data safety and appropriate data usage. There was no known risk of data collection to patients. Some discomfort resulted from the time spent answering research questions and extension of patient

waiting time. Written informed concert was obtained from participants after an explanation of the purpose. benefits and disadvantages were explained in languages patients could understand. Patients understood they could withdraw from study at anytime without any consequence. Data collected. There are no conflict of interest issues to declare.

CHAPTER FOUR

RESULTS

4.1 Introduction

This chapter contains results based on the findings of the study. The issues examined are the level of unwillingness of type 2 diabetics to initiate or intensify insulin therapy when it is indicated, and the factors that are associated with this unwillingness. This was done in stata version 14 using chi squared test to determine the association of some selected variables with unwillingness to use insulin in type 2 diabetics. It also sought to determine the strength of this association using multiple logistic regression models for those variables that showed significant association with unwillingness to use insulin. The perception and knowledge of insulin therapy were gained from questions on knowledge and perception of insulin therapy from a structured questionnaire validated and used in Trinidad.

The number of responses differ per question as patients did not respond to some questions asked in the questionnaire.

4.2 Demography

The number of patients who participated in the research was 302. Sixty five (21.5%) were on insulin and 273 (78.5%) were not on insulin. As shown in Table 2, the various demographic parameters were analyzed on whether or not they use insulin. The number of responses for the various parameters differs.

Table 4.1: Demographic data

Parameters	All (n=302)	Users (n=65)	Non-Users (n=237)
Age: mean ± SD	59.3 ± 10.2	55.5 ± 11.8	60 ± 9.6
Sex (n=299)			
Male	85 (28.4%)	22 (33.8%)	63 (26.9%)
Female	214 (71.6%)	43 (66.2%)	171 (73.1%)
Ethnicity (278)			
Akan	53 (19.1%)	10 (17.2%)	43 (19.5%)
Fante	188 (67.6%)	40 (69.0%)	148 (67.3%)
Ewe	13 (4.7%)	1 (1.7%)	12 (5.5%)
Others	24 (8.6%)	7 (12.1%)	17 (7.7%)
Education (292)			
No formal education	75 (25.7%)	11 (18.3%)	64 (27.6%)
Primary	78 (26.7%)	26 (43.3%)	52 (22.4%)
Secondary	96 (32.9%)	18 (30.0%)	78 (33.6%)
Tertiary	43 (14.7%)	5 (8.3%)	38 (16.4%)
Monthly_income ± SD (range) GH¢ (n=67)	719 ± 658 (20 - 2788.13)	350 ± 410 (20 - 1,392)	807 ± 678 (50 - 2,788)
Hb1Ac Knowledge (n=168)			
Yes	64 (38.1%)	9 (29.0%)	55 (40.1%)
No	104 (61.9%)	22 (71.0%)	82 (59.9%)
Hb1Ac level: mean ± SD	8.0 ± 2.0	8.5 ± 1.4	7.9 ± 2.2
Hb1Ac level_category (%)			

	<7	17 (24.6%) 2 (20.0%)	15 (25.4%)
	>=7	52 (75.4%) 8 (80.0%)	44 (74.6%)

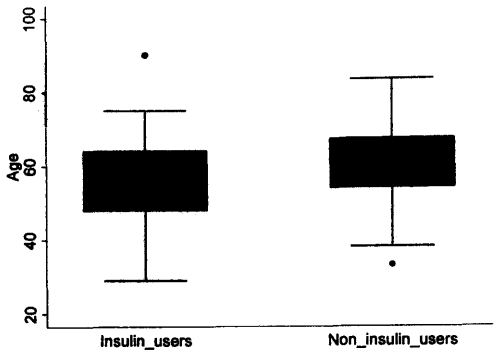

Figure 4.1: Box plot on the ages of patients of insulin and non-insulin users

4.2 Unwillingness to use insulin and associated factors

As shown in table 4.2 the level of unwillingness to initiate insulin therapy is 39%. With regards to gender there was no significant difference between the male and female patients on the level of unwillingness to initiate insulin therapy. The mean age is 60 years for both those that are willing and unwilling to use insulin. The level of education was not a differentiating factor as to whether or not participants accept insulin therapy. The level of HbA1C was not associated with participants unwillingness to initiate insulin therapy, neither was the fear of side effects. The

side effect included hypoglycemia, coma, weight gain, and scarring, shorter life. Fear of injection was associated with unwillingness to use insulin.

Table 4.2: Tests for willingness to use insulin among non-insulin users

Variables		Unwilling (n=68)	Willing (n=106)	P-value
Sex (n=174)				
	Male	15 (22.1%)	35 (33.0%)	0.119
	Female	53 (77.9%)	71 (67.0%)	
Age: mean ± SD		60.0 ± 10.4	59.8 ± 8.8	0.849
Education				
	No formal education	14 (20.6%)	30 (28.6%)	0.285
	Primary	14 (20.6%)	21 (20.0%)	
	Secondary	31 (45.6%)	34 (32.4%)	
	Tertiary	9 (13.2%)	20 (19.0%)	
Hb1Ac level category				
	<7	3 (25.0%)	8 (26.7%)	0.912
	>=7	9 (75.0%)	22 (73.3%)	
Fear of Injection				
	Yes	44 (64.7%)	46 (44.2%)	0.030
	No	17 (25.0%)	43 (41.4%)	
	Do not know	7 (10.3%)	15 (14.4%)	

Perception of pain with injection			
	Painful 49 (72.1%)	57 (54.8%)	0.037
	Not painful 13 (19.1%)	24 (23.1%)	
	Do not know 6 (8.8%)	23 (22.1%)	
Fear of side effects			
hypoglycaemia			
	Yes 28 (41.2%)	43 (41.4%)	0.999
	No 8 (11.8%)	12 (11.5%)	
	Do not know 32 (47.0%)	49 (47.1%)	
Coma			
	Yes 10 (15.4%)	16 (16.0%)	0.825
	No 15 (23.1%)	27 (27.0%)	
	Do not know 40 (61.5%)	57 (57.0%)	
weight gain			
	Yes 11 (16.9%)	24 (23.8%)	0.526
	No 13 (20.0%)	21 (20.8%)	
	Do not know 41 (63.1%)	56 (55.4%)	
Scarring			
	Yes 20 (30.8%)	30 (29.7%)	0.849
	No 13 (20.0%)	24 (23.8%)	
	Do not know 32 (49.2%)	47 (46.5%)	
Shorter life			
	Yes 7 (10.8%)	10 (9.8%)	0.715

No	13 (20.0%)	26 (25.5%)	
Do not know	45 (69.2%)	66 (64.7%)	
Embarrassment with insulin use			
Yes	27 (39.7%)	43 (41.4%)	0.900
No	33 (48.5%)	51 (49.0%)	
Do not know	8 (11.8%)	10 (9.6%)	
Knowledge of Insulin			
great deal	4 (6.0%)	8 (7.6%)	0.468
some	19 (28.4%)	19 (18.1%)	
little	24 (35.8%)	42 (40.0%)	
nothing	20 (29.8%)	36 (34.3%)	
Duration of treatment: mean ± SD	6.4 ± 5.6	7.4 ± 6.7	0.289
Expensive insulin therapy			
Yes	30 (44.1%)	43 (40.9%)	0.761
No	10 (14.7%)	13 (12.4%)	
Do not know	28 (41.2%)	49 (46.7%)	
Monthly income ± SD (GH¢)	810 ± 679	1,279 ± 1,918	0.3132

The results of the multiple logistic regression of unwillingness to use insulin against selected variables of sex, fear of injection and pain are shown in table 4.3 indicating the odds ratios and p values.

Table 4.3: Multivariate logistic regression analysis of sex, fear of injection and pain against unwillingness

Variables	Unwilling (n=68)	Willing (n=106)	Odds ratio (Confidence Interval)	p-value
Sex (n=174)				
Male	15 (22.1%)	35 (33.0%)	1.65 (0.79 - 3.44)	0.184
Female	53 (77.9%)	71 (67.0%)	Reference	
Fear of Injection				
Yes	44 (64.7%)	46 (44.2%)	0.39 (0.17 - 0.92)	0.031
No	17 (25.0%)	43 (41.4%)	Reference	
Do not know	7 (10.3%)	15 (14.4%)	0.63 (0.20 2.00)	0.43
Perception of pain with injection				
Painful	49 (72.1%)	57 (54.8%)	1.12 (0.44 - 2.85)	0.804
Not painful	13 (19.1%)	24 (23.1%)	Reference	
Do not know	6 (8.8%)	23 (22.1%)	2.89 (0.83 - 10.01)	0.094

There was 75.38% (49) unwillingness for the increase in frequency of insulin therapy among insulin users.

4.3 Knowledge and practice of patients on insulin Therapy

About 85% 0f the patients interviewed were on two injections of insulin a day as shown in the figure below.

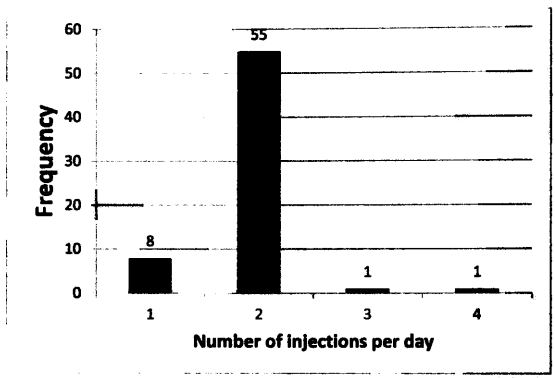

Figure 4.2: Bar graph of the number of injections per day of insulin users

There was no association of recommendation for insulin by doctors with HbA1C categories of below 7% and 7% and above (P-value=0.585). No association was established between patients' willingness to use insulin and the various categories of HbA1C. PR=0.713.

Of the 64 people that were on insulin, 6 (9.38%) use pens and 58 (90.63%) use syringes. No one use pump. Among those who use insulin, 80% (52) self-administered their insulin while 20% (13) had their insulin administered to them by another person.

ble 4.4: **painful experience with administration of insulin by type 2 diabetics**

Painful administration	Frequency	Percentage (%)
Never	10	15.38
sometimes	38	58.46
Most times	9	13.85
Always	8	12.31

ble 4.5: **Insulin users' experience on control of blood sugar with insulin therapy**

Better control	Frequency	Percentage (%)
Control	46	70.77
No control	7	10.77
Don't know	12	12

nong those who use insulin 75% (48) indicated their need for more communication on insulin erapy and 25% (16) indicated they did need it.

ıere were more female than males, with a ratio of 2:1. Of the 278 of the participants that licated their ethnicity, Fantes were dominant with 67.6%.

ı the knowledge of their current HbA1C, 61.9% did not know their HbA1C value. The mean bA1c was 8.0% with standard deviation of 2. For those who use insulin their mean HbA1c was

8.5%, and that of non-users of insulin, 7.9% with standard deviation of 1.4 and 2.2 respectively. About 25% of those with HbA1C had their HbA1C level below 7.0%. Those using insulin has 20% with HbA1C below 7. Patients with high HbA1c are put on insulin. The success of HbA1C control depends on early insulin therapy. The late onset of management of HbA1c could be the reason for high mean of HbA1c among insulin users.

On the availability of insulin for free, 53.85% get insulin free all the time. However, 46.1 5% do not get their insulin for free

Table 4.6: supply of insulin

Free	35	53.85%
Not free	30	46.15%
total	65	100

Table 4.7: Cost of Insulin

Costly	28	73..68%
Not Costly	6	15.79%
Don't know	4	10.53%
total	38	100

Table 4.8: Responses to fear of side effects of insulin

SIDE EFFECTS	YES	NO	DON'T KNOW	TOTAL
Hypoglycaemia	27 (43.55)	24 (38/71)	11 (17.74)	62 (100)
Weight gain	26 (41.27)	23 (36.51)	14 (22.22)	63 (100)
Shorter life	16 (25.40)	19 (30.16)	28 (44.44)	63 (100)
Scarring	18 (29.03)	28 (45.16)	16 (25.81)	62 (100)
Coma	13 (20.31)	22 (34.38)	29 (45.31)	64 (100)

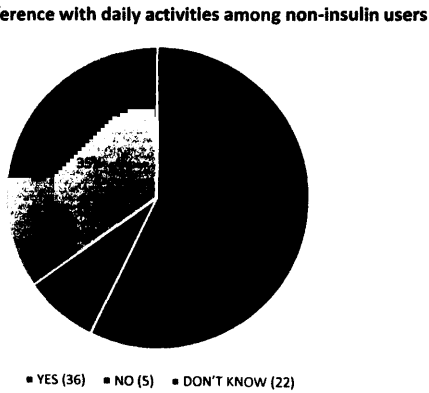

Figure 4.3: Perceived insulin interference with daily activities

Table 4.9: Experiences with insulin injection

Experiences	YES	NO
Self-conscious taking injection in public	33 (51.56)	31 (48.44)
Insulin injection is convenience	42 (64.62)	23 (35.38)
Easy taking all doses	55 (84.62)	10 ()15.38
Following regime	57 (87.69)	8 (12.31)
Easy with current frequency	43 (68.25)	20 (31.75)

Table 4.10: Dietary change with insulin therapy

Change	Frequency	Percentage
Changed diet	30	46.15
No change in diet	15	23.08
Don't know	20	30.77
Total	**65**	**100**

Table 4.11: **Perception of insulin side effects among non-insulin users**

PERCEPTION OF INSULIN SIDE EFFECTS	YES	NO	DON'T KNOW	TOTAL
Hypoglycaemia	34 (35.74)	23 (9.79)	128 (54.47)	235 (100)
Coma	29 (12.72)	57 (25.00)	142(62.28)	228 (100)
Shorter life	19 (8.30)	42 (18.34)	168 (73.36)	229 (100)
scarring	57 (24.89)	48 (20.96)	124 (54.15)	229 (100)
Weight gain	45 (19.65)	37 (16.16)	147 (64.19)	229 (100)

Table 4.12: **barriers to insulin acceptance**

BARRIERS TO INSULIN	YES	NO	DON'T KNOW	TOTAL
Expensive	78 (33.33)	36 (15.38)	120 (51.28)	234 (100)
Fear of injection	144 (48.51)	72(30.64)	49 (20.85)	235 (100)
Think insulin is painful	123 (52.34)	53 (22.55)	59 (25.11)	235 (100)
Time consuming	40 (17.02)	81 (34.47)	114 (48.51)	235 (100)
Difficult diet control	38 (16.17)	63 (26.81)	134 (57.02)	235 (100)
Embarrassed using in public	91 (38.72)	100 (42.55)	44 (18.72)	235 (100)

Table 4.13: Perceived interference with daily activities

Level of Perceived interference	frequency	Percentage
A little	53	22.84
A lot	25	10.78
Not at all	71	30.60
Don't know	83	35.78

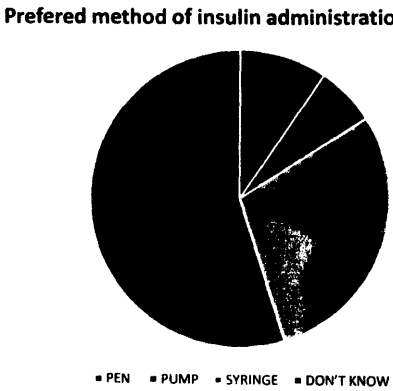

Figure 4.4: Preferred method of insulin administration among non-insulin users

Majority of the patients admitted to know little or nothing about insulin therapy as shown in figure 4.5.

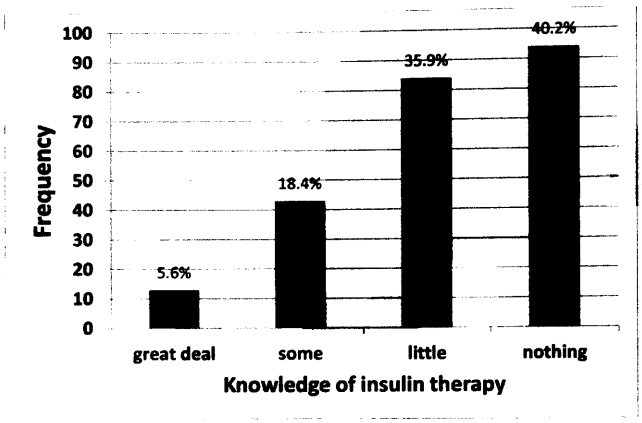

Figure 4.5: The knowledge of patients on insulin therapy

On the question of whether they would need more communication on insulin therapy with their doctors 87 (38%) said "no" while 145 (62%) responded in the affirmative.

CHAPTER FIVE

DISCUSSIONS

5.1 Introduction

The results were discussed in this order: first is a discussion of the demographic parameters with the use of insulin; then the willingness to use insulin and the factors affecting it; and finally, the knowledge and practice of patients on insulin therapy.

5.2 Demography

There were 302 participants, 65 (21.5%) of them were insulin users and 273 (78.5%) of them were non-insulin users. The female were 214 (71.6%) and the male 85 (28.4%). The proportion of female among non-users was 73.1% compared 66.2% among users. There were three major ethnic representations. The Fante ethnic group was 67.6% Akan 19.1 %, Ewe 4.7% and others 8.6%. The mean age of all respondent was 59.3 years with a standard deviation of 10.2. The mean age of users of insulin was 55.5 with a standard deviation of 11.8. For the non-users, the mean age was 60 years with a standard deviation of 9.6 year.

Two hundred and ninety-two (292) participants responded to their educational status. And the proportions were 25.6%, 26.7%, 32.9% and 14.7% for no formal education, primary, secondary and tertiary education respectively. Among non-user of insulin the proportion of participants with secondary and tertiary levels of education was higher. The mean monthly income of respondents was 719 Ghana Cedis with the lowest income being 20 Ghana Cedis and highest being 2788.13. Only 67 participants answer the question on their monthly income. The mean

income of insulin users was 350 Ghana Cedis. With standard deviation of 410; and that of non-users of insulin was 807 Ghana Cedis with standard deviation 678 Ghana Cedis.

Concerning the knowledge of their current HbA1c, less than 40% know their values. In a study, by Beneby et al; (2015) 96.6 % did not know their last HbA1c level and a recent HbA1c result was available for 48.9%. In that study current HbA1c was available for 55.6%. Most participants, 75.4%, had HbA1c of 7% and above. This proportion is 80% among users and 74.6 % among non-users of insulin. In another study by Ferroni et al, (2016), more than 70% had at least one HbA1C test in 2013. This reduced to about 40% for two HbA1c tests in a year. HbA1c level are higher among insulin users with a mean HbA1c of 8.5% for insulin users and 7.9% for non-users.

5.3 Unwillingness to use insulin and associated factors

Unwillingness to use insulin among non-insulin users was 39.0%. In a study done in South Africa by Nadasen and Naidoo, (2012) with the sample size of 59, the Unwillingness to initiate insulin therapy was 56% and from a total of 1703 patients in Libya 94.6% were unwilling to start insulin (Sabei & Sammud, 2015). Khan et al, (2008), had Unwillingness prevalence of 42.5% with 212 patients who required insulin therapy.

There was no association between sex and their willingness to initiate insulin therapy. The P-value was 0.119.

Also, the age of participants had no association with unwillingness to initiate insulin therapy. The mean age for both groups was 60 years. Also, the level of education was not a factor in

participants determining whether to initiate insulin therapy or not. Concerning HbA1c categories, it was not a significant factor affecting the choice for insulin therapy.

However the fear of injection was a statistically significant factor affecting unwillingness to start insulin therapy by insulin naïve type two diabetics. The P-value was 0.030 however; the fear of side effects such as hypoglycemia, hypoglycemic coma, weight gain, scarring at injection site, and shorter life did not significantly affect the choice of insulin therapy. Also, willingness to start insulin was not affected by the duration of treatment, perception of insulin cost, knowledge of insulin. The perception that insulin injection was painful was a significant contributing factor. After adjusting for sex, and pain with injection of insulin naive participants, patients who had fear of insulin injections were 39.9% less likely to start insulin therapy compared with individuals who did not fear insulin injections. The fear of injection had a P-value of 0.031, while sex and perception of pain had P-values of 0.184, and 0.804 respectively. This means fear of injection is strongly associated with unwillingness to use insulin and requires attention if unwillingness level is to be reduced.

Of the 64 participants on insulin therapy, 49 (75.8%) were unwilling for the intensification of their insulin therapy. Work done by Jha et al, (2015) showed patients on insulin desired to avoid additional injections but indicated more willingness to increase the dose of existing injections to avoid additional injections.

5.4 Knowledge and practices of patients on insulin Therapy

5.4.1 Insulin users

About 86% of those on insulin therapy had two (2) injections a day while twelve (12) had an injection per day and two percent 2% had three (3) or more injection per day.

Insulin injection was painful always for 12.31% of participants, painful most of the time for 13.8% participants, while 58.46% of participants felt pains on administering insulin sometimes. About 15% never experience pain with insulin therapy. This means 75% of patients experience pain with insulin. The method of administering the insulin and multiple use of syringes could be a factor. The majority of insulin users, 70.77% think insulin has better controlled their blood sugar level while 10.77% think insulin does not control their blood sugars. The rest don't know whether insulin controls their blood sugars or not. Over 90% of those on insulin at the Cape Coast Teaching Hospital use syringe. about 9% use pens to administer their insulin. No one uses pump. Insulin is self-administered in 80% of patients.

Majority of the insulin users are comfortable with their current frequency of taking their insulin injection. However, 31.75% are not comfortable with their frequency of their injections. Those not comfortable with their injection frequency are likely to default on treatment leading to uncontrolled blood sugars even though they are on therapy.

Insulin is available for free always for 35 (53.85%) while 30 (46.15%) sometimes buy their insulin. As shown in table 4.7, 28(73.68%) of these participants who buy their insulin think it's expensive. The cost of insulin could deter some people from accepting insulin therapy. Further

information is needed on how some patients are able to get free insulin always to consider whether the same process could be extended to all patients on insulin as is applied to Trinidad.

From table 4.8 the fear of the side effects of insulin and the responses are shown. Of the insulin users, the fear of hypoglycaemia has the highest response of 43.55% followed by weight gain 41.27%, scaring 29.03%, shorter life, 25.40% and com 20.31%. As discussed in the literature, the more stringent the therapy of insulin, the more likely the occurrence of hypoglycaemia. Patients should be prepared to detect early symptoms of hypoglycaemia and the other side effects and take precautionary measures and report to the diabetic management team before they get worse.

Insulin interferes with daily activities among 57.14% of participants, however 34.92% of insulin users do not know about insulin therapy interfering with their daily activities. The rest, 7.94% do not have their daily activities interfered with as shown in figure 4.3. Furthermore, with regards to insulin interfering with their diet, 46.15% thinks their diet has changed with insulin therapy and 30.77% do not know if their diet has changed.

Dietary therapy is not optional in diabetes management whether patient is on tablet or insulin injection. Without an adjustment of diet to suit the patient's life style and insulin dosage, this will result in poor glycaemic control or side effects. However 23.08% of participants on insulin have not experience any change in diet since they commenced using insulin.

From table 4.11 the experiences of patients with insulin are shown. When patients were ask whether they have concerns with taking insulin in public 51.56% answered in the affirmative, and 48.44% had no self-consciousness taking insulin in public. Also, 64.62 patients on insulin thinks insulin therapy is convenient and 84.62% find it easy taking all their doses of insulin, and

87.69% are following their treatment regime as prescribed by their doctor, also 68.25% are comfortable with their current therapy. Insulin acceptance and compliance appears high among insulin users. It means that patients overcome the initial phobia that hinder them from starting therapy as they are exposed to treatment, and those on insulin therapy may be receiving more education on insulin therapy than those who are not.

5.4.2 Non-insulin users

The fear of side effects of insulin could lead to some people refusing to use insulin as shown in table 4.13. concerning the fear of side effects among patients who are not on insulin therapy, the responds to fear of hypoglycaemia was 35.74%. Next to hypoglycaemia, the fear of scaring with injections had a responds of 24.89%, followed by weight gain, which had a phobia responds of 19.65%.

However the lowest fear response was to shorter life. Very few participants (8.3%) fear their life span will be shorter with insulin therapy. To improve acceptance to insulin therapy efforts should also focus on these side effects- especially hypoglycaemia.

Other barriers to insulin examined among patients included cost of insulin, fear of rejection, pain with injection, time consumption with insulin therapy, interference with diet, and embarrassment with public use of insulin. The responds to injection being painful, fear of injections, and insulin therapy being costly were 52.34%, 48.51% and 33.3% respectively. Those who would be embarrass using insulin in public 38.72%, 42.55% will not feel embarrassed taking insulin in public. People who consider insulin therapy think about pain, cost, and public perception. The administration method affects determines pain. The various instruments being available can help

to reduce unwillingness as more suitable options are provided apart from the syringes mostly used in the clinic at the Cape coast Teaching Hospital. Public education on insulin use could reduce stigma on those insulin use in public.

Concerning how they perceive insulin therapy will interfere with their daily activities, 35.78% do not know whether insulin therapy will affect their daily activities. Also 30.6% thinks it will not affect their activities at all and 22.84% think it will affect them a little. However 10.78% think it will interfere with their daily activities a lot. This group is the smallest as shown in the table 4.13.

Participants who do not use insulin and had little or no knowledge about were 76.1%. About 18% had some knowledge and 6% had great deal of knowledge.

Doctors' recommendation for insulin therapy did not differ on the bases of HbA1c level. This may be because many medical officers do not know the benefits of insulin in poorly controlled diabetes mellitus (Haque et al, 2005). According Cheekati et al, (2009), resident doctors were not familiar with existing institutional policies for insulin therapy. With regards to the needs for more communication on more insulin therapy 62% thinks they need it whiles 38% thinks otherwise.

CHAPTER SIX

CONCLUSIONS AND RECOMMENDATIONS

6.1 Introduction

In this section, a summary of the main findings of the study are presented. Also, the main conclusions from the findings are generated and recommendations as a result.

The complications of diabetes mellitus that result from uncontrolled blood sugar levels such as blindness, stroke, heart diseases, leg ulcers and erectile dysfunction are debilitating. Patients' compliance to insulin therapy which is required for those with HbA1c of 7% and above is important. Patients need to have HbA1c done to inform doctors on the prescription of insulin. There are factors that influence patients' willingness to use insulin. These factors and the knowledge of the patients on type 2 diabetes were studied.

An analytical cross-sectional study was done, using a consecutive sampling method and a sample size of 302. Data was gathered using a structured questionnaire and analyzed using stata version 14.

6.2 Conclusions

6.2.1 Level of unwillingness

About Four out of every ten type two diabetics who needs to be on treatment with insulin at the Cape Coast Teaching hospital will not accept it. Among those who are already on insulin majority of them will not accept to have their number of insulin injections increased in order to control their blood sugars.

6.2.2 Factors associated with unwillingness

The fear of injections is the reason why most people at the Cape Coast teaching hospital will not accept insulin treatment.

6.2.3 Knowledge and perception on insulin therapy

Most of the patients had not done the blood test (HbA1c) which the doctors use to decide whether they should be on insulin or not. Even those who did it, it appeared it was not used to decide whether patients should be treated with insulin or not.

Majority of patients did not have enough knowledge about insulin therapy and were willing to receive teachings from their doctors on insulin therapy. There is a prevalence of negative perception on the use of insulin among diabetic patients which could affect the acceptance of insulin therapy.

Insulin therapy is not always free as some patients with no access to free insulin have to acquire it at a high cost.

It is not all diabetic patients who need to be on insulin who will accept it even though it will help them avoid problems that arise because blood sugar levels are higher than normal. This is because they fear insulin injections. The knowledge of patients about insulin treatment is poor; a reason for their desire for more interactions with their doctors about treatment with insulin.

6.3 Limitations of the study

The determination of patient's diagnoses of type two diabetes mellitus was based on clinical judgment and not serum C-peptide levels which is more exact. The study was undertaken within

three weeks within which period it could not get a sample that was representative of the population of type 2 diabetics that attend the clinic using the method of participant selection.

6.4 Recommendations

Patients' fear of insulin injections must be allayed so that they can accept insulin therapy to control their blood sugars and reduce the complications of diabetes mellitus such as stroke, blindness, heart diseases, amputations, and chronic leg ulcers. This should be done by diabetes health educators who have been trained for this purpose.

Doctors should spend some more time to explain to their patients the reasons for doing HbA1c, and the need for insulin therapy so that the patients will be empowered to take a decision based on information provided.

To remove the barrier of cost of insulin, diabetic clinic staff should encourage patients to patronize the national health insurance scheme so they can get insulin for free or at a subsidy.

Education on insulin therapy should be given to patients by diabetic educators on regular bases at the diabetic clinic. For non-users of insulin, focus should be on dealing with the fear of insulin injection.

Further research should be done on unwillingness to use insulin using a larger and more representative sample size so that results can be applied to the general population.

REFERENCES

Abu Hassan, H., Tohid, H., Mohd Amin, R., Long Bidin, M. B., Muthupalaniappen, L., & Omar, K. (2013). Factors influencing insulin acceptance among type 2 diabetes mellitus patients in a primary care clinic: a qualitative exploration. *BMC Family Practice*, *14*(1), 164. http://doi.org/10.1186/1471-2296-14-164

Araszkiewicz, A., Zozulinska-Ziolkiewicz, D., Trepinska, M., & Wierusz-Wysocka, B. (2008). Knowledge after five-day teaching program in intensive insulin therapy performed at the onset of type 1 diabetes influence the development of late diabetic complications. *Diabetes Research and Clinical Practice*, *81*(1), 61–67. http://doi.org/10.1016/j.diabres.2008.02.009

Balducci, Stefano, Sacchetti, Massimo, Haxhi, Jonida, Orlando, Giorgio, D'Errico, Valeria, Fallucca, Sara, Menini, Stefano, Pugliese, G. (2014). Physical Exercise as therapy for type II diabetes. *Diabetes/Metabolism Research and Reviews*, *32*(30), 13–23. http://doi.org/10.1002/dmrr

Balkau, B., Calvi-Gries, F., Freemantle, N., Vincent, M., Pilorget, V., & Home, P. D. (2015). Predictors of HbA1c over 4 years in people with type 2 diabetes starting insulin therapies: The CREDIT study. *Diabetes Research and Clinical Practice*, *108*(3), 432–440. http://doi.org/10.1016/j.diabres.2015.02.034

Batais, M. A., & Schantter, P. (2016). Prevalence of unwillingness to use insulin therapy and its associated attitudes amongst patients with Type 2 diabetes in Saudi Arabia. *Primary Care Diabetes*, 1–10. http://doi.org/10.1016/j.pcd.2016.05.007

Beneby, N., Isaacs, C., King, L., Taylor, A., Thompson, C., & Ward, J. (2015). Knowledge , Attitudes and Perceptions of Patients towards Insulin Therapy at Primary Care Centers in Trinidad. 2–7.

Centers for Disease Control and Prevention. (2014). National Diabetes Statistics Report , 2014 Estimates of Diabetes and Its Burden in the Epidemiologic estimation methods. *US Department of Health and Human Services*, 2009–2012.

Cheekati, V., Osburne, R. C., Jameson, K. A., & Cook, C. B. (2009). Insulin therapy for inpatients with diabetes: Perceptions of resident physicians from disparate geographic training programs. *Insulin*, *4*(2), 106–113. http://doi.org/10.1016/S1557-0843(09)80019-5

Chen, C.-C., Chang, M.-P., Hsieh, M.-H., Huang, C.-Y., Liao, L.-N., & Li, T.-C. (2011). Evaluation of perception of insulin therapy among Chinese patients with type 2 diabetes mellitus. *Diabetes & Metabolism*, *37*(5), 389–394. http://doi.org/10.1016/j.diabet.2010.12.008

Danquah, I., Bedu-Addo, G., Terpe, K.-J., Micah, F., Amoako, Y. a, Awuku, Y. a, … Mockenhaupt, F. P. (2012). Diabetes mellitus type 2 in urban Ghana: characteristics and associated factors. *BMC Public Health*, *12*(1), 210. http://doi.org/10.1186/1471-2458-12-210

Diabetes, D. O. F. (2011). Diagnosis and classification of diabetes mellitus. *Diabetes Care*, *34*(SUPPL.1). http://doi.org/10.2337/dc11-S062

Gomes, M. B., & Negrato, C. A. (2016). Adherence to insulin therapeutic regimens in patients with type 1 diabetes. A nationwide survey in Brazil. *Diabetes Research and Clinical Practice*, *120*, 47–55. http://doi.org/10.1016/j.diabres.2016.07.011

Haas, L. B. (2007). Optimizing Insulin Use in Type 2 Diabetes: Role of Basal and Prandial Insulin in Long-Term Care Facilities. *Journal of the American Medical Directors Association*, *8*(8), 502–510. http://doi.org/10.1016/j.jamda.2007.08.002

Haque, M., Navsa, M.. Emerson, S. ., Dennison, C. ., & Levitt, N. . (2005). Barriers to initiating

insulin therapy in patients with type 2 diabetes mellitus in public-sector primary health care centres in Cape Town. *Journal of Endocrinology, Metabolism and Diabetes of South Africa*, *10*(3), 94–99. http://doi.org/10.1080/22201009.2005.10872127

Holmes-Truscott, E., Browne, J. L., & Speight, J. (2016). The impact of insulin therapy and attitudes towards insulin intensification among adults with type 2 diabetes: A qualitative study. *Journal of Diabetes and Its Complications*, *30*(6), 1151–1157. http://doi.org/10.1016/j.jdiacomp.2016.03.027

Holmes-Truscott, E., Skinner, T. C., Pouwer, F., & Speight, J. (2016). Explaining psychological insulin resistance in adults with non-insulin-treated type 2 diabetes: The roles of diabetes distress and current medication concerns. Results from Diabetes MILES - Australia. *Primary Care Diabetes*, *10*(1), 75–82. http://doi.org/10.1016/j.pcd.2015.06.006

Jha, S., Panda, M., Kumar, S., Gupta, R., Neemani, A., Jacob, J., … Agarwal, G. (2015). Psychological Insulin Resistance in Patients with Type 2 Diabetes. *The Journal of the Association of Physicians of India*, *63*(7), 33–39. Retrieved from http://ovidsp.ovid.com/ovidweb.cgi?T=JS&PAGE=reference&D=medl&NEWS=N&AN=26731825

Kelly, J. (2011). Diabetes: What is diabetes? *CDC National Center for Chronic Disease Prevention and Health Promotion*, 1–3.

Khalili, M., Sabouhi, F., Abazari, P., & Aminorroaya, A. (2016). Comparing the quality of life in insulin recipient and refusal patients with type 2 diabetes. *Iranian Journal of Nursing and Midwifery Research*, *21*(4), 351. http://doi.org/10.4103/1735-9066.185571

Leahy, J. L., & Cefolu, W. T. (2002). *Insulirl Therapy edited by*.

Lipsky, B. A., Apelqvist, J., Bakker, K., Netten, J. J. Van, & Schaper, N. C. (2015). The

challenge of diabetes in sub-Saharan Africa, *8587*(15), 675–677. http://doi.org/10.1016/S2213-8587(15)00236-3

Need, W. Y., Diabetes, K. A., & Put, S. (2010). *Diabetes A to Z, 6th Edition*.

Owens, D. R. (2013). Clinical evidence for the earlier initiation of insulin therapy in type 2 diabetes. *Diabetes Technology & Therapeutics*, *15*(9), 776–85. http://doi.org/10.1089/dia.2013.0081

Sicree, B. R., Shaw, J., & Zimmet, P. (2012). The Global Burden Diabetes and Impaired Glucose Tolerance. *IDF Diabetes Atlas*, 1–105. http://doi.org/10.1097/01.hjr.0000368191.86614.5a

Stang J, S. M. (eds). (2005). Guidelines for Adolescent Nutrition Services. *Book.Shtm*, 167–182. http://doi.org/10.1152/physrev.00003.2010.

Swinnen, S. G., Hoekstra, J. B., & DeVries, J. H. (2009). Insulin therapy for type 2 diabetes. *Diabetes Care*, *32 Suppl 2*. http://doi.org/10.2337/dc09-S318

Wild Sarah, Roglic Gojka, Green Anders, Sicree Richard, & Hilary, K. (2004). Global Prevalence of Diabetes: Estimates for the year 2000 and projection for 2030. *Diabetes Care*, *27*(5). 1047–1053. http://doi.org/10.2337/diacare.27.5.1047

APPENDICES

APPENDIX 1: information sheet and consent form for type 2 diabetics at Cape Coast Teaching Hospital

SCHOOL OF PUBLIC HEALTH

COLLEGE OF HEALTH SCIENCES

UNIVERSITY OF GHANA

Consent form

Title:	Patient factors affecting unwillingness to use insulin in type 2 diabetics at the Cape Coast Teaching Hospital
Principal investigator:	Salifu Bawa
Affiliated institution:	School of Public Health, College of Health Sciences, University of Ghana
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For further information on this research from GHS ethical review committee contact

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General information about the research

The study seeks to assess patient factors affecting unwillingness to use insulin in type 2 diabetics at the Cape Coast Teaching Hospital. Respondents consisting of type 2 diabetic patients 18 years and above who are attendants of the diabetic clinic. Respondents will be asked to respond to questions on their diabetes status, knowledge on diabetes and willingness to use insulin if indicated.

Possible risk and discomfort

The research will pose a minimum of risk on the respondent. Discomfort involved

Consent form

Permission

You have been selected to participate in this study. The objective of the study is to assess patient factors affecting unwillingness to use insulin in type 2 diabetics. Your consent is therefore required. However, you can refuse to participate or withdraw from participating from the study at any point during the study without fear of victimization or harm.

Confidentiality

All information you provide in this study will be kept confidential. Numbers will be assigned to questionnaire not names. Thus you are assured of anonymity.

Benefits with participating

This study seeks to asses patient factors affecting unwillingness to use insulin in type 2 diabetics. Although there will no direct benefit for participating, the findings are expected to inform sound policy decisions and programs aimed at improving the management of diabetes mellitus.

Undertaken

I have read the content of the information herein written, or it has been read to me. I have been given opportunity to ask questions. All questions I have asked have been answered to my satisfaction. I therefore willingly consent to be a participant in this study and I understand that I have the right to withdraw from the study at any time without in any way it affecting my further medical care.

.....	.....
Code of participant	Date and signature/thumb print of participant
.....	.....
Name of researcher/research assistant	Date and signature of researcher/assistant

APPENDIX 2: Questionnaire On Patient Factors Affecting Unwillingness To Use Insulin By Type 2 Diabetics At The Cape Coast Teaching Hospital

☐Male ☐Female

Age _____

Ethnicity:————————————

Education:

☐ Primary Level ☐ Secondary Level ☐ Tertiary Level ☐No formal education

Address_____ _____

_____

Monthly income————————————

How long have you had diabetes? ___Years ___Months

Do you know your last HbA1c result? ☐Yes ☐ No. What is it? _____ (To obtain most recent result from patient chart)

Are you currently on insulin therapy? ☐ Yes ☐ No *If Yes, Answer Questions 1-18

*If No, Answer Questions 19- 32

INSULIN USERS

1. What type of insulin administering device do you use? ☐ Pen ☐ Pump ☐ Syringe

2. Do you think insulin administration with a pen device is easier compared to insulin syringes?

☐ Yes ☐ No ☐ Don't Know

3. How long have you injected insulin? ___Years ___Months

4. Number of injections per day? ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ More than 4

5. If you had to inject insulin more frequently, would this trouble you? ☐ Yes ☐ No

Are you currently on insulin therapy? ☐ Yes ☐ No *If Yes, Answer Questions 1-18

6. Do you find it easy to take insulin the way you are taking it now? ☐ Yes ☐ No

7. Do you administer insulin to yourself? ☐ Yes ☐ No

8. Is insulin administration painful? ☐ Never☐ Sometimes☐ Most times☐ Always

9. Is your insulin therapy always free? ☐ Yes ☐ No

If "No" when you have to purchase your insulin is it expensive? ☐ Yes ☐ No ☐ Don't know

10. Are you self-conscious about taking insulin in public? ☐ Yes ☐ No

11. Do you find insulin administration convenient? ☐ Yes ☐ No

12. Do you find it easy to take all the doses recommended by the doctor?

☐ Yes ☐ No

13. Are you following the insulin regimen/ guide recommended by the doctor?

☐ Yes ☐ No

14. Are you fearful of any of the following resulting from insulin?

Low blood sugar (hypoglycemia) ☐ Yes ☐ No ☐ Don't know ☐

Weight gain ☐ Yes ☐ No ☐ Don't know ☐

Shorter life ☐ Yes ☐ No ☐ Don't know ☐

Scarring at the site of injection ☐ Yes ☐ No ☐ Don't know ☐

Passing out (coma) ☐ Yes ☐ No ☐ Don't know

15. How much does your current insulin treatment interfere with your everyday activities (social, leisure work or school activities?

☐ A little ☐ A lot ☐ Not at all

low much has your diet changed since you started insulin therapy?

little ☐ A lot ☐ Not at all

o you think your diabetes is better controlled since you started insulin?

'es ☐ No ☐ Don't know

lave you ever felt the need for more communication from your doctor about your insulin

py?

'es ☐ No

- USERS

low much do you know about insulin therapy? ☐ A great deal ☐ Some ☐ Little ☐

ing

las your clinic doctor ever recommended insulin therapy to better control your diabetes?

'es ☐ No

f your doctor ever recommended insulin therapy to better control your diabetes would you

it?

'es ☐ No ☐ Don't Know

)o you think insulin therapy is expensive? ☐ Yes ☐ No ☐ Don't Know

If you had to take insulin therapy:

23. Would you be afraid of insulin needle injections? ☐ Yes ☐ No ☐ Don't Know

24. Do you think insulin injections would be painful? ☐ Yes ☐ No ☐ Don't Know

25. Do you think your glucose level would be better controlled on insulin? ☐ Yes ☐ No ☐ Don't Know

26. Do you feel that taking insulin injections would be time consuming?

☐ Yes ☐ No ☐ Don't Know

27. Do you think it would be difficult to control your diet if on insulin therapy?

☐ Yes ☐ No ☐ Don't Know

28. Would you feel embarrassed by taking an insulin injection in public?

☐ Yes ☐ No ☐ Don't Know

29. Do you feel insulin therapy can result in any of the following?

☐ Low sugar ☐ Yes ☐ No ☐ Don't Know

☐ Passing out (coma) ☐ Yes ☐ No ☐ Don't Know

☐ Weight Gain ☐ Yes ☐ No ☐ Don't Know

☐ Scarring around injection sites ☐ Yes ☐ No ☐ Don't Know

☐ Shorter life ☐ Yes ☐ No ☐ Don't Know

30. Do you think insulin treatment would interfere with everyday activities (social, leisure work or school activities?

☐ A little ☐ A lot ☐ Not at all ☐ Don't Know

31. If insulin therapy was suggested for you which method of administration would you prefer?

☐ Pen ☐ Pump ☐ Syringe ☐ Don't Know

32. Have you ever felt the need for more communication from your doctor about insulin therapy?

☐ Yes ☐ No

GHANA HEALTH SERVICE ETHICS REVIEW COMMITTEE

In case of reply the number and date of this Letter should be quoted.

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MyRef. GHS/RDD/ERC/Admin/App/566
Your Ref. No.

Salifu Bawa
University of Ghana
School of Public Health
Legon, Accra

The Ghana Health Service Ethics Review Committee has reviewed and given approval for the implementation of your Study Protocol.

GHS-ERC Number	**GHS-ERC: 106/02/17**
Project Title	Patient Factors Affecting Unwillingness to Use Insulin in Type 2 Diabetics at the Cape Coast Teaching Hospital
Approval Date	1st June, 2017
Expiry Date	31st May, 2018
GHS-ERC Decision	**Approved**

This approval requires the following from the Principal Investigator

- Submission of yearly progress report of the study to the Ethics Review Committee (ERC)
- Renewal of ethical approval if the study lasts for more than 12 months,
- Reporting of all serious adverse events related to this study to the ERC within three days verbally and seven days in writing.
- Submission of a final report **after completion** of the study
- Informing ERC if study cannot be implemented or is discontinued and reasons why
- Informing the ERC and your sponsor (where applicable) before any publication of the research findings.

Please note that any modification of the study without ERC approval of the amendment is invalid.

The ERC may observe or cause to be observed procedures and records of the study during and after implementation.

Kindly quote the protocol identification number in all future correspondence in relation to this approved protocol

SIGNED.....
DR. CYNTHIA BANNERMAN
(GHS-ERC CHAIRPERSON)

Cc: The Director, Research & Development Division, Ghana Health Service, Accra