

**PREVALENCE AND SEVERITY OF COMORBID
DEPRESSION IN AMBULATORY TYPE 2
DIABETES PATIENTS AT THE KENYATTA
NATIONAL HOSPITAL (KNH)**

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DECLARATION

This dissertation is my original work and has not been presented for a degree at any other university.

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A rectangular box containing a handwritten signature in blue ink, which appears to read 'J. Kanu'.

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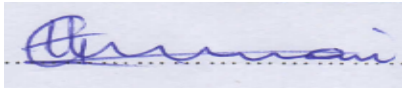
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DEDICATION

This work is dedicated in loving memory of my late father, Mr. Edward Kabba Kanu..

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LIST OF ABBREVIATIONS

ADA	-	American Diabetes Association
BMI	-	Body Mass Index
CBT	-	Cognitive Behavioral Therapy
CESD	-	Center for Epidemiologic Studies Depression Scale
DSM IV	-	Diagnostic and Statistical Manual IV edition
DOPC	-	Diabetes Out-Patients Clinic
OH	-	Oral Hypoglycaemic drugs
HADS	-	Hospital Anxiety and Depression Scale
HBA _{1C}	-	Glycated Haemoglobin
KNH	-	Kenyatta National Hospital
PHQ-9	-	Patient Health Questionnaire 9
PRIME MD	-	Primary Care Evaluation of Mental Disorders
MDD	-	Major Depressive Disorder
RCT	-	Randomized Clinical Trial
WHO	-	World Health Organization

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ABSTRACT

Background: Diabetes mellitus and depression are emerging health problems in developing countries including sub-Saharan Africa.

Depression is a serious co-morbid condition in diabetes patients that negatively affects self-management, drug adherence, treatment outcomes and quality of life.

Various studies have shown that depression is still largely unrecognized by health care providers managing patients with diabetes and even when recognized only one-third of patients with diabetes and depression are appropriately treated.

Objective: To determine the prevalence and severity of co-morbid depression in ambulatory type 2 diabetes patients at KNH and to document the socio-demographic and clinical characteristics of the study population with depression.

Methodology:

Study design: Cross-sectional descriptive study.

Study site: Outpatient diabetes clinics at KNH.

Subjects: Ambulatory type 2 diabetes patients on follow up at KNH.

A systematic sampling method was used to recruit 220 subjects from the diabetic clinic in KNH and the PHQ-9 was used to assess for depression. Socio-demographic and clinical details were obtained from patients and medical records. BMI and blood pressure were measured. Blood samples were collected to measure HBA_{1C} as a parameter for glycaemic control. Statistical associations of patients characteristics and co-morbid depression was analyzed using Chi-square test.

Results: The prevalence of comorbid depression in patients with type 2 diabetes at the DOPC in KNH using the PHQ-9 was 32.3%, of which 13.6% had mild depression, 13.2% had moderate depression and 5.5% had severe depression. Increasing age > 65years (p=0.006), longer duration of diabetes ≥ 5years (p=0.044) and over-weight/obesity (p=0.035) were significant associations with co-morbid depression.

A significant proportion of patients with comorbid depression had poor glycaemic control with $HBA_{1C} > 7\%$ (39.2%) compared to 16.4% with good control ($HBA_{1C} \leq 7\%$).

Conclusion About one-third (32.3%) of the study subjects with type 2 diabetes had comorbid depression and more than half (18.7%) had moderate to severe depression.

This study attempts to explore potential risk factors for comorbid depression in type -2 diabetes patients in KNH. Older age (>65 years, $p=0.006$), longer duration of diabetes (≥ 5 years, $p=0.044$) and over-weight/obesity ($\geq 25Kg/m^2$, $p=0.035$) were found to be associated with comorbid depression.

CHAPTER1: INTRODUCTION AND PROBLEM STATEMENT

Diabetes is a metabolic disorder characterized by hyperglycemia resulting from defects in insulin secretion, insulin utilization, or both¹.The vast majority of diabetes is type 2 diabetes comprising about 90% of cases ¹.

Diabetes is a chronic disease which affects virtually every organ in the human system. The global prevalence of diabetes is continuously rising and the World Health Organization (WHO) projected that 300 million people will suffer from diabetes by 2025 ².

The prevalence of diabetes in Sub-Saharan Africa is expected to triple by 2030, making it a cause for concern not only for health professionals but also policy makers as they initiate strategies to tackle it.³

Kenya, like other developing countries, is experiencing this emerging diabetes epidemic. It is estimated that the prevalence of diabetes in the country is about 3.3%. This figure is projected to rise to 4.5% by 2025 if this trend is not checked according to Kenya National Diabetes Strategy ⁴.

Depression is a chronic psychopathological state that involves a triad of symptoms with low or depressed mood, anhedonia, and low energy or fatigue. Other symptoms, such as sleep and psychomotor disturbances, feeling of guilt, low self- esteem, suicidal tendencies, as well as autonomic and gastrointestinal disturbances, are also present⁵.

The lifetime prevalence of depression is as high as 20% in the general population worldwide with a female to male ratio of about 5:2 ⁵. According to WHO, depression is ranked as the fourth global burden of disease, responsible for the greatest proportion of burden associated with non-fatal health outcomes and account for approximately 12% of total years lived with disability⁶. It is predicted to become second only to ischemic heart disease as a cause of morbidity worldwide⁷.

Associations between depression and diabetes were described by physicians since several hundred years ago⁸. Thomas Willis, an early English physician wrote during the mid-1600's that diabetes is caused by "sadness or long sorrow and other depressions"⁸.

Patients with type 2 diabetes have a rate of major depression 1.6-2 times higher than those in the general population affecting one in every 10 diabetic patients.⁹

Depression is common among patients with type 2 diabetes and it is associated with worse diabetes outcomes¹⁰. Compared with patients with diabetes alone, patients with depression and diabetes have shown poor diligence in maintaining dietary restrictions and exercise, poorer self-management and poor medication adherence¹¹. Thus they are more likely to suffer from uncontrolled hyperglycemia and complications, thereby resulting in increased health care use and costs, increased disability, lost productivity and higher mortality rates¹²⁻¹³.

While depression may contribute to poor diabetes-related outcomes, diabetes and its complications may also contribute to poor depression outcomes¹⁴.

Depression is still largely unrecognized by health care providers managing patients with diabetes mellitus. It is estimated that only one-third of patients of both diabetes and major depression are recognized and appropriately treated for both disorders¹⁵. Therefore recognition of depression becomes important as cost-effective treatment is available resulting in improvement of diabetic care as well¹⁶.

CHAPTER 2: LITERATURE REVIEW

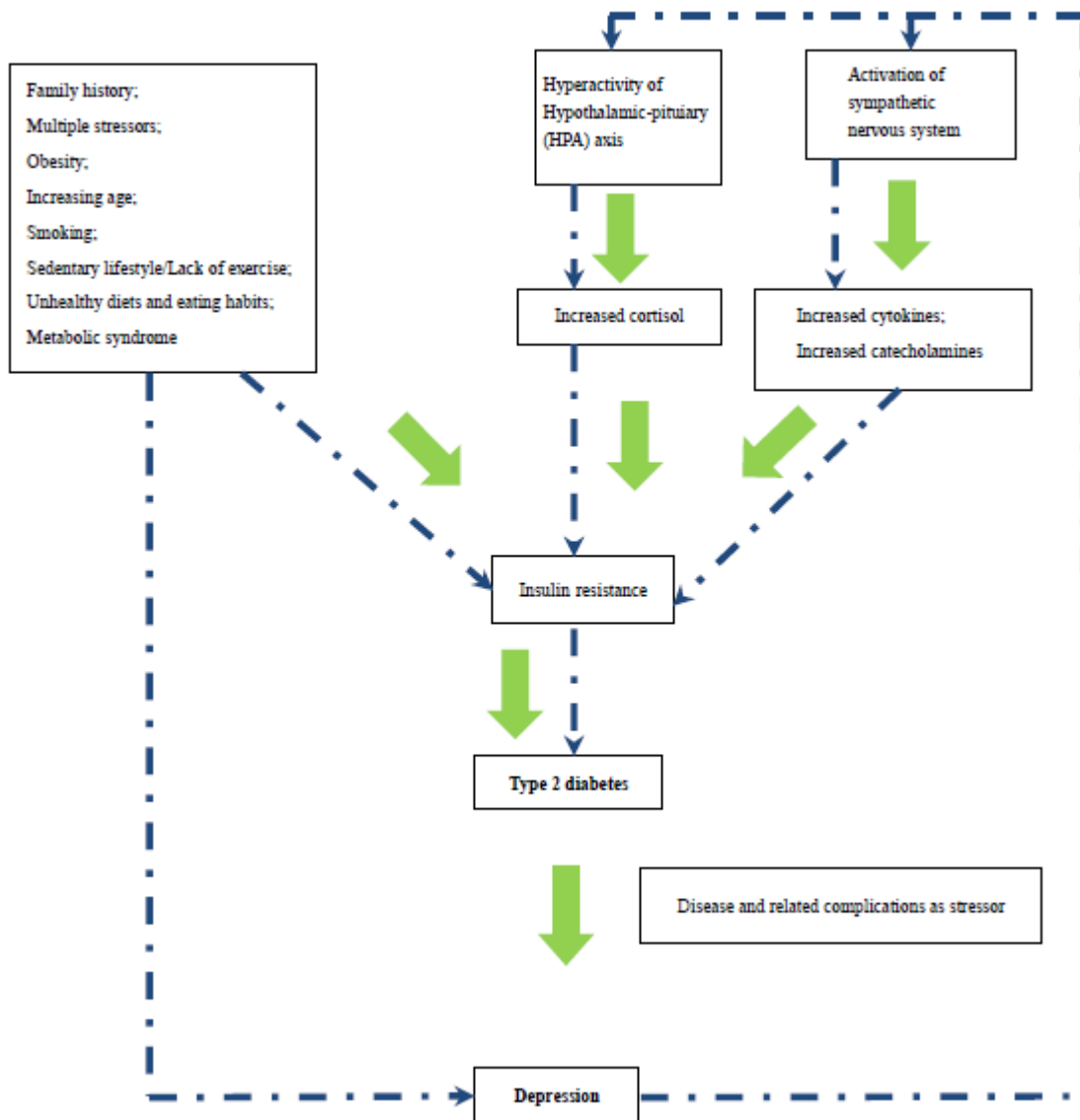
2.1 BACKGROUND

Pathophysiology of depression and diabetes

Diabetes and depression are two common problems seen in primary care settings and epidemiologic data indicate that diabetes and depression are intimately related. Depression is a risk factor for diabetes¹⁷ and depression risk is increased by a factor of two in patients with diabetes¹⁸. Depression is not only common in patients with diabetes but also contributes to poor adherence to medication and dietary regimens, poor glycaemic control, reduced quality of life , higher complication rates and increased health care expenditures¹⁹.

Two major hypotheses currently exist to explain the causal pathway between diabetes and depression²⁰. One hypothesis asserts that depression precedes type 2 diabetes although the exact mechanisms are not clear. However depression as a chronic psychological stress is associated with sub-clinical hyper-cortisolism, secondary to the activation of the hypothalamic – pituitary – adrenal axis²⁰⁻²¹. Sustained cortisol release induces visceral obesity, insulin resistance, dyslipidaemia and hypertension (metabolic precursors to type 2 diabetes). Cortisol also stimulates the sympathetic nervous system, increases inflammatory responses and decrease insulin sensitivity. This suggests that increased cortisol in diabetes is a risk factor for the presence of depression. The second hypothesis is that depression in patients with diabetes results from chronic psychosocial stressors of having a chronic medical condition²⁰⁻²¹.

Figure 1.0 Bidirectional relationship between depression and diabetes. It shows the pathophysiologic mechanisms and risk factors that are involve in both depression and type 2 diabetes



Musselman DL, Larsan H, Philips LS. Relationship of depression to diabetes type 1 and 2: Epidemiology, biology and treatment: Biol. Psychiat 2003; 54: 317-329²⁰

2.2 SCREENING INSTRUMENT FOR DEPRESSION (PATIENT HEALTH

QUESTIONNAIRE 9 (PHQ-9) -

The Patient- Health Questionnaire is a self-administered version of the Primary Care Evaluation of Mental disorders (PRIME-MD) \and has been validated in many studies. Because it is entirely self-administered and has a diagnostic validity compare to the clinician administered PRIME-MD, PHQ-9 is now the most commonly used version in both clinical and research settings²²⁻²³.

The PHQ-9 is a multipurpose instrument for screening, diagnosing and measuring the severity of depression. The PHQ-9 is based directly on the diagnostic criteria for major depressive disorder in the Diagnostic and Statistical Manual 4th edition (DSM 1V) and is used as a brief self-report tool which takes about 5-10 minutes to complete. The tool rates the frequency of the symptoms which factors into the scoring severity index²⁴

The PHQ-9 consists of nine items on a 4-point scale. It has been shown to have high sensitivity and specificity with regard to identifying cases of depression as well as being sensitive to change over time²⁵⁻²⁶.

As a tool to measure severity of depression, the PHQ-9 scores ranges from 0 to 27, because each of the 9 items can be scored from 0 (“not at all”) to 3 (“nearly every day”) Standard cut-off scores are used with the PHQ-9 to classify depression into Mild (10-14) , Moderately (15-19) and Severe (20-27)²⁵⁻²⁶.

The PHQ-9 can be used as a screening tool, with recommended cut-off scores of ≥ 10 being found to have 88% sensitivity and 88% specificity for a diagnosis of clinical depression or major depressive disorder MDD²⁷

A 10th item was added at the end of the PHQ-9 questionnaire asking patients to assess functional impairment related to their depressive symptoms²⁷.

The single added item is not used in calculating any PHQ score or diagnosis but rather represents the patient’s global impression of symptoms related impairment. It is an excellent

rating of functional impairment and has been shown to correlate strongly with a number quality of life, functional status and health care single model and can be useful in decision regarding initiation or adjustments to treatment²⁸A decline in the total PHQ-9 score of ≤ 5 points is necessary to qualify for a clinically significant response to treatment for depression.²⁸.

Table 1 shows the PHQ-9 severity scores and treatment actions for depression.

PHQ-9 Score	Depression severity/ Provisional Diagnosis	Treatment recommendations
0 - 4	None or Minimal symptoms	No action recommended
5 - 9	Mild symptoms	Watchful waiting, repeat PHQ-9 and follow up
≥ 10	* MAJOR DEPRESSION	
10 - 14	Major depression (mild)	Treatment plan, considering counselling, follow up and /or pharmacotherapy
15 - 19	Major depression (moderate)	Active treatment with pharmacotherapy and/or psychotherapy
20 - 27	Major depression (severe)	Immediate initiation of pharmacotherapy and psychotherapy and if poor response to therapy refer to a mental health specialist for further management and / or collaborative management

Kroenke K and Spitzer RL. The PHQ-9: A New Depression Diagnostic and Severity Measure
Psychiatric Annals 2002; 32:509-52²⁹

The PHQ-9 has been validated across different regions including Africa, America, Asia and Europe and can be used to screen for depression in patients with chronic disorders such as diabetes, cardiovascular diseases, malignancies and HIV³⁰⁻³¹.

In 2013, Galaye B et al did a study to validate the PHQ-9 for depression screening and diagnosis among 926 medical out-patients attending a major referral hospital in Ethiopia. They reported that the PHQ-9 has a good internal consistency (Cronbach's alpha) of 0.81 and test – retest reliability of 0.92. The results concluded that the PHQ-9 is a reliable and valid tool for the diagnosis of depression in medical out-patients³².

Van Steenberger et al in 2010 did a study to validate PHQ-9 as a screening tool for depression among 197 diabetes out-patients attending specialized clinics in Netherlands. They reported that the PHQ-9 has a good internal consistency of 0.757 and a test re-tests reliability of 0.80. They concluded that the PHQ-9 is an efficient instrument for screening for depression among diabetes patients.³³

In 2006, Omoro SA et al did a study to validate and translate the PHQ-9 into Swahili version. A total of 48 patients with Head and neck cancer attending the ENT clinic in KNH were involved. They reported that the Swahili PHQ-9 version had a good internal consistency of 0.80 and a test- retests reliability of 0.71³⁴.

Monahan PO et al in 2009 did a study to validate PHQ-9 among 347 patients with HIV in Western Kenya.. They reported that the PHQ-9 has an internal consistency of 0.78 and a test -r-test reliability of 0.59. It was concluded that PHQ-9 appears valid for assessing DSM-IV depressive disorders³⁵.

Adewuya et al in 2006 did a study to validate the PHQ-9 among university students as a screening tool for depression. They reported that the PHQ-9 has a good internal consistency of 0.85 and a test- retest reliability of 0.894³⁶.

2.3 . PREVALENCE AND SEVERITY OF DEPRESSION AMONG TYPE 2

DIABETES PATIENTS

Depression is twice as likely to occur in individuals with diabetes mellitus compare with apparent healthy controls ⁴⁹. Prevalence rates varies from 11% to 60%, depending on study setting (clinical versus community), assessment tool (self-report questionnaire versus clinical interview) and design (uncontrolled versus controlled). Female gender, low socio-economic status and the presence of other physical illnesses are associated with an increased likelihood of depression³⁷⁻³⁸.

In a cross-sectional study done in Ethiopia by Teklay et al in 2011 to determine the prevalence of depression among type 2 diabetes out-patients at the Jimma University Specialized Hospital (JUSH) , a total of 267 patients \geq 18yrs and on follow up for the last 3 months were recruited and the results shows that the prevalence of depression using the PHQ-9 scale was 33%³⁹..

In 2011, Tapash et al conducted a three month cross-sectional study to determine the prevalence of co-morbid depression in ambulatory type -2 diabetes patients from three major diabetes clinics in Bangladesh using the PHQ-9. 417 patients who have been diagnosed with type 2 diabetes for at least \geq 1yr were involved and the results shows that the prevalence was 34% with 17.5% having mild depression and 16.5% having moderate to severe depression⁴⁰.

Amitt Ravel et al in 2009, did a cross-sectional study to determine the prevalence of depression among type 2 diabetes patients attending the diabetic clinic at a tertiary care center in India. 300 participants with established type 2 diabetes were involved and the PHQ-9 was used to assess depression and the results shows that the prevalence of depression was 41% with 18% having mild to moderate depression and 23% having severe depression ⁴¹.

Table 2 below shows the prevalence of depression from different studies using PHQ-9.

STUDY	TOOL	SAMPLE SIZE	PREVALENCE OF DEPRESSION	SEVERITY OF DEPRESSION
Teklay et al 2011	PHQ-9	267	33%	-
Tapash et al, 2011, Bangladesh	PHQ-9	417	34%	17.5% mild & 16.5% moderate to severe depression
Amitt Ravel et al, 2009, India	PHQ-9	300	41%	18% mild to moderate & 23% severe depression

2.4 FACTORS ASSOCIATED WITH DEPRESSION IN DIABETES PATIENTS

(a) Socio-demographic and clinical characteristics.

Studies have shown that patients suffering from diabetes mellitus are also at a higher risk of developing depression [54]. The long term stress of having diabetes can lead to an increased likelihood of depression ⁴².

Research on predictors of depression in diabetes has shown that socio-demographic characteristics such as younger age, female sex, less education and unemployment are associated with increased likelihood of depression in diabetes.⁴³⁻⁴⁵

In 2004, Katon W et al did a population based survey on factors associated with depression among 4,385 diabetes attending different out-patients clinics in Washington USA. PHQ-9 was

used to screen for depression. They reported that younger age, female sex, less education, longer duration of diabetes and $BMI > 30\text{Kg/m}^2$ were associated with depression ($p < 0.001$).⁴⁶

In 2010, Nitin et al conducted a cross-sectional study on the determinants of depression in type 2 diabetes patients in various tertiary care hospitals in Mangalore city, South India. A total of 230 participants with established type 2 diabetes were recruited in a consecutive sampling method and PHQ-9 was used to screen for depression. In this study, they reported that depression was associated with increased age ($p = 0.006$), female gender ($p = 0.019$), low socio-economic status ($p = 0.0003$), insulin injection therapy ($p = 0.001$) and obesity ($p < 0.001$)⁴⁷.

In a cross-sectional study on clinical depression in type 2 diabetes done by Mary De Groot et al in 2007, a total of 201 patients were consecutively recruited from different endocrine clinics in Appalachia (rural counties of Ohio and Virginia in USA with low socio-economic and huge burden of diabetes compared to other counties). They reported that younger age, unemployment and lack of home ownership significantly predicted depression status ($p < 0.05$)⁴⁸

In a Nigerian cross-sectional descriptive study in 2006 done by TM Agbir et al on depression among type 2 diabetes attending the medical outpatient clinic at Jos University Teaching Hospital JUTH. A total of 160 patients were recruited through consecutive sampling. They reported that depression was strongly correlated with gender ($p = 0.001$) with a female to male ratio of 3:1, as well as significant association with marital status ($p = 0.002$). However depression was not found to be correlated to employment status ($p = 0.84$), educational status ($p = 0.268$) or age ($p = 0.216$)⁴⁹

In a multi-center cross-sectional study done by Ali Khan et al in 2010 in Karachi, Pakistan, to determine associated factors of depression in type 2 diabetes from different clinics. a total of 889 patients were recruited into the study. They reported that there was an association between depression and female gender ($p < 0.001$), older age ($p < 0.001$), longer duration of diabetes ($p = 0.030$), and having hypertension ($p < 0.001$).⁵⁰

(b) Depression and diabetes complications

Earlier studies have examined the association of depression with diabetic complications and there is evidence to suggest that the long-term complications of diabetes are associated with depressive symptoms⁵¹

A meta-analysis of 27 studies conducted by de Groot et al to determine whether an association existed between depression and diabetes complications reported that depression was associated with retinopathy, neuropathy, nephropathy and macro-vascular disease⁵²

Van Steenbergen et al did a cross-sectional study on co-morbid depression in patients with type 2 diabetes with multiple complications in a specialized diabetic clinic in Amsterdam, Netherlands. 596 patients were screened for depression using PHQ-9. Additional data on the type of diabetic complications was taken from the patient's medical records. Prevalence of depression was 26% and the presence of two or more complications was significantly associated with depression (OR=2.23, 95% CI= 1.02-2.94)⁵³.

(c) Depression and glycaemic control.

There is substantial evidence that co-morbid depression among individuals with diabetes is associated with poor diabetes outcomes such as glycaemic control. Lustman et al completed a meta-analysis of 24 studies and found that depression was significantly associated with poor glycaemic control in individuals with diabetes⁵⁴.

Richardson et al, went a step further and assessed the longitudinal effects of depression on glycaemic control⁵⁵. They found that over 4 years of follow-up there was a significant longitudinal relationship between depression and glycaemic control and that depression was associated with persistently higher HbA1c levels over the time period⁵⁵.

In 2002 Grass R et al did a cross-sectional survey to determine association between depression and glycaemic control among Hispanics with type 2 diabetes. A total of 209 patients from Columbia University Teaching Hospital, USA were recruited. PHQ-9 was used to screen for depression and HbA_{1c} results was extracted from patients hospital records. They reported that there was an association between severity of depression and poor glycaemic control (p=0.01)⁵⁶.

Bot M et al in 2012 did a study on the association between depression and glycaemic control from a multi-center depression screening research among type diabetes out-patients . The PHQ-9 was used to screen for depression and a total of 646 patients from three tertiary diabetes clinics in the Netherlands were involved. HBA_{1C} values were extracted from patients medical records. They reported that depression was significantly associated with poor glycaemic control (p=0.001) ⁵⁷.

In Brazilian a cross-sectional study done in Rio de Janeiro by Marcello et al in 2011 in which seventy patients with type 2 DM age 30- 65years were consecutively recruited into the study . They reported a prevalence of 18.6% for depression using the Beck Depression Inventory tool BDI- II . The study also shows that patients who had clinical depression had a poorer glycaemic control with a mean HBA_{1C} of 8.6 compare to 7.5 in those without depression⁵⁸.

2.5. TREATMENT OF DEPRESSION IN DIABETES

Depression has a strong impact not only on medical outcomes in diabetes but also on psychological and social outcomes. Generic quality of life is considerably reduced with respect to psychological, physical and social functioning (e.g. the ability to work) ⁵⁹. Furthermore, it was demonstrated that patients with depression and diabetes were physically less active, were more likely to smoke tobacco, had less healthy eating habits and adhered less to diabetes treatment ⁶⁰⁻⁶¹

Unfortunately, depression in diabetes is considerably underdiagnosed and undertreated. As an example, results of a US study that included more than 9000 patients with diabetes revealed a recognition rate for major depression of 51%, whereas 43% of the patients received one or more antidepressant prescriptions and only 6.7% had received four or more psychotherapy sessions over a 12-month period ⁶².

Considering the significant evidence base that depression has an adverse effect on both psychological wellbeing and diabetes outcomes, treatment of depression in diabetes should be directed toward improving both psychological and medical outcomes. Improvement in depressive symptoms or remission is the major objective regarding the mental aspects. The physical treatment targets include an improvement in glycemic control and a reduction in risk for short-term and long-term complications and premature mortality ⁶²

Concerning the interventions strategies for treating depression in patients with diabetes, they fall into three broad categories:

- (a) Diabetes self-care management education
- (b) Psychotherapy
- (c) Pharmacotherapy

These strategies are not mutually exclusive and this leads to a more recent approach called Collaborative care (combination of diabetes self-care education, psychotherapy and/or pharmacotherapy)⁶³.

(a). Diabetes self-care management education

According to a meta-analysis of 43 studies by Gonzalez et al, depression was significantly associated with poor self-care practices (diet, medication adherence, exercise, blood sugar monitoring and medical out-patients attendance)⁶⁴.

Diabetes programs that focus on behavior have been successful in helping patients improve their metabolic control, manage weight loss and other cardiovascular risk factors. They also improve patients sense of well-being and quality of life⁶⁵.

(b) . Psychotherapy/Psycho-social intervention

The psychotherapy intervention that has received the most attention is Cognitive Behavioral Therapy CBT, a short term skills based interventions designed to change negative thinking and increase positive behavior such as problem solving and relaxation ⁶⁵. This approach has reported improvements in depressive symptoms as well an better diabetes management⁶⁶.

(c) . Pharmacotherapy

Among pharmacological interventions, the Selective Serotonin Re-uptake Inhibitors SSRIs Including Fluoxetine, Paroxetine, Sertraline and Nortriptyline are the most commonly prescribed anti-depressants because of their safety profile and efficacy ⁶⁷⁻⁶⁸. They have been recommended in depressed patients with diabetes, because they may reduce blood sugar and cause moderate weight loss in addition to their anti-depressant properties⁶⁹.

Van der Feltz- Cornellis et al conducted a meta-analysis of 14 RCTs to evaluate the efficiency of various interventions in the treatments of depression in diabetes mellitus (6 studies of pharmacotherapy, 5 studies on psychotherapy and 3 studies on psychotherapy combined with diabetes self-care education interventions). They reported a large size effect (-0.56) on depressive symptoms improvements for psychotherapeutic interventions combined with diabetes self- management interventions and a moderate effect size (-0.467) for pharmacological interventions ⁷⁰. With regards to glycaemic control, psychotherapeutic interventions often accompanied by self-care educational interventions yielded moderate to large size effect . On the contrary pharmacotherapy except for Sertraline had no significant influence on glycaemic control. Van der Feltz-Cornellis et al concluded that psychotherapy combined with diabetes self-care educational interventions emerges as the 1st line treatment for depression in diabetes based on the large effect size on both depression and glycaemic control⁷⁰.

2.6 JUSTIFICATION (RATIONALE OF THE STUDY)

Depression is a serious co-morbid condition in diabetes patients that negatively affects self-management, drug adherence, treatment outcomes and quality of life.

Depression has been noted to be a modifiable risk factor whose treatment could improve health outcomes in patients with diabetes.

Various studies have shown that depression is still largely unrecognized by health care providers managing patients with diabetes and even when recognized only one-third of patients with diabetes and depression are appropriately treated.

There is no published data on prevalence and severity of depression in ambulatory type 2 diabetes in Kenya. This study was to determine the prevalence and severity of depression among type 2 diabetes in KNH and results obtained from our study was used to inform the administration about the burden of depression in these patients.

2.7 RESEARCH QUESTION

What is the burden of depression among ambulatory type 2 diabetes patients at KNH?

2.8 OBJECTIVES

(a) BROAD OBJECTIVE

To determine the prevalence and severity of co-morbid depression in ambulatory type 2 diabetes patients at KNH and to document the socio-demographic and clinical characteristics of the study population with depression.

(b) SPECIFIC OBJECTIVES

1. To determine the prevalence of depression among type-2 diabetes out-patients at KNH.
2. To describe the severity of depression among type 2 diabetes out-patients at KNH.
3. To document the socio-demographic and clinical characteristics (age, sex, employment, education, duration of diabetes, type of diabetes treatment. blood pressure and BMI) of study patients with co-morbid depression.

(c) SECONDARY OBJECTIVE

1. To determine the association between depression and quality of diabetes control in type 2 ambulatory patients at KNH.

CHAPTER 3: METHODOLOGY

3.1 STUDY SITE

This study was conducted at the Diabetes Out-Patient Clinic at the Kenyatta National Hospital; one of only two tertiary referral facilities in the public sector in Kenya. The diabetes clinic is one of the largest out-patients clinics in KNH with an estimated 6,000 registered patients according to the records department in KNH. There is a mini clinic that opens from Monday to Thursday with an average of 30-40 patients per day and a major diabetic clinic on Friday with an average of 80-100 patients per clinic day. The clinics are usually run by Residents and Consultants Endocrinologists.

3.2 STUDY DESIGN

The study was a descriptive cross-sectional study on the prevalence and severity of depression among type 2 diabetes out-patients at KNH.

3.3 STUDY POPULATION

Study population consisted of patients' age ≥ 30 years with a diagnosis of type 2 diabetes for ≥ 1 year and was on follow up at the diabetes clinic.

3.4 CASE DEFINITIONS

Type 2 diabetes- Patients ≥ 30 years and previously diagnosed with type 2 diabetes and were on oral hypoglycaemic drugs (OHD) and/or insulin.

Depression – A patient with a PHQ-9 score of ≥ 10 is described as clinical depression.

3.5 INCLUSION CRITERIA

1. Patients age ≥ 30 years with a documented diagnosis of type 2 diabetes of ≥ 1 year attending the diabetes clinic and gave informed consent.
2. Participants should be able to speak and understand Kiswahili and/or English

3.6 EXCLUSION CRITERIA

1. Patients on follow up for psychiatric illness other than depression.

2. Patients with diagnosis of dementia.

3. Patients who do not give informed consent.

3.7 SAMPLE SIZE

Using the Cochran formula, with 95% confidence interval

$$N = \frac{Z^2 \times Pq}{d^2}$$

Where P = Prevalence taken from a similar study done in Ethiopia where they reported a prevalence rate of 33%

Z = Confidence interval at 95% (standard value at 1.96)

$$q = 1 - P$$

d = precision

$$\text{Precision } d = 6.5\% = 0.065$$

$$q = 1 - p = 1 - 0.33$$

$$= 0.67$$

$$N = \frac{1.96^2 \times 0.33 \times 0.67}{(0.065)^2}$$

$$= 201 + 10\% \text{ sampling effect}$$

$$= 220$$

The sample size for this study was 220

3.8 SAMPLING METHOD

A systematic sampling method was used to recruit subjects where in every 2nd patient on the minor clinic day and every 4th on the major clinic day that met the inclusion criteria was selected.

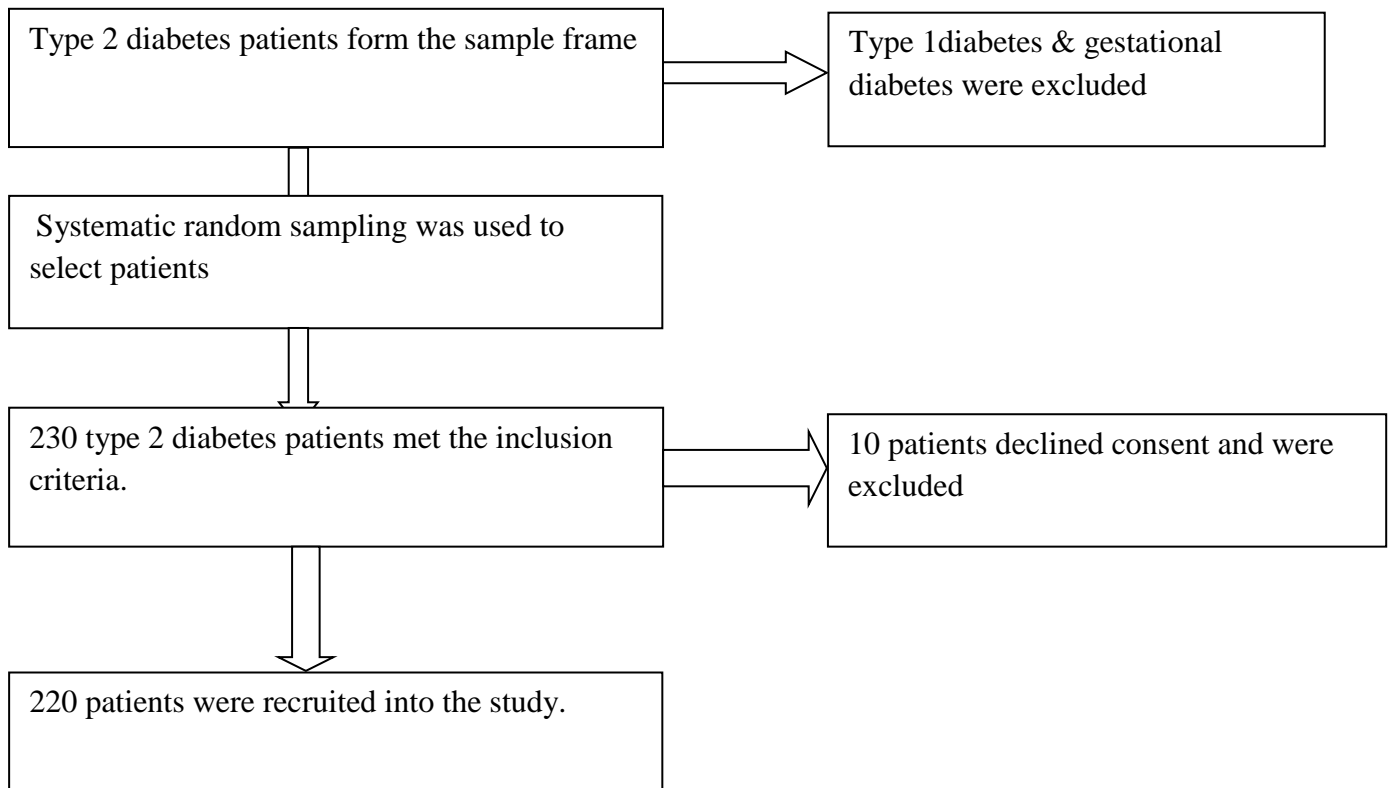
3.9 STUDY INSTRUMENTS

The following instruments were used:

1. A standard questionnaire was used to collect socio-demographic and clinical data such as age, sex, marital status, educational status, employment status, duration of diabetes, type of diabetes treatments, blood pressure and body mass index.
2. Patient Health Questionnaire 9 PHQ-9
3. A manual sphygmomanometer to measure blood pressure, a standard digital weighing scale to measure weight, a set square and tape to measure height

3.10 PROCEDURE / DATA COLLECTION

Figure 2 showing a flow chart of subject recruitment into the study



The list of patients registered for a clinic day formed the sampling frame for drawing a study sample. A systematic random sampling procedure was used to enroll subjects in the study and based on this every 2nd patient was selected into the study from the Monday to Thursday mini clinic while every 4th patient from the Friday major clinic. A total of 230 patients were eligible for the study but 10 declined from taking part in the study. 220 type - 2 diabetes were recruited in the study. Those who meet the inclusion criteria were explained to the study terms and procedures and informed consent obtain.

A standard questionnaire was used to collect socio-demographic and clinical details given by patients and this information were also verified from patients medical files.

The PHQ 9 was given to subjects to complete (either English or Kiswahili Version). For subjects who had challenges in completing the questionnaire, they were assisted by the principal investigator or research assistants (trained and licensed clinical officers) and statements from the PHQ-9 was read to them.

After completion of the PHQ-9 and socio-demographic details taken, blood pressure, weight, height and BMI was be recorded.

Blood pressure was measured using a manual sphygmomanometer and the patient was requested to remove any tight fitting clothes on the arm and rest it on a comfortable position at the level of the heart and results recorded to the nearest 2mmhg

Anthropometry measurements such as weight and height were measured. Weight was recorded from a standing digital weighing scale to the nearest 0.1Kg. Height measurement was done by asking the patient to stand without shoes with their back against the wall tape, eyes looking straight ahead with a set square resting on top of the scalp and against the wall. Values were recorded to the nearest 0.5m.

A 2ml venous blood sample was collected into an EDTA bottle for each subject by the principal investigator or research assistants. These bottles were assigned a code that matches with respective patients codes. Samples were then conveyed to lancet laboratory by a courier and they were stored at a temperature of 2 to 8 °C. Analysis of blood samples was done after 4 weeks interval. The anti-coagulated whole blood specimen was haemolyzed automatically on COBAS

INTEGRA system with HBA_{1C} reagent in the pre-dilution cuvette. Total Hb and HBA_{1C} concentrations were determined after haemolysis of the blood sample. The ratio of both concentrations yielded the final percent HBA_{1C} results [HBA_{1C} %].

3.11 DEFINITION OF STUDY VARIABLES

(i) Depression – A patient with a PHQ-9 score of ≥ 10 is described as clinical depression.

(ii) Severity of depression-

Clinical depression was categorized into Mild (10-14), Moderate (15-19) and Severe (20-27).

(iii) Body mass index BMI: This was calculated and express in Kg/m² and classified as: Underweight (<19 kg/m²), Normal (20-24.9 kg/m²), Pre-obese/overweight (25-29.9kg/m²) and obese (≥ 30 kg/m²) (The International Obesity Task Force of WHO 2000)⁷¹.

(iv) Blood pressure: A subject was considered hypertensive if he/she is a known hypertensive on blood pressure lowering drugs. For subjects with no prior history of hypertension, a blood pressure $\geq 140/90$ mmhg was considered hypertensive. (JNC 8 Guildlines 2014)⁷²

(v) Diabetes control – This is assessed by measuring HBA_{1c}. HBA_{1c} $\leq 7\%$ is good control and HBA_{1c} $> 7\%$ is poor control.(ADA 2015 Recommendations)⁷³

3.12 QUALITY ASSURANCE

The PHQ-9 is a validated tool for the screening, diagnosis and assessing the severity of depression and it has been validated in diabetes patients. It has also been validated in Kenya among different patient groups.

Trained research assistants in the administration of the PHQ-9 and sample collection help to minimize error.

The recommended procedure for specimen collection, paper labeling and storage was followed strictly.

Samples for HBA_{1C} were put in a cool box which was conveyed by a courier to Lancet Laboratories for analysis. Lancet Laboratories has both internal and external checks for quality assurance.

3.13 DATA MANAGEMENT AND ANALYSIS

All data from study proforma and laboratory test (HBA_{1c}) results was coded, entered and managed in Microsoft access data base Data cleaning was conducted at the end of data entry and any errors resolved using the questionnaires. Data analysis was performed in SPSS version 21.0 software.

Study population was described using socio-demographic and clinical characteristics. Continuous variables such as age were summarized as mean and standard deviation while categorical variables such as gender, occupation, marital status and level of education were presented as proportions.

Prevalence of co-morbid depression was calculated and presented as a percentage with 95% confidence interval. In addition, severity of depression was presented using percentages. Factors associated with depression were analyzed using Chi square tests. The statistical test was tested at 5% level of significance (p value less or equal to 0.05 was interpreted as significant).

Presentation of the findings was done using tables and figures where appropriate.

3.14 ETHICS

Permission and approval was obtained from the Department of Clinical Medicine and Therapeutics of the University of Nairobi and Kenyatta Research and Ethics Committee before data collection.

Purpose of the study was explained to all subjects and informed written informed consent was obtained.

Subjects were assured that blood specimen collection would be done by aseptic technique and involves minimal risk. Patients were free to withdraw from the study at any point without discrimination.

Patient's confidentiality was maintained and questionnaires were assigned codes.

Blood samples were used only for the purpose of this study and were discarded after the study.

Blood pressure, BMI and HBA_{1c} results were communicated to patients as well as their primary physicians for clinical decision making.

Patients who were found to have comorbid depression were referred to the department of mental health for appropriate psychiatrist review.

CHAPTER 4: RESULTS

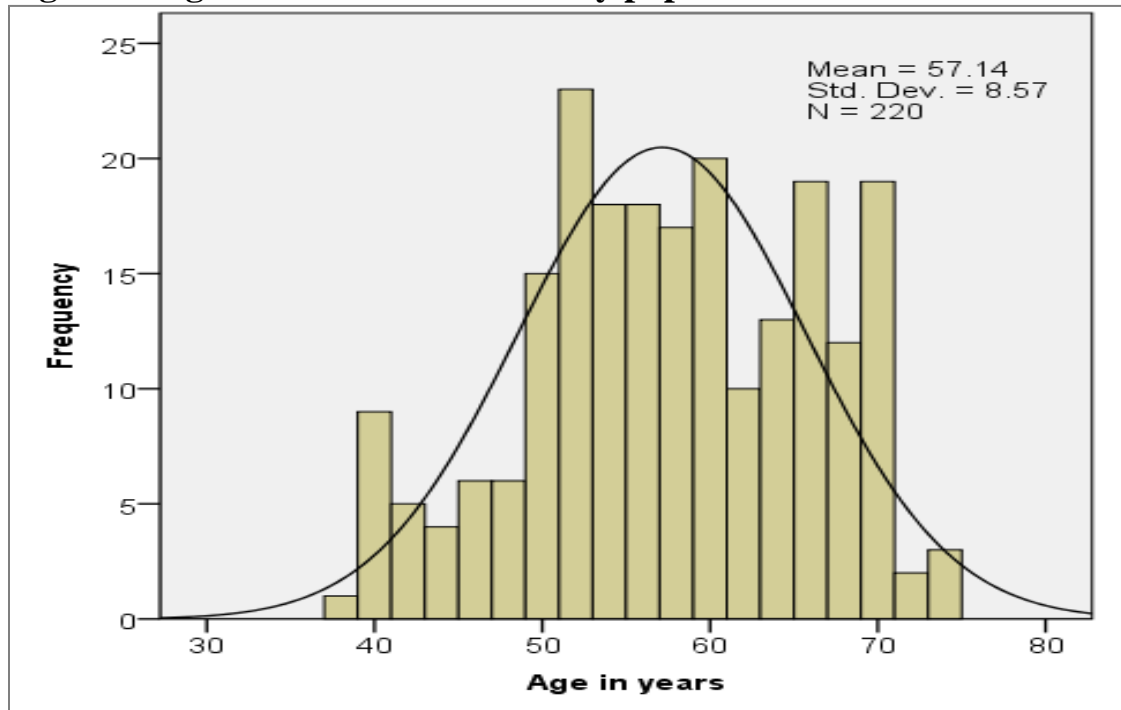
4.1 SAMPLE POPULATION CHARACTERISTICS

A total of 220 type 2 diabetes out-patients were recruited in this study and most of the study participants were aged 45 to 64 years with a mean age of 57.1 ± 8.6 years. As shown in Table 3, majority were females 59.5% (n=131). 85.5% were married with the remainder classified as single, separated or widowed. More than two-thirds of the study participants had some formal education, primary level (39.1%, n=86), secondary level (n=84, 38.2%) and tertiary level (n=30,13.65) while 64.5% (n=142)of the study subjects were un- employed.

Table 3: Socio-demographic characteristics of the study subjects

Variable	Categories	Frequency	Percentage (%)
Age (yrs)	35-44	19	8.6
	45-54	68	30.9
	55-64	78	35.5
	>=65	55	25.0
Gender	Male	89	40.5
	Female	131	59.5
Marital Status	Single	18	8.2
	Married	188	85.5
	Separated/Divorced	4	1.8
	Widowed	10	4.5
Formal employment status	Employed	78	35.5
	Unemployed	142	64.5
Level of Education	None	20	9.1
	Primary	86	39.1
	Secondary	84	38.2
	Tertiary	30	13.6

Figure 3. Age distribution of the study population



4.2 CLINICAL CHARACTERISTICS OF THE STUDY POPULATION

55.5% (n=121) of the study participants had been diagnosed with diabetes for ≥ 5 years. 53.6% (n=118) were on OH drugs alone while 36.4% were on combined treatment of OH drugs and insulin. 61.3% n=135) of study subjects had BMI ≥ 25 Kg/m² with 36.8% been over-weight and 24.5% been obese.

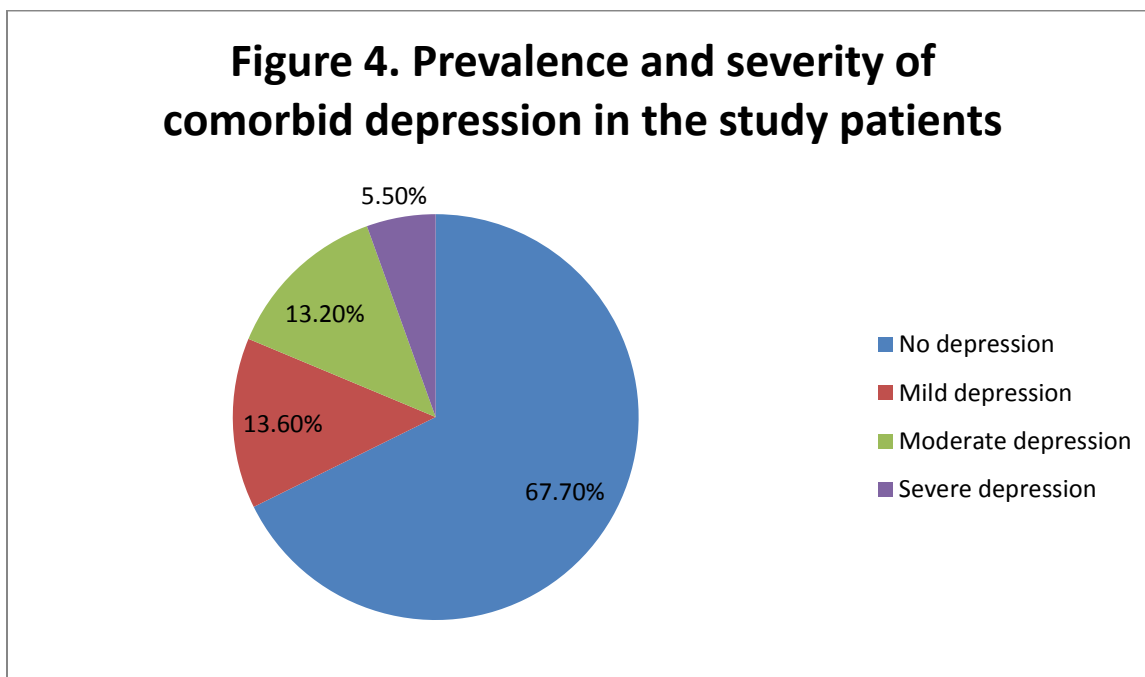
Table 4: Clinical characteristics of the study subjects

Variable	Categories	Frequency	Percentage (%)
Duration of Diabetes (yrs)	<5	99	45.0
	5-10	63	28.6
	>10	58	26.4
Diabetes treatment	OH drugs alone (n=118)		
	Metformin	60	27.3
	Glibenclamide	2	0.9
	Metformin + other OH	56	25.5
	Insulin alone	22	10.0
	OH drugs + Insulin	80	36.4
BMI (Kg/m²)	Under weight	4	1.8
	Normal	80	36.4
	Over-weight	81	36.8
	Obese	54	24.5
Hypertension	Yes	157	71.4
	No	63	28.6

4.3 PREVALENCE AND SEVERITY OF DEPRESSION

About a third, (32.3%) of the study population had clinical depression with a PHQ-9 score of ≥ 10 . Among the type -2 diabetes subjects with co-morbid depression 13.6% had mild depression (PHQ-9 score of 10 -14) while 13.2% had moderate depression (PHQ-9 score of 15-19) and 5.5%% had severe depression (PHQ-9 score of 20-27).

The mean age of the population with comorbid depression is 59.1 ± 8.5 yrs.



4.4 FACTORS ASSOCIATED WITH COMORBID DEPRESSION

As shown in table 5 below, 45.5% of the patients age > 65years have comorbid depression while only 15.8% of younger patients age 35-44 years have depression.

Male patient had a higher proportion of depression 38.2% compare to 28.5% in females.

38.3% of subjects without formal employment had depression while 27.8% of those with formal employment had depression.

There is a similarity in the proportion of depression among study subjects with primary (33.7%) and secondary (34.5%) level of education.

Married subjects had a relatively lower proportion of depression (31.9%) compare to unmarried subjects (34.4%).

Subjects on combination therapy of insulin plus OH drugs (37.9%) have a higher proportion of depression compare to those on OH alone (27.5%) or insulin alone (33.3%).

38.0% of study patients with longer duration of diabetes \geq 5years had depression while 25.3% of those with diabetes < 5years had depression.

Study participants with hypertension had higher proportion of depression (34.4%) compare to those without hypertension (27.0%)

Study subjects who are overweight/obese (37.8%) had higher proportion of depression compare to those with normal weight (23.8%).

A significant proportion of patients with comorbid depression had poor glycaemic control with $HBA_{1C} > 7\%$ (39.2%) compare to 16.4% have $HBA_{1C} \leq 7\%$.

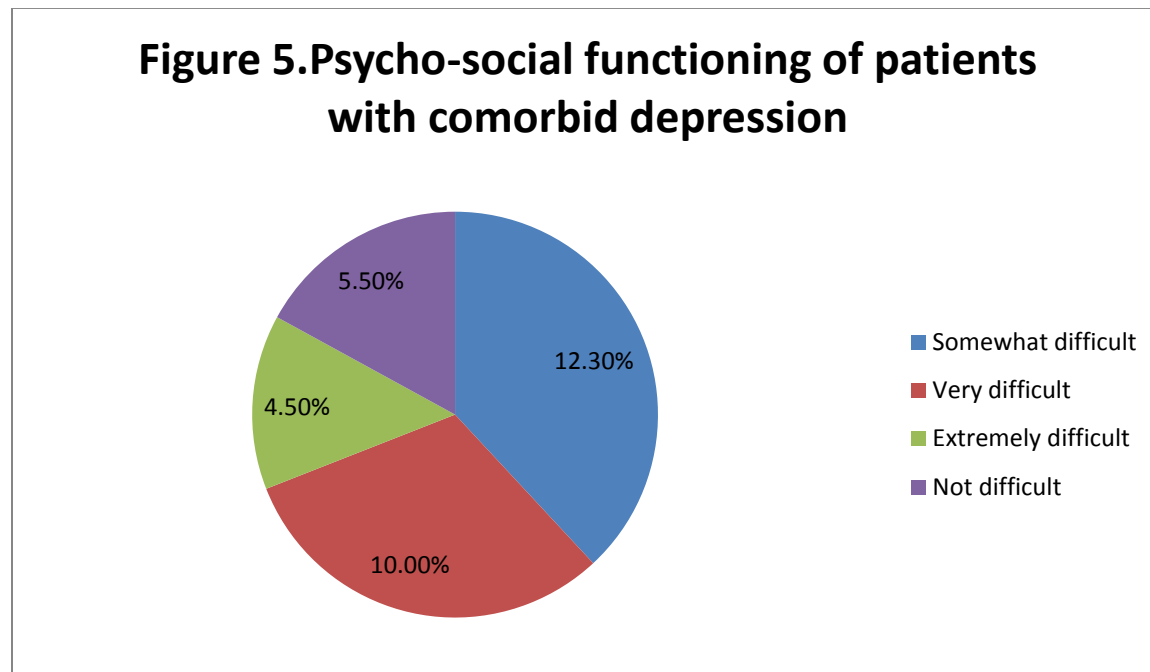
Table 5: Factors associated with depression in diabetic patients

Variable	Co-morbid Depression	No co-morbid depression	OR (95% CI)	P value
Age (yrs)				
35-44	3 (15.8%)	16 (84.2)	1.0	
45-54	21 (30.9%)	47 (69.1)	2.4 (0.6-9.0)	0.203
55-64	22 (28.2%)	56 (71.8)	2.0 (0.6-7.9)	0.210
≥65	25 (45.5%)	30 (54.5)	4.4 (1.2-17.0)	0.029
Gender				
Male	34 (38.2%)	57 (61.8%)	1.6 (0.9-2.8)	0.130
Female	37 (28.5%)	94 (71.5%)	1.0	
Employment				
Employed	35 (27.8%)	91 (72.2%)	1.0	
Not employed	36 (38.3%)	58 (61.7%)	0.6 (0.4-1.1)	0.110
Education				
None	6 (30.0%)	14 (70.0%)	1.4 (0.4-5.0)	0.599
Primary	29 (33.7%)	57 (66.3%)	1.7 (0.6-4.4)	0.293
Secondary	29 (34.5%)	55 (65.5%)	1.7 (0.7-4.5)	0.261
Tertiary	7 (23.3%)	23 (76.7%)	1.0	
Marital status				
Married	60 (31.9%)	128 (68.1%)	1.0	
Not married	11 (34.4%)	21 (65.6%)	1.1 (0.5-2.5)	0.783
Diabetes treatment				
OH drugs alone	30 (27.5%)	79 (72.5%)	0.6 (0.4-1.1)	0.135
OH drugs + Insulin	32 (37.9%)	48 (62.1%)	1.5 (0.9-2.7)	0.147
Insulin alone	8 (33.3%)	14 (66.7%)	1.1 (0.4-2.6)	0.906
Hypertension				
Yes	54 (34.4%)	103 (65.6%)	1.4 (0.7-2.7)	0.288
No	17 (27.0%)	46 (73.0%)	1.0	
Duration of diabetes (yrs)				
<5	25 (25.3%)	74 (74.7%)	1.0	
≥5	46 (38.0%)	75 (62.0%)	1.8 (1.0-3.3)	0.044
BMI (Kg/m²)				
Under weight	0 (0.0%)	4 (100.0%)	-	0.999
Normal	19 (23.8%)	61 (76.3%)	1.0	
Overweight/Obese	51 (37.8%)	84 (62.2%)	1.9 (1.0-3.6)	0.035
Glycemic control				
Good HBA _{1C} ≤ 7%	11 (16.4%)	56 (83.6%)	1.0	
Poor HBA _{1C} > 7%	60 (39.2%)	93 (60.8%)	3.3 (1.6-6.8)	0.001

4.5 PSYCHO-SOCIAL FUNCTIONAL STATUS OF THE POPULATION WITH DEPRESSION.

A 10th item in the PHQ-9 assesses psycho-social functioning of patients with depression. Although this item is not part of the scoring for depression yet it is useful in assessing patients functional impairment related to depressive symptoms.

As shown in figure 5 below more than two-thirds (26.8%) of the subjects with comorbid depression (32.3%) had some form of difficulties with psycho-social functioning.



CHAPTER 5: DISCUSSION

The purpose of this study was to determine the prevalence of comorbid depression in type 2 diabetes outpatients at KNH using the PHQ-9.

This study revealed that the prevalence of comorbid depression in type 2-diabetes out-patients in KNH using the PHQ-9 was 32.3%. More than half (18.7%) had moderate to severe depression and this is significant because this group of patients require immediate psychiatry referral with active imitiation of treatments (pharmacotherapy and/or psychotherapy).

This prevalence of comorbid depression is lower than that reported in a cross-sectional study by Ndeti DM et al in 2005 including 2,770 general medical out-patients across 10 different health facilities in Kenya and they reported that 42.3% of the study patients had clinical depression using BDI⁷⁴. The cohort of patients in Ndeti's study had various diagnosis including cancer, respiratory diseases, cardiovascular diseases, diabetes, HIV etc. and more than half of the patients suffering from cancer (59.6%) and HIV/AIDS (52.2%) had depression. These variations in study subjects as well as study design probably explain the difference in prevalence rate of depression from our study.

The overall prevalence of comorbid depression in our study was similar to other studies done in Africa among type 2 diabetes out-patients, including Tekley et al in Ethiopia (Prevalence rate of 33%, using PHQ-9, Cross-sectional, hospital based study, 2011)³⁹, Camara A et al in Guinea (Prevalence rate of 34.4%, using HADS, Cross-sectional, hospital based study,2014)⁷⁵ as well as James BO et al in Nigeria, (Prevalence rate of 30% using BDI, Cross-sectional hospital based study,2010)⁷⁶. This similarity in the prevalence rates of comorbid depression in type 2 diabetes may be due to shared psycho-social stressors among Africans throughout the continent. Also Sub-Saharan Africa share health system challenges which may help explain part of this similarity in prevalence.

However the prevalence of depression in our study was lower than that reported in a study by Amit R et al in India⁴¹ (Prevalence rate 41%,using PHQ-9, Cross-sectional hospital based study,2009) but relatively higher than that reported in Western studies on type -2 diabetes including Ali S et al in UK⁷⁷ (Prevalence = 9.3%,using CESD, Cross-sectional design,2009) and Chaoyang Li et al,USA⁷⁸ (PR=8.3%, using PHQ-9, Population based survey,2008)

The differences in prevalence rates might be due to variation in attributes of study participants,

use of different psychometric tool for depression, study design and diversity in psycho-social stressors from one community .to another

Among the study participants with comorbid depression we also analysed the frequency of depression on the basis of socio-demographic and clinical parameters (including age, gender, marital status, education, employment, and duration of diabetes, type of diabetes treatment, blood pressure and BMI).

In our study the mean age of the population with comorbid depression is 59.1 ± 8.5 years and this is similar to the mean age of the overall study population 57.1 ± 8.6 years. 45.5% of the patients age > 65 years have comorbid depression compare to 15.8% in the younger patients age 35-44 years. Older age ≥ 65 yrs was significantly associated with comorbid depression. ($p=0.006$). This is important because of the challenges of retirement and inadequate earning that comes around this age. All of these factors contribute to major stressors in this age group. This finding is similar to studies done by Nitin J et al India(cross-sectional, 2010)⁴⁷ Camara A et al Guinea⁷⁵, and Kurubaran G et al Malaysia(cross-sectional,2014)⁷⁹ where they reported an association between older age and comorbid depression in type 2 diabetes. These studies also reported older populations, who are likely to have had diabetes for longer with other comorbidities in addition to other stressors such as retirement and inadequate earning capacities^{47, 75, 79}.

Females had a lower frequency of depressive symptoms (28.5%) compare to males (38.2%).This may be due to the fact that women are more into health support networks and these groups usually help in providing psycho-social support for their members .In our study there was no significant association between gender and comorbid depression ($p=0.130$) . However, Nitin J et al in India⁴⁷ and Ali Khan et al in Pakistan (multicenter cross-sectional study, 2010)⁵⁰ in their studies, found an association with female gender.

Marital status, employment status and educational status were not significantly associated with comorbid depression ($p = 0.783$, $p = 0.110$ and $p = 0.261$ respectively) in this study. These findings are similar to those in a study done in Jos, Nigeria⁴⁹ by TM Agbir et al (cross-sectional, 2006). These findings may be due to differences in psycho-social stressors from one study cohort to another.

71.2% of the study subjects on combination therapy (OH drugs + insulin) or insulin alone had comorbid depression compare to 27.5% on OH alone. Medication burden as well as daily insulin injections are potential stressors in this group of subjects. However there was no significant association between type of diabetes treatment and comorbid depression ($p > 0.05$).

Increase in BMI $\geq 25\text{kg/m}^2$, was observed to be significantly associated with comorbid depression ($p=0.035$). This is important because obesity can be associated with other comorbidities which increases disease burden as well as confer extra cost of care in diabetes patients.

Also depression can be a risk factor for overweight /obesity resulting from over-eating, low self-esteem, lack of exercise as well as use of anti-depressants.

This finding is similar to what was reported in studies done by Amit R et al in India⁴¹ and Ali Khan et al Pakistan⁵⁰ where they reported that overweight /obesity was associated with comorbid depression in type 2 diabetes.

38.0% of the patients with diabetes ≥ 5 yrs had depression compare to 25.3% in those with diabetes <5 years. This is because patients with longer duration of diabetes are likely to have more co-existing diabetes complications with high disease burden and additional health care cost. These factors are potential stressors for depression in among diabetes patients.

There was a significant association between longer duration of DM ≥ 5 yrs and comorbid depression. ($p= 0.044$). Other studies done in by Tapesh et al in Bangladesh (cross-sectional,2011)⁴⁰, Nitin J et al in India⁴⁷, Ali Khan et al in Pakistan⁵⁰ also reported that longer duration of diabetes was found to be significantly associated with depression.

34.4% of the study subjects with hypertension had comorbid depression compare to 27.0% without hypertension. This is probably because patients with diabetes and hypertension have more comorbidities which can also be potential sources of stressors in this population of patients. However hypertension was not significantly associated with comorbid depression ($p=0.288$).

Out of the 32.3% of the subjects with comorbid depression more than two-thirds (26.8%) had some form of difficulties with psycho-social functioning. Even when this observation is not part of the scoring for depression, yet is significant because poor psycho-social functioning negatively affects self-care and adherence which forms an integral component in achieving glycaemic control and other care goals in diabetes.

39.2% of the participants with comorbid depression had poor glycaemic control with HBA_{1C} > 7% compare to 16.4% of with good control HBA_{1C} ≤7%. This is probably because subjects with comorbid depression have some difficulty with psychosocial functioning which in turn negatively affects patients self-management. There was a significant association between comorbid depression and poor glycaemic control (p=0.001). Bot et al in Netherlands (multicenter cross-sectional)⁵⁷ and Marcello et al in Brazil(cross-sectional,2011)⁵⁸ also reported that depression was associated with poor glycaemic control in their study patients.

CONCLUSIONS

About one-third (32.3%) of the study subjects with type 2 diabetes had comorbid depression and more than half (18.7%) had moderate to severe depression.

This study attempts to explore potential risk factors for comorbid depression in type -2 diabetes patients in KNH. Older age (>65years, $p=0.006$), longer duration of diabetes (≥ 5 years, $p=0.044$) and over-weight/obesity ($\geq 25\text{Kg/m}^2$, $p=0.035$) were found to be associated with comorbid depression.

Our study also documented that comorbid depression was associated with inadequate glycaemic control ($\text{HBA1C} > 7\%$, $p=0.001$), implying the comorbid depression imposes an extra care burden on patients with type 2 diabetes.

RECOMMENDATION

- I. We recommend that all type 2 diabetes patients and especially those with potential risk factors for comorbid depression should be routinely assessed for depression using a simple screening tool (e.g PHQ-9)
- II. We further recommend that larger multi- center studies should be carried out across the country to look at the burden and the risk factors of depression in diabetes patients and to design effective interventional programs.
- III. A multi-disciplinary team should be involved in the management of diabetes patients.

STUDY LIMITATIONS

- I. This study is a cross-sectional study performed at a single center therefore not representative of the general population in Kenya.
- II. Cross-sectional design of this study could be a limitation as it prevents the searcher to infer about causality between depression and diabetes.
- III. The study lacked adequate power to make correlations between various socio-demographic/clinical parameters and depression.
- IV Recall bias cannot be totally eliminated but was minimized by reviewing patients medical records.

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APPENDECES

APPENDIX 1: PATIENT INFORMATION FORM

My name is Dr. Joseph Edwin Kane. I am a post- graduate student of Internal Medicine at the University of Nairobi. The purpose of this statement is to inform you about a research study that I am carrying out. I am doing a research study on the prevalence and severity of depression in ambulatory type 2 diabetes patients at Kenyatta National Hospital. The aim of this study is to determine the burden of co-morbid depression in type 2 diabetes uot-patients. Recommendation can be made to the administration on how to improve management practices.

Participation in this study is voluntary. Should you accept to participate then the following is a summary of what the study involves.

1. Obtaining socio-demographic information such as age, gender, employment status, educational status, duration of diabetes and type of diabetes treatment from you.

NOTE – your name and hospital identification number will not be included in this information for your privacy

2. A brief physical examination to measure your blood pressure and as well as weight and height to calculate your BMI by a trained and qualified medical personnel
3. Administration of a PHQ-9 Questionnaire to assess for depression
4. A 2ml blood venous sample shall be withdrawn and sent to Lancet for HBA_{1C} and they will be discarded immediately after this study
5. This will require about 25-30 minutes of your time.

All information will be kept confidential

Your primary health physician shall be informed of any findings relevant to your medical care. A consent form shall be given to you to sign if you agree to participate.

If you do not agree to participate, there will be No consequences. Your medical care continues as usual. Even if you agree to participate, you are free to withdrawn from the study at any time with NO consequences at all.

Thank you for taking your time to read this information

If you have any question, please do not hesitate to ask

Clarifications may also be addressed to any of the following:

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Department of Mental Health Kenyatta National Hospital

APPENDIX 2: CONSENT FORM

Introduction

This research study is being conducted by Dr. Joseph Edwin Kane at the Kenyatta National Hospital to determine the Prevalence and severity of depression in ambulatory Type 2 diabetes in Kenyatta National Hospital.

Procedures

Socio-demographic information would be collected from you.

You will be given a self administering PHQ-9 questionnaire to complete

A brief physical examination including blood pressure as well as weight and height would be recorded

A 2 ml venous blood sample would be withdrawn and sent to Lancet Laboratories for HBA_{1C}.

Risks/Discomforts

There are minimal risks for participating in this study. However you will feel emotional discomfort when answering questions about personal life. You will also feel mild pain and discomfort from the site where blood samples will be withdrawn

Benefit

There are no direct benefits to subjects. However, it is good that your participation will help researchers learn more about the burden of depression in type 2 diabetes. The results from this study will be communicated back to participants or primary care physician including depression status and HBA_{1C}.

Confidentiality

All information provided will remain confidential and will only be reported as group data with no identifying information. All data including questionnaires will be kept in a secure location and only those directly involved with the research will have access to them. After the research is completed the questionnaires will be destroyed.

Compensation

Participants will not receive any monetary compensation for participating in the study.

Participation

Participation in this research study is voluntary. You have the right to withdrawn at any time or refuse to participate entirely without any fear of victimization.

Questions about the Research

If you have questions regarding this study , you may contact Dr. Joseph Edwin Kane at josepkanu17@yahoo.com or call 0712784923

I hereby consent to take part in this research study on the Prevalence and severity of comorbid depression in ambulatory Type2 diabetes in KNH.

The nature of this study has been explained to me by Dr. Joseph Edwin Kane/research assistant. I have been assured that the participation iin this study is voluntary and will not negatively affect my medical care and that any information obtained will be treated as confidential.

Signed/thumbprint

On this day and date.....

Witness by

Date

Investigator Statement

I the investigator have provided an explanation on the purpose and implications of the above research study to participants

Signed.....

On this day and date

APPENDIX 3: STUDY PROFORMA

Tick where applicable

1. How long have you had diabetes?

Less than 5yrs	5-10 yrs	>10yr
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

2. What is your gender? Male

Female

3. What is your date of birth ? Year

4. What is your highest level of education you achieved?

None at all

Primary School

High School

College/ University

5. What is your marital status

Single

Divorced

Married

Widowed

Separated

6. Employment statement

Employed

Not employed

7. Which medication are you taking for your diabetes

Oral hypoglycaemic drugs If yes, which type

Insulin

Insulin + oral hypoglycaemic drug

9. Do you have high blood pressure YES NO

If yes , which type of anti-hypertensive medication are you taking?

Specify.....

PHYSICAL EXAMS

10. Blood pressure (mm/hg)

11. Weight (Kg)

12. Height (m)

13. BMI

PATIENT HEALTH QUESTIONNAIRE-9 (PHQ-9)

Over the last 2 weeks, how often have you been bothered by any of the following problems?
(Use "✓" to indicate your answer)

	Not at all	Several days	More than half the days	Nearly every day
1. Little interest or pleasure in doing things	0	1	2	3
2. Feeling down, depressed, or hopeless	0	1	2	3
3. Trouble falling or staying asleep, or sleeping too much	0	1	2	3
4. Feeling tired or having little energy	0	1	2	3
5. Poor appetite or overeating	0	1	2	3
6. Feeling bad about yourself — or that you are a failure or have let yourself or your family down	0	1	2	3
7. Trouble concentrating on things, such as reading the newspaper or watching television	0	1	2	3
8. Moving or speaking so slowly that other people could have noticed? Or the opposite — being so fidgety or restless that you have been moving around a lot more than usual	0	1	2	3
9. Thoughts that you would be better off dead or of hurting yourself in some way	0	1	2	3

FOR OFFICE CODING 0 + + +
=Total Score:

If you checked off any problems, how difficult have these problems made it for you to do your work, take care of things at home, or get along with other people?

Not difficult
at all

Somewhat
difficult

Very
difficult

Extremely
difficult

Developed by Drs. Robert L. Spitzer, Janet B.W. Williams, Kurt Kroenke and colleagues, with an educational grant from Pfizer Inc. No permission required to reproduce, translate, display or distribute.

KIDODOSI JUU YA AFYA YA MGONJWA -9 (PHQ-9)

Katika kipindi cha wiki mbili zilizopita ni mara ngapi umesumbuliwa na matatizo haya yafuatayo?
(Tumia "✓" ili kuashiria jibu lako)

	Haijatoke zea kabisa	Siku kadhaa	Zaidi ya nusu ya siku hizo	Takriban kila siku
1. Kutokuwa na hamu au raha ya kufanya kitu	0	1	2	3
2. Kujisikia tabu sana au kukata tamaa	0	1	2	3
3. Matatizo ya kupata usingizi au kuweza kulala au kulala sana	0	1	2	3
4. Kujisikia kuchoka au kutokuwa na nguvu	0	1	2	3
5. Kutokuwa na hamu ya kula au kula sana	0	1	2	3
6. Kujisikia vibaya-au kujiona kuwa umeshindwa kabisa au umejiangusha au kuikatisha tama familia yako	0	1	2	3
7. Matatizo ya kuwa makini kwa mfano unaposoma gazeti au kuangalia TV	0	1	2	3
8. Kutembea au kuongea taratibu sana mpaka watu wakawa wameona tofauti? Au kinyume chake kwamba hutulizani na unahangaika sana kuliko ilivyo kawaida	0	1	2	3
9. Mawazo kuwa ni afadhali zaidi ufe au ujidhuru kwa namna fulani	0	1	2	3

FOR OFFICE CODING 0 + _____ + _____ + _____
=Total Score: _____

Kama ulitia alama matatizo voyote, matatizo hayo yamefanye iwe vigumu kivipi kwako kufanya kazi yako, kushughulikia vitu nyumbani, au kutangamana na watu wengine?

Sio ngumu hata kidogo <input type="checkbox"/>	Ngumu kiasi <input type="checkbox"/>	Ngumu sana <input type="checkbox"/>	Ngumu zaidi <input type="checkbox"/>
------------------------------------------------------	--------------------------------------------	-------------------------------------------	--------------------------------------------