Non-adherence to Diabetic Drug Therapy and Associated Factors among Type 2 Diabetic Patients at the Diabetic Clinic of Jimma University Specialized Hospital, Southwest Ethiopia

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Abstract

Background: *Treatment non-adherence for chronic illnesses such as diabetes is a common problem. Multiple factors related to the patient, disease, therapeutic regimen, and health-care system may contribute for medication non-adherence. Non-adherence leads to poor glycemic control and increases the risk of diabetes related complications. The prevalence and factors associated with non-adherence in this resource limited settings has not been determined before.*
Objective: *The study was conducted to assess the pattern of non-adherence to diabetic drug therapy and associated factors among type 2 diabetic patients.*

Methods: *A cross sectional study was conducted from February 15 – March 16, 2011, at the diabetic clinic of Jimma University Specialized Hospital. All patients attending the diabetic clinic during the study period who fulfilled the inclusion criteria were enrolled as study subjects. Data on patient socio-demography, non-adherence to medication, and factors related to non-adherence was collected using a pre-tested structured questionnaire through interview and from patient medical records. Data were entered into SPSS for windows version 16. Chi-square test and binary logistic regression was used to analyze the association between non-adherence and tested factors. P-value of less than 0.05 was considered as statistically significant.*

Results: *A total of 267 type 2 diabetic patients were enrolled in the study. About 179 (67%) of the participants were in the age group 31-59 while 77 (28.8%) were in the age ≥60. The mean age was 52.4 ± 11.9 years. Non-adherence was observed in 65 patients accounting for 24.3%. The most common reasons for non-adherence were forgetting to take medication 42(64.6%) followed by feeling healthy 19(29.2%). Factors independently associated with non-adherence were presence of depressive symptoms (AOR= 2.404, 95% CI = 1.323-4.366, P =0.004); side effects (AOR =1.868, 95% CI =1.012-3.446, P =0.046); and complex regimen (AOR = 3.413, 95% CI =1.652-7.050, P =0.001. Non-adherence was also found to be associated with diabetes related hospitalization (COR =2.966, 95% CI =1.540-5.712, P =0.001); diabetes complications (COR =2.609, 95% CI = 1.250-5.445, P =0.011) and uncontrolled fasting blood glucose (COR =2.115, 95% CI =1.111-4.027, P =0.023).*

Conclusion: *The prevalence of non-adherence in the current study was 24%. Factors related to the disease (depression), therapeutic regimen (side effect and complexity of regimen) and poor diabetic outcomes were significantly associated with non-adherence.*

Recommendation: *Health care providers should strengthen diabetes education and design strategies to improve adherence to those patients at higher odds of medication non-adherence, as this could substantially improve clinical outcomes.*

Key words*: type 2 diabetes, non-adherence, drug therapy, associated factors*

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Table of contents

List of tables

List of figures

List of abbreviations

ADA	American Diabetes Association
AOR	Adjusted Odds Ratio
BMI	Body Mass Index
BMQ	Beliefs about Medicines Questionnaire
CI	Confidence Interval
COR	Crude Odds Ratio
FBG	Fasting Blood Glucose
GI	Gastrointestinal
HbA1c	Glycosylated Hemoglobin or Hemoglobin A1c
HIV	Human Immunodeficiency Virus
HRQL	Health Related Quality of Life
JUSH	Jimma University Specialized Hospital
MMAS	Morisky Medication Adherence Scale
OADs	Oral Anti-diabetic Drugs
OHA	Oral Hypoglycemic Agents
OR	Odds Ratio
PHQ	Patient Health Questionnaire
RSQ	Relationship Scales Questionnaire
SMBG	Self Monitoring of Blood Glucose
SPSS	Statistical Package for Social Sciences
T2DM	Type 2 Diabetes Mellitus
US	United States
WHO	World Health Organization

Definition of terms

Diabetes complication – Refers to both acute and chronic diabetes complications. Acute complications include diabetic ketoacidosis and hyperosmolar hyperglycemic state. Chronic complications include neuropathy, nephropathy, retinopathy, ischemic heart disease, myocardial infarction, stroke, peripheral arterial disease, and impotence.

Family support – Family encouragement in patient self care, taking medications, treatment follow up, reassurance or listening to the patient talk about his/ her diabetes, helping with materials and/or financial support.

Glycemic control – Target levels of blood glucose in a person with diabetes mellitus. According to American Diabetes Association the glycemic goals of treatment are: HbA1c <7%, pre-prandial (fasting) plasma glucose of 70-130 mg/dl and postprandial plasma glucose < 180 mg/dl (American Diabetes Association, 2010).

Non-adherence – Individual patient's failure to take anti-diabetic medications as prescribed by their health care provider. This includes failure or delay to refill a prescription on time, intentional and non-intentional discontinuation of medications.

Side effects - A harmful and undesired effect of anti-diabetic medications used at normal doses, which is related to the pharmacological properties of the drug. Common side effects of anti-diabetic drugs include hypoglycemia, weight gain, GI side effects (nausea, vomiting, diarrhea and constipation). Hypoglycemic symptoms may include: tremulousness, palpitations, sweating, hunger, sensations of warmth, weakness, fatigue, difficulty of thinking and confusion.

Type 2 diabetes mellitus – A metabolic disorder of fat, carbohydrate, and protein metabolism characterized by high blood glucose in the context of insulin resistance and relative insulin deficiency.

1. Introduction

1.1. Background

The burden of chronic non-communicable diseases is emerging as a major public health challenge worldwide, especially in developing countries where these diseases have been assumed to be less common. Diabetes is highly prevalent, affecting approximately 150 million people worldwide, and this number is expected to rise to 300 million by the year 2025 (International Diabetes Federation, 2006). Much of this increase is expected to occur in developing countries. This has been attributed in part to ageing population, urbanization, western style diet, increasing obesity and sedentary lifestyles. World Health Organization (WHO) estimated the number of diabetics in Ethiopia to be about 800,000 cases by the year 2000, and the number is expected to increase to 1.8 million by 2030 (WHO, 2003).

Diabetes mellitus is a group of metabolic disorders of fat, carbohydrate, and protein metabolism that results from defects in insulin secretion, insulin action (sensitivity), or both. The two major types of diabetes mellitus are type 1 (insulin deficient) and type 2 (combined insulin resistance and relative deficiency in insulin secretion). Uncommon types of diabetes include gestational diabetes mellitus, and diabetes due to endocrine disorders (acromegaly, Cushing's syndrome), pancreatitis and due to drugs (e.g., glucocorticoids, protease inhibitors, pentamidine, niacin, and α-interferon). Type 1 and type 2 diabetes differ in terms of clinical presentation, onset, etiology, and progression of disease. Both types of diabetes mellitus are associated with acute and chronic complications (Triplitt, *et al*., 2008; American Diabetes Association, 2010).

Treatment of type 2 diabetes mellitus typically includes appropriate diet, physical activity, oral hypoglycemic medications and/or insulin. The goals of therapy are directed towards attaining normoglycemia, reducing the onset and progression of diabetes related complications, intensive therapy for associated cardiovascular risk factors, and improving quality and longevity of life. Patient education and ability to demonstrate self-care and adherence to therapeutic lifestyle and pharmacologic interventions are crucial to successful outcomes (International Diabetes Federation, 2006; Triplitt, *et al*., 2008; American Diabetes Association, 2010).

The WHO defines the term adherence when used in chronic disorders as "the extent to which a person's behavior in terms of taking medication, following a diet, and/or executing lifestyle changes corresponds with agreed recommendations from a health-care provider". Adherence connotes a willingness on the patient's part to follow the health-care provider's recommendations (WHO, 2003).

Accurate assessment of adherence behavior is necessary for effective and efficient treatment planning. The methods available for measuring adherence can be broken down into direct and indirect methods. Direct observed therapy, measurement of concentrations of a drug or its metabolite in blood or urine, and detection or measurement in blood of a biologic marker added to the drug formulation are examples of direct methods of measures of adherence. Indirect methods of measurement of adherence include asking the patient about how easy it is for him or her to take prescribed medication (self-report), assessing clinical response, performing pill counts, ascertaining rates of refilling prescriptions, using electronic medication monitors, measuring physiologic markers and asking the patient to keep a medication diary. Each method has advantages and disadvantages, and no method is considered the gold standard. (Lars and Terrence, 2005; Bosworth, 2010)

Many methods have been recommended in the literature for measuring treatment adherence. A multi-method approach that combines feasible self-reporting and reasonable objective measures supported by effective patient–provider communication is likely to be the best method for identifying problems with treatment adherence in clinical setting. Patient self reported medication adherence measure is the simplest and commonly used method (Bosworth, 2010).

1.2. Statement of the problem

In Ethiopia, diabetes was rare 40 years back but now is emerging as a major public health problem and has burdened the health care system. The prevalence of diabetes in the Gondar region of northern Ethiopia has been reported as approximately 0.3% (Alemu and Watkins, 2004). Higher prevalence (5.3%) of type 2 diabetes was reported in a study done in Jimma town, Southwest of Ethiopia (Yemane, *et al*., 2007), though it needs other community based studies.

The prevalence of treatment non-adherence generally ranges from 20 to 60% for chronic illnesses such as diabetes (Bosworth, 2010). Medication adherence statistics in the United States shows that 22% of patients take less than what is stated on the label, 12% of patients do not fill their prescription at all and 12% of patients do not take medication at all after they buy the prescription (Kocurek, 2009). Non-adherence to diabetic treatment recommendations is a common problem in every practice and many patients have difficulty in taking medications and following lifestyle changes. Diabetes treatment contains many aspects that unavoidably contribute for treatment non-adherence. One aspect of the disease is that it is a chronic disorder requiring a lifelong treatment, which may be complex, intrusive and inconvenient. Second, it requires life style changes. Thirdly, diabetes related complications and co-morbidities are common requiring additional pill burden (Israel, 2005).

A number of studies have documented many factors related to diabetes regimen non-adherence. Factors related to patient demography, psychosocial, disease and medication related factors, patient-provider relationship/communication, health care system and medical cost affects treatment adherence (Israel, 2005; Rubin, 2005; Delamater, 2006; Kocurek, 2009). Major predictors associated with poor adherence include presence of psychological problems such as depression, treatment of asymptomatic disease, inadequate follow-up or discharge planning, side effects of medication, patient's lack of belief in the benefits of treatment, patient's lack of insight into the illness, poor provider–patient relationship/communication, complexity of treatment, and cost of medications (Lars and Terrence, 2005).

Access to care is a major problem in the rural areas of Ethiopia which may contribute to poor prognosis for people with diabetes. Patients have to travel long distances to the nearest medical centre in order to get medical care and medications. In addition, high cost of medications also remains a very serious problem as in most of sub Saharan and other developing countries (Alemu and Watkins, 2004). Diabetic care was found suboptimal in health centers and regional hospitals of Addis Ababa, Ethiopia. Only 21% of patients had access for blood glucose monitoring at the same health institutions. The emphasis given for diabetic education was less than expected (24%). Only 11 (5%) of diabetic patients were able to do self blood glucose monitoring at home. None of diabetic patients had haemoglobin Alc (HbA1c) determination. Nearly 75% of the patients required admissions directly or indirectly due to uncontrolled diabetes (Feleke and Enquselassie, 2005).

Adherence clearly and directly optimizes clinical benefit and health-related quality of life of patients. Whereas, medication non-adherence leads to considerable morbidity, mortality, and avoidable health-care costs. Non-adherence accounts for substantial worsening of disease and development complications hence increased rates of hospital admissions, physician office visits, use of expensive medical resources, unnecessary change of medications, unexplained treatment failures, and increased direct and indirect costs (Kocurek, 2009).

These barriers of the Ethiopian health care system together with other factors related to patient, patient-provider relationship, disease and therapeutic regimens may affect patient adherence to diabetes drug treatments. Thus, there is a continuing need to assess treatment adherence rates among patients with diabetes. Previous studies conducted at the diabetic clinic of Jimma University Specialized Hospital, demonstrated that about 47% of patient had poor glycemic control and many patients developed diabetes related complications (Kelemu, 2006; Worku, *et al*., 2010).

The above studies did not assess non-adherence as factor contributing to poor glycemic control and the extent of non-adherence and associated factors in the Ethiopian setup has not been investigated before. Thus, our study was done to fill the above mentioned gap.

2. Literature review

It has been generally recognized for years that non-adherence rate for chronic illness regimens is approximately 50% (Delamater, 2006). Regimen adherence problems are common in individuals with diabetes, making glycemic control difficult to attain. Substantial studies have documented a number of factors related to diabetes regimen non-adherence.

Among the 151 diabetic cohorts from an urban primary-care clinic, New York City, 28% of patents were poor adherent to their diabetic medicine. Predictors of poor medication adherence were: believing that they have diabetes only when their blood sugar was high (OR = 7.4;2–27.2), saying there was no need to take medicine when the glucose was normal (OR = 3.5;0.9–13.7), worrying about side-effects of diabetes medicines (OR = 3.3;1.3–8.7), lack of self-confidence in controlling diabetes (OR = 2.8;1.1–7.1), and feeling medicines are hard to take (OR = 14.0;4.4–44.6). Disease and medication beliefs inconsistent with a chronic disease model of diabetes were significant predictors of poor medication adherence (Mann, *et al*., 2009).

About, 2074 participants from the US National Health and Wellness Survey and the Ailment Panel of Light speed Online Research were studied. The study's aim was to quantify prevalence of tolerability issues among patients with T2DM currently treated with OADs and to assess its association with treatment adherence, satisfaction and health-related quality of life (HRQL). The majority (71.7%) experienced at least one tolerability issue in the past 2 weeks; 49.7% experienced more than two. Tolerability issues include signs/symptoms of hypoglycemia (57.2%), constipation/diarrhea (28%), headaches (25.6%), weight gain (22.9%) and water retention (21.0%). There was a significant association between the number of tolerability issues and both the likelihood of non-adherence ($r = 0.20$, $p < 0.01$) and reduced treatment satisfaction ($r = -0.42$, $p < 0.01$). Each additional tolerability issue was associated with 28% greater likelihood of medication non-adherence. Constipation/diarrhea ($b = -0.02$, $p < 0.01$) and symptoms of hypoglycemia ($b = -0.08$, $p < 0.01$) were significantly associated with lower HRQL scores (Pollack, *et al*., 2010)

A study done in France, problems of adherence to medication, dietary advice, and physical activity recommendations were reported by 17%, 62%, and 47% of the patients respectively. Six independent factors were found associated with adherence problems: young age, body-mass index (BMI) > 30 kg/m^2, glycosylated haemoglobin (HbA1c) > 8%, single life, depression, and perception of medication as a constraint (Moreau, *et al*., 2009).

A cross-sectional study investigated if depressive symptoms may be associated with non-adherence to medications. Of the 391 respondents studied, 73 (18.7%) were categorized as having depression. Depressed patients had significantly worse adherence to diabetes medications (F = 4.82; *P* = 0.03). The association between depression and medication adherence was stronger in men than in women. (F = 5.93; *P* = 0.01) (Nau, *et al*., 2007). Similarly, a prospective study of 866 type 2 diabetes patients aimed to examine the longitudinal relationship between depression, behavioral factors, and glycemic control. Glycemic control was determined by levels of glycosylated hemoglobin (HbA1c); a level of >7% was judged as unsatisfactory. Patients with depression revealed increased rates of medication non-adherence (adjusted OR: 2.67; CI: 1.38–5.15). Adjusted ORs for poor glycemic control (HbA1c >7%) were also increased for patients with baseline depression (2.01; CI: 1.10–3.69) (Dirmaier, *et al.*, 2010).

A retrospective cohort of 2920 subjects carried in the Tayside region of Scotland found adequate adherence (≥ 90%) in 31% of those prescribed sulphonylureas alone, and in 34% of those prescribed metformin alone. There were significant linear trends of poorer adherence with each increase in the daily number of tablets taken (P = 0.001) and increase in co-medication (P = 0.0001) for sulphonylureas alone after adjustment for other factors (Donnan, *et al*., 2002).

The prevalence of adherence to medicine taking was 92.2% in a cross-sectional study of 243 type 2 diabetic patients seeking care at a tertiary hospital diabetic clinic in Bangkok, Thailand. About 46.5% reported received good social support for diabetes from their family. Approximately 33.3% achieved good glycemic control (HbA1c ≤7%), while 50.2% had poor control (HbA1c >8%) (Howteerakul, *et al*., 2007). Another cross-sectional study enrolled in a research and extension education center in the State of Sao Paulo, southeastern Brazil, of the 46 subjects studied, 78.3% were adherent and 21.7% were non-adherent to anti-diabetic drug therapy (Gimenes, *et al*., 2009).

The prevalence of non-adherence was 28.9% in a cross sectional study carried in 402 type 1 and 2 diabetic outpatients in Mulago Hospital, Uganda. Factors that were independently associated with non-adherence were: female gender (OR = 2.9, 95%CI = 1.4 – 6.3), not understanding the drug regimen well (OR = 4.0, 95%CI = 1.0 – 16.3), affording only some or none of prescribed drugs (OR = 3.7, 95%CI = 1.8 – 7.6) and longer time since last visit to a health worker (OR = 7.3, 95%CI = 2.7 – 19.9) (Kalyango, *et al*., 2008). The adherence rate to medication was found sub optimal (39%), in a study done in 226 Type 2 diabetic outpatients in Egypt. The most important social factors significantly associated with good adherence rate to the prescribed glucose lowering agent(s) were married individuals ($P< 0.01$), presence of family support ($P < 0.01$), and higher socio-economical level ($P<0.01$). Other patient factors found with improved therapeutic adherence were: patients with adequate knowledge about the disease, good patients' belief and motivation about prescribed drugs, and patients who regularly self monitor their blood glucose level ($P < 0.01$). Patients on many prescribed drugs (polypharmacy), complex drug regimens, and patients who experience drug side effects were among the drug factors negatively affecting adherence rate ($P <0.05$) (Shams, *et al*., 2010).

A cross-sectional study done on 121 type 2 diabetic ambulatory patients in southwestern Nigeria, the commonly cited intentional non-adherence practice was dose omission (70.2%). Almost 50% respondents were fed up with daily ingestion of drugs and 19.8% found inconvenient to take drugs outside home and these were their perceived reasons for dose omission. Forgetfulness (49.6%) and high cost of medication (35.5%) were mentioned as major non-intentional reasons for non-adherence and significant association exist between sex, occupation and patients' tendencies to forget doses of prescribed oral medications ($P<0.05$) (Adisa, *et al*., 2009). Another study on adherence to anti-diabetic drug therapy in Nigeria, 59% of patients were non-adherent with the previous anti-diabetic drugs due to lack of finance (51.7%); side effects (34.5%); perceived ineffective of prescribed anti-diabetic drugs leading to self-medication with local herbs (13.8%). Only 20% of those non-adherent patients claimed disclosure to physicians during consultation. The identified factors for non-disclosure were lack of privacy during consultation (58%); and short consultation time (42%) (Yusuff, *et al*., 2008).

In Ethiopia, studies on diabetes treatment non-adherence and associated factors are limited. A retrospective cross sectional study on factors contributing to poor glycemic control among 217 diabetic patients in Jimma University Specialized Hospital showed poor glycemic control in 99(45.6%) of cases. Younger age, being far distance from the diabetic center and type 1 diabetes were significantly associated with poor glycemic control ($P<0.05$) (Kelemu, 2006). Another cross sectional study on patterns of diabetes complications, in the same study area, found that both acute and chronic diabetes complications were common (Worku, *et al*., 2010).

In summary, literatures show that adherence problems are common among patients with diabetes. Factors related to patient knowledge and belief about medications, social and emotional factors, cost, side effects, number and complexity regimens was found to affect adherence to diabetic medications.

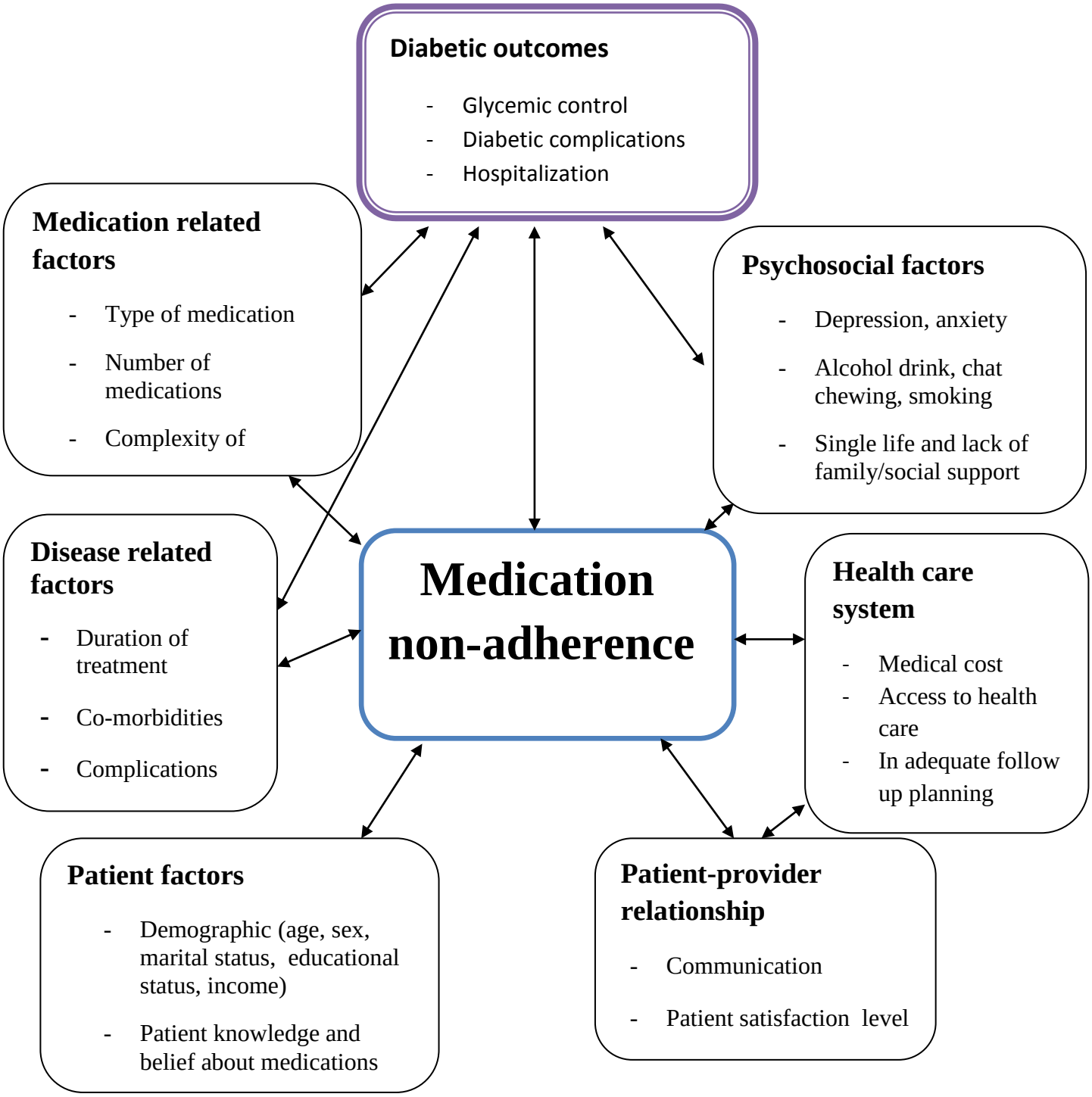


Figure 1: Conceptual framework: factors contributing to diabetic medication non-adherence and its relationship with diabetic outcome (Source: from literature review)

3. Significance of the study

Diabetes mellitus has become an emerging major public health problem in the Ethiopian setup. Being a non-curable chronic disease, management of diabetes has now put a considerable pressure in the already constrained health care budget and infrastructure (Feleke and Enquselassie, 2005). Therefore studying non-adherence to drug treatment and associated factors among diabetic patients in the Ethiopian setup is of paramount importance.

The output of this study indicates the level of non-adherence and associated factors among type 2 diabetic patients in Jimma University Specialized Hospital. This figure has multiple implications; one, it helps to map the level of non-adherence with similar patient groups in other Ethiopian health care setups. Second, it helps to identify patient groups who need interventions to improve adherence. Third, it will help to design strategies to improve medication adherence and to make intervention for better quality of diabetic care in the study setting and for the country in general. Thus, treatment costs incurred to treat acute and chronic diabetes complications and over all treatment costs would be prevented. Finally, the study will serve as input for further studies in the area.

4. Objectives of the study

4.1. General objective

- The aim of the study was to assess the pattern of non-adherence to diabetic drug therapy and associated factors among type 2 diabetic patients at the diabetic clinic of Jimma University Specialized Hospital from February 15 to March 16, 2011.

4.2. Specific objectives

- To assess the prevalence of non-adherence to diabetic drug therapy among type 2 diabetic patients at the diabetic clinic of JUSH.
- To assess perceived reasons for medication non-adherence among type 2 diabetic patients at the diabetic clinic of JUSH.
- To determine patient demographic factors associated with medication non-adherence among type 2 diabetic patients at the diabetic clinic of JUSH.
- To determine patient psychosocial factors associated with medication non-adherence among type 2 diabetic patients at the diabetic clinic of JUSH.
- To assess disease and medication related factors affecting medication adherence among type 2 diabetic patients at the diabetic clinic of JUSH.
- To assess the relationship of medication non-adherence with diabetic outcomes (glycemic control, diabetic complications and hospitalization) among type 2 diabetic patients at the diabetic clinic of JUSH.

5. Study subjects and methods

5.1. Study area and period

The study was conducted in the diabetic clinic of Jimma University Specialized Hospital (JUSH) found in Jimma town, Oromia regional state, from February 15 to March 16, 2011. Jimma town is located 352km southwest of Addis Ababa, the capital city of Ethiopia, at an altitude of 1500-2700 above sea levels. JUSH is a teaching and tertiary level hospital and gives health service for more than 10 million people living in southwest of Ethiopia (Worku, *et al*., 2010). The hospital provides inpatient services in six clinical departments (Internal medicine, surgery, gynecology and obstetrics, pediatrics, psychiatry and ophthalmology) and outpatient services in the chronic illness follow up clinics (diabetes, cardiovascular, asthma, epilepsy, tuberculosis and HIV). The diabetic clinic provides service for about 2800 diabetic follow-up patients, of these type 2 diabetic patient accounts for about 1700 (Ethiopian health sector, 2010).

5.2. Study design

A cross sectional, quantitative study was employed.

5.3. Population

5.3.1. Source population

The source population were all type 2 diabetic follow-up patients (aged 18 years and above) in the diabetic clinic of Jimma University specialized hospital.

5.3.2. Study population

The study population were type 2 diabetic follow up patients attending the diabetic clinic during the study period.

5.3.3. Study subjects

All patients attending the diabetic clinic during the study period who fulfilled all the following inclusion criteria were enrolled as study subjects.

Inclusion criteria

- Type 2 diabetic follow up patients aged 18 years and above
- Duration of diabetic drug treatment for three months and above
- Patients who agree to voluntarily participate in the study
- Patients who are capable of providing consent

Exclusion criteria

- All type 1 diabetic patients
- Type 2 diabetic patients with age less than 18 years
- Type 2 diabetic patients on insulin therapy only
- Pregnant patients
- Newly diagnosed and duration of treatment less than three months, and
- Acutely ill and mentally impaired patients were excluded from the study

5.4. Sample size and sampling technique

The sample size required for the study was determined using the formula for single population proportion: $n_0 = \frac{z^2_{\alpha/2}\, p(1-p)}{e^2}$ where, n_0 = sample size

p = estimate of prevalence rate non-adherence

e = margin of sampling error tolerated

z = the standard normal value at 95% confidence interval which is 1.96

Considering the prevalence rate of non-adherence 29%, based on a study done in Uganda (Kalyango, *et al*., 2008), and 5% margin of error at 95% confidence interval gives a sample size (n_0) of 316. Since the diabetic patient population in the study setting was known (N<10,000), the sample size was adjusted using the formula for finite population correction for proportions (Daniel, 2005).

$$n = \frac{n_0 N}{N + (n_0 - 1)}$$

n = adjusted sample size

n_0 = sample size

N = source population

The source population were all type 2 diabetic patients (N=1700) and the adjusted sample size (n) becomes 267. This sample size was taken using convenient sampling technique where all patients attending the diabetic clinic during the study period who fulfilled the inclusion and exclusion criteria were enrolled.

5.5. Study variables

Independent variables

- Socio-demographic variables (age, sex, marital status, educational status, income, distance from the clinic, family support and habits of smoking, chat chewing and alcohol drinking)
- Patient belief about diabetic medication
- Patient-providers relationship
- Disease related variables (depressive symptoms, co-morbidities, duration of diabetes treatment and duration since last visit)
- Medication related variables (number of drugs, complexity of regimen and drug side effects)

Dependent variables

- Non-adherence to drug therapy
- Glycemic control
- Diabetes complications
- Hospitalization

5.6. Data collection tools

Data was collected using a pre-tested structured questionnaire and data abstracting format. The questionnaire consists of six parts that assess: patient socio-demography characteristics, patient belief about diabetes medications, patient-provider relationship, history of depressive symptoms, medication related factors, patient self reported medication non-adherence based on the 4 item Morisky Scale and perceived reasons for medication non-adherence. The data abstracting format was designed to collect data on number and dosing of all prescribed medications, glycemic control levels (FBG), diabetes related complications, co-morbid conditions and diabetes related admission from patient medical records.

5.7. Operational definitions

Medication non-adherence

Medication non-adherence was measured using the self-reported 4-item Morisky scale, a commonly used and validated method (Morisky, *et al*, 1986; Rigby, 2007; Lizheng, *et al*., 2010). Sensitivity and specificity with positive and negative predictive values were 77.61%, 45.37%, 46.84% and 76.56%, respectively in a translation and validation of Malaysian version (Al-Qazaz, *et al*, 2010). The Morisky scale assesses patients' forgetfulness about taking medications, carelessness about taking medications, stopping medication when feeling better, and stopping medication when feeling worse. Questions were answered as 'yes' and 'no' and scored one point for 'yes' and zero point for a 'no' response. Scores were summed to give total score, ranging from 0 to 4. Non-adherence was defined as a score greater than zero. This scale assumes optimal adherence 100% thus adherent patients had to score zero.

Glycemic control

Glycemic control was assessed using fasting blood glucose (FBG). Last reading value of FBG was abstracted from patients' records. FBG of 70 to 130 mg/dl was classified as controlled, and FBG >130 uncontrolled glycemic level. FBG level of < 70 was considered as hypoglycemic risk (American Diabetes Association, 2010).

Complexity of regimen

The overall number of medications a diabetic patient was taking to treat diabetes and diabetes related complications and co-morbidities were assessed. A drug regimen was considered complex if a patient was taking ≥2 drugs with daily dosing of twice or more each (Park, *et al*., 2010; Shams, *et al*., 2010).

Patient belief about diabetic medications

Patients' belief and insight to anti-diabetic medicines was assessed based on the Beliefs about Medicines Questionnaire (BMQ), which has been validated and studied for use in chronic illnesses (Horne, *et al*., 1999). A three item scale (agree, neutral and disagree) questions were designed to assess patients' beliefs about the necessity of prescribed medication for controlling their illness and patients' concern about the potential adverse consequences of taking medication. Concern questions were reverse scored ('agree' 3, 'neutral' 2 and 'disagree' 1 point) and scores obtained from each question were summed to give total score. By dichotomizing at the scale midpoint, scores was interpreted as a continuous scale where lower scores indicate good beliefs and higher scores indicate weaker beliefs towards anti-diabetic medications.

Patient-provider relationship

The patient -health care provider relationship/communication was assessed using four questions, designed based on the Relationship Scales Questionnaire (RSQ), a valid and reliable instrument (Ciechanowski, *et al*., 2001). These questions were intended to assess health care providers' communication with the patient, patient participation in decision making and patient satisfaction with the health providers' relationship. Questions were answered as 'yes' or 'no' and were scored 1 for 'yes' and 0 for 'no' answers. Total score was summed and ranges between 0 and 4. Scores were interpreted as good (total score 3 and 4), moderate (total score 2) and weak (total score 0 and 1) relationship a patient had with his/her health care provider.

Depressive symptoms

Depressive symptoms were assessed using the Patient Health Questionnaire (PHQ), a well validated and commonly used instrument (78% sensitivity and 98% specificity) (Kroenke, *et al*.,

2001). An eight-item version was used in this study and questions assess patient emotional symptoms of bothering, feeling depressed or hopeless, loss of interest or pleasure in doing things, trouble in sleeping, problem in eating, feeling tired or loss of energy, feeling bad and trouble in concentrating. A patient answered 'yes' to four or more of the questions including the first two questions was considered as having depressive symptoms (scoring was done based on the criteria stated by the original developers of the questionnaire) .

5.8. Data collection methods and process

Data was collected by three pre-trained BSc nurses, who can speak and interview in Afan-Oromo and Amharic languages. Data was collected through face to face patient interview and simultaneously abstracting patient clinical data from medical records.

The questionnaire was first forward translated from English to Afan-Oromo and Amharic languages by native speakers of the languages and proficient in English. These primary versions were made to be reviewed and compared with the original English version by other speakers of the languages and proficient in English. Then, reverse translation of the questionnaire to English was carried out by other translators. Finally, discussion between the translators and principal investigator was made to resolve inconsistencies and a semi-final version was generated ready for pre-testing. After pre-test, necessary corrections were made and the final Afan-Oromo and Amharic version of the questionnaire was used for the study.

After refill, all patients who fulfill the inclusion criteria were approached and requested to participate in the study. Data on patient socio-demography (age, sex, marital status, educational status, income, distance from the clinic, family support and habits of smoking, chat chewing and alcohol drink), patient belief about diabetic medications, patient-providers relationship, history of depressive symptoms, experienced drug side effects, duration of diabetes treatment and duration since last visit was collected through interview using the structured questionnaire. The Morisky scale which is based on patient self-report was used to assess patient adherence to anti-diabetic medications. Non-adherent patients was asked their reasons for not taking medications in accordance to health care providers recommendation.. Data on recorded drug side effects,

number and dosing of drugs, diabetes related complications, co-morbidities, and fasting blood glucose (FBG) was abstracted from patient medical records using the data abstracting format.

Attempt was made not to collect data twice from a single patient. Spot checking and regular supervision (on daily base) of the data collection process was made by the principal investigator. Filled questionnaires were collected each day by the principal investigator.

5.9. Data processing and analysis

Once all necessary data were obtained, data were checked for completeness and a particular questionnaire with incomplete data was excluded before analysis was made. Data were entered into SPSS for windows version 16 statistical software. Chi-square test and logistic regression were used to analyze the significant association between non-adherence and assessed factors. Differences between non adherent and adherent characteristics were first explored by chi-square tests since all variables were categorical. P value of <0.05 was considered significant for all analysis. Binary logistic regression analysis was carried out to identify the independent factors related to non-adherence (binary outcome "yes' with "no"). Estimates of the risk factors were expressed as adjusted odds ratios (OR) with 95% confidence intervals (CI).

5.10. Ethical considerations

The study was conducted after ethical clearance (Ref. No. RPGC/170/2011) was obtained from the ethical review board of College of Public Health and Medical Sciences, Jimma University. The hospital administration was communicated with official letter from department of pharmacy and permission was obtained from Clinical Director of JUSH to carry out the study in the diabetic clinic.

The objective and purpose of the study was made clear to all participants included in the study. Informed verbal consent was obtained from the patient and only volunteers were interviewed and their record charts abstracted. Good relationship with the participants was established before exploring to any sensitive issues. The cultural values and traditions of the participants were also

respected. Patients' data was kept confidential. Data collected from participants was only identified by a code number instead of name and only the study team members know that number. Data collectors were trained on how to ensure participants' data confidentiality. Collected data was kept with the principal investigator in a lockable cabinet. Finally, all sheets used in the data collection were disposed properly. Individual participant received an incentive of Et. Birr 5 to compensate for the time he/she spent. During the study, patients with undiagnosed medical conditions, especially unrecognized depressive symptoms and drug side effects were referred to the respective health professionals for further investigations and treatment.

5.11. Pre-test

A one day pre-test was conducted before the actual study to identify potential problems in the proposed study methods, data collection tools and to check the performance of the data collectors. The pre-test was conducted on 13 type 2 diabetic patients (5% of the sample size) in the diabetic clinic of JUSH. Patients were interviewed using structured questionnaires and their record chart was reviewed using data abstracting format. Necessary corrections were made on the data collection tools. For instance some elaborative words were added so that participants could understand easily.

5.12. Data quality assurance

A one day training of data collectors was given on how to interview patients and abstract data from patient record charts. The data collection methods, tools and how to handle ethical issues was discussed with the data collectors. Afan Oromo and Amharic version of questionnaire was used for data collection. Spot checking and supervision was made each day during the data collection by the principal investigator to ensure that all necessary data were properly collected. During data processing all questionnaires was rechecked and a particular questionnaire of missing data was excluded before analysis was made. Questionnaires used in the pre-test were not included in the analysis as part of the actual study.

5.13. Study limitations

A self reported, 4-item Morisky medication adherence scale was used to assess medication non-adherence. The patients were required to answer the questions on the basis of their adherence behavior since the previous visit. The time between visits was relatively longer where patients may fail to remember everything about their medication taking behaviors. However, self reported adherence measure correlates well with suboptimal adherence as measured by electronic medication monitors and pill counts (Lizheng, *et al*., 2010). Particularly this is the best method for routine practice if supported by assessment of the patient's clinical and laboratory response.

One limitation of this study design is its weakness for establishing cause-effect relationship of non-adherence and diabetic outcomes. We studied non-adherence and diabetic outcomes (status of glycemic control, diabetes related complication and hospitalization) at the same time. Longitudinal studies could help to know the effect of medication non-adherence on diabetic outcomes. Another limitation of this study is the measure used to assess glycemic control. Measurement of glycosylated hemoglobin (HbA1c) is the standard method for assessing long term glycemic control. Fasting blood glucose was used to assess levels of glycemic control because HbA1c measurement was not available in the study setup. Incomplete recording which lacked some important laboratory data was also a considerable limitation.

6. Results

In this study, a total of 267 type 2 diabetic patients were enrolled. Of these, 148 (55.4%) were males while 119 (44.6%) were females. The mean age of the patients was found to be 52.4±11.9 with 179 (67%) and 77 (28.8%) of these represented the age group 31-59 and ≥ 60, respectively. The marital status of participants showed that 230 (86.1%) of the participants were married while 22 (8.2%), 10 (3.9%), 5 (1.9%) were divorced, widowed and single, respectively.

Regarding the educational status of the respondents, 104 (39%), 48 (18%) and 43 (16%) had primary, secondary and tertiary educational levels, respectively and 72 (27%) were illiterate. The monthly income of the majority patients 178(66.7%) was below Et. Birr 500. In addition, 57 (58.8%) of the respondents had no support from family. Moreover, about half of these participants had to travel long distance to reach the diabetes clinic (table 1).

Table 1: Socio-demographic characteristics of type 2 diabetic patients at the diabetic clinic of JUSH, March, 2011.

Socio-demographic characteristics		N	%
Age	18-30	11	4.2
	31-59	179	67.0
	≥60	77	28.8
	Total	267	100.0
Sex	Male	148	55.4
	Female	119	44.6
	Total	267	100.0
Marital status	Married	230	86.1
	Widowed	22	8.2
	Divorced	10	3.8
	Single	5	1.9
	Total	267	100.0
Educational status	Illiterate	72	27.0
	Primary	104	39.0
	Secondary	48	18.0
	Tertiary	43	16.0
	Total	267	100.0
Monthly income (Et.Birr)	<500	178	66.6
	500-2000	72	27.0
	>2000	17	6.4
	Total	267	100.0
Family support	Yes	110	41.2
	No	157	58.8
	Total	267	100.0
Distance from the clinic (km)	<6	134	50.1
	6-24	45	16.9
	>24	88	33.0
	Total	267	100.0
Habits of smoking	Yes	1	.4
	No	266	99.6
	Total	267	100.0
Habits of chat chewing	Yes	17	6.4
	No	250	93.6
	Total	267	100.0
Habits of alcohol drink	Yes	7	2.6
	No	260	97.4
	Total	267	100.0

Table 2, illustrates the distribution of patient, disease, and medication related variables among type 2 diabetic patients. Majority, 221 (82.3%) of the participants believed that diabetic medications helps to control their diabetes and stay healthy, while 43 (16.1%) and 3 (1.1%) had moderate and weak believe and insight towards diabetic medications, respectively. A large number, 244 (91.4%) of patients had good relationship with their health care provider and were satisfied with the health services. Based on Patient Health Questionnaire (PHQ), 88 (33%) of patients had emotional symptoms of depression.

Regarding the type of diabetic drug regimen, about half, 140 (52.4%) of the patients were on combination oral hypoglycemic agents and 90 (33.7%) were on one oral hypoglycemic medication while 37 (13.9%) were on insulin containing combination regimen. Out of the combination regimens, Metformin with Glibenclamide, Insulin with Metformin and Insulin with Glibenclamide were prescribed in 140 (52.4%), 32 (12.0%) and 5 (1.9%) patients, respectively. On the other hand, Glibenclamide and Metformin alone were prescribed in 60 (22.5%) and 30 (11.2%) patients, respectively.

The finding from the patient medical records has revealed the presence of various co-morbidities among the studied diabetic patients. Co-morbid hypertension was found to be the leading co-morbid condition observed in 139 (52.1%) patients. Other co-morbidities were dyslipidemia, heart failure, psychiatric disorders, together accounted for 15 (5.6%). Consequently, about half (50.1%) of the patients had to take three or more medications to treat diabetes related complications and co-morbidities. The mean number of medications per patient was 2.71 $\pm$ 1.14. Larger proportions of patients, 175 (65.5%) were on complex regimen, taking two or more drugs with daily dosing of twice or more each, while 92 (34.5%) were on simple drug regimen.

Table 2: Distribution of patient, disease, and medication related variables among type 2 diabetic patients at the diabetic clinic of JUSH, March, 2011.

Variables		N	%
Belief to medications	Good	221	82.8
	Moderate	43	16.1
	Weak	3	1.1
	Total	267	100.0
Patient-provider relationship	Good	244	91.4
	Moderate	21	7.9
	Weak	2	.7
	Total	267	100.0
Depressive symptoms	Yes	88	33.0
	No	179	67.0
	Total	267	100.0
Side effects	Yes	81	30.3
	No	186	69.7
	Total	267	100.0
Duration of diabetes Rx(yrs)	<1	14	5.3
	1-5	136	50.9
	>5	117	43.8
	Total	267	100.0
Duration since last visit	1 month	75	28.1
	2 months	165	61.8
	3 months	27	10.1
	Total	267	100.0
Diabetes related hospitalization	Yes	49	18.4
	No	218	81.6
	Total	267	100.0
Type of diabetic medications	One oral hypoglycemic	90	33.7
	Combination oral hypoglycemic	140	52.4
	Insulin containing combination	37	13.9
	Total	267	100.0

Table 2: Cont'd

Variables		N	%
Number of medications	1	33	12.4
	2	100	37.5
	3	65	24.3
	4	51	19.1
	5	16	6.0
	6	2	0.7
	Total	267	100.0
Complexity of regimen	Simple	92	34.5
	Complex	175	65.5
	Total	267	100.0
Co-morbidities	Yes	144	53.9
	No	123	46.1
	Total	267	100.0
Diabetes complications	Yes	192	71.9
	No	75	28.1
	Total	267	100.0
Fasting blood glucose (mg/dl)	<70	2	0.7
	70-130	94	35.3
	>130	171	64.0
	Total	267	100.0

As measured by the self-reported 4-item Morisky scale, the prevalence of non-adherence was 24.3%, observed in 65 patients. The most common reasons for non-adherence were forgetting to take medication 42 (64.6%) followed by feeling healthy 19 (29.2%) (figure 2).

In the present study, it was found that none of the patients had their HbA1c value determined and recorded on the patient medical record. The level of glycemic control was evaluated using fasting blood glucose (FBG). The mean fasting blood glucose was found to be 163 ± 64.60 mg/dl. About 171 (64.0%) of patients had uncontrolled blood glucose (FBG >130mg/dl) while 94 (35.3%) patients had FBG level of 70-130 mg/dl.

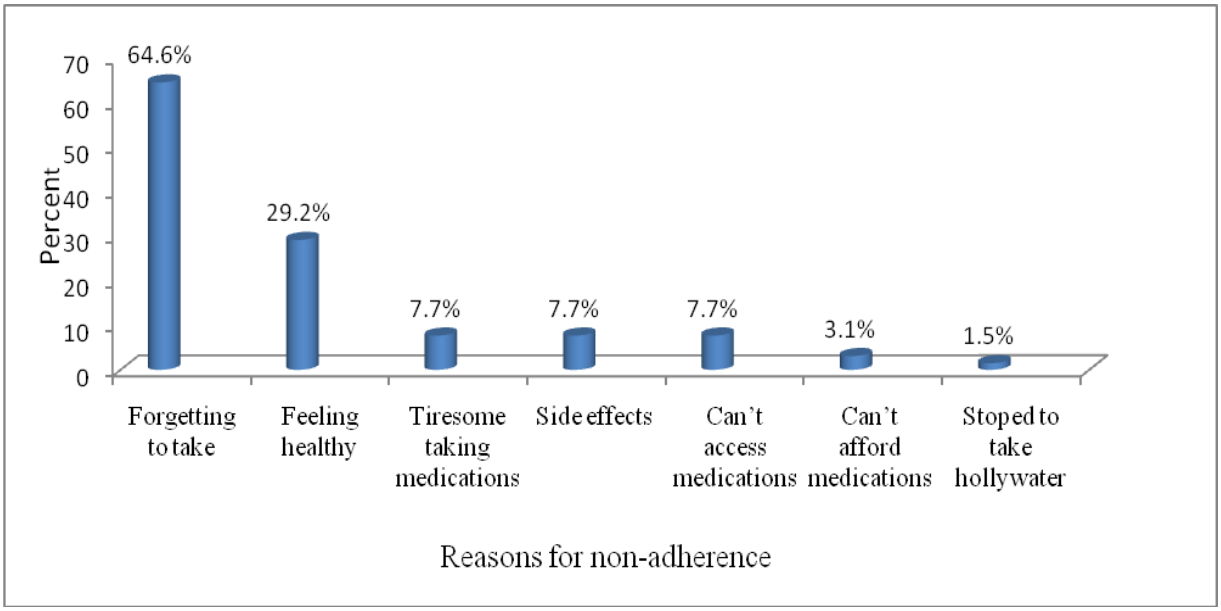


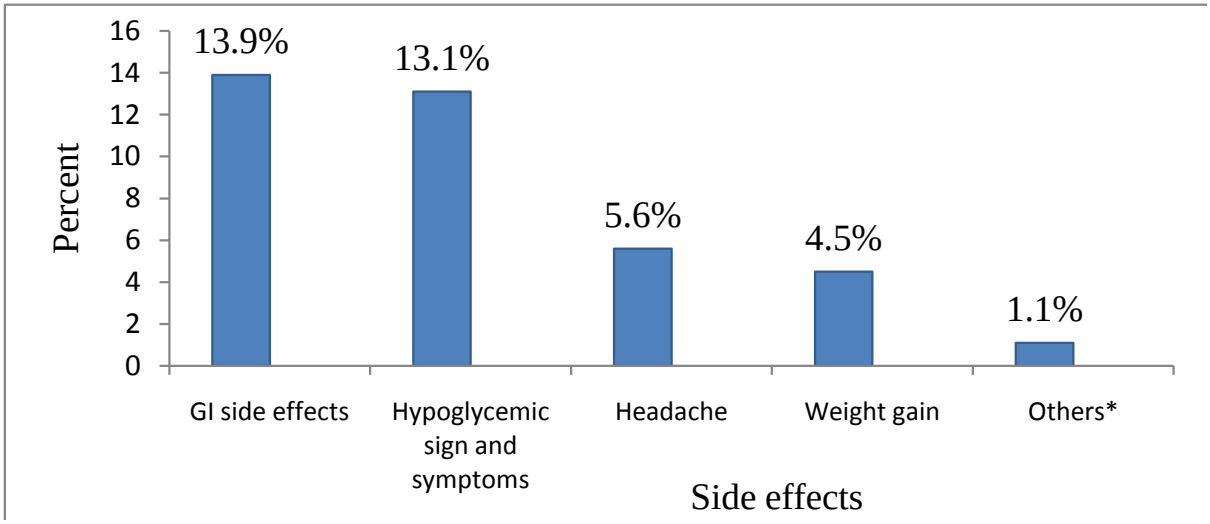
Figure 2: Reasons for non-adherence among type 2 diabetic patients at the diabetic clinic of JUSH, March, 2011.

Regarding the duration of treatment, 117 (43.8%) of the patients had been on diabetes treatment for more than five years while 136 (50.9%) had duration between one and five years. The mean duration of treatment was 5.96±4.94 years. Moreover, significant proportions, 192 (71.9%) of the patients had developed at least one diabetes related complications and 49 (18.4%) of patients had diabetes related hospital admission during the course of their treatment in which acute diabetic complications were the most common reasons for admission (table 3).

Table 3: Prevalence of acute and chronic diabetes complications among type 2 diabetic patients at the diabetic clinic of JUSH, March, 2011.

Diabetes complications		**N (%)**
Acute complications	Diabetic ketoacidosis	26 (9.7)
	Hyperosmolar hyperglycemic state	7 (2.6)
Chronic complications	Retinopathy	152 (56.9)
	Neuropathy	90 (33.7)
	Impotence	76 (28.5)
	Nephropathy	35 (13.1)
	Ischemic heart disease	7 (2.6)
	Infection/foot ulcer	5 (1.9)
	Stroke	1 (0.4)

As demonstrated in figure 3 below, at least one side effects to diabetic medications had been reported by 81 (30.3%) of participants. The common perceived side effects were GI side effects 37 (13.9%), hypoglycemic sign and symptoms 35 (13.1%) and headache 15 (5.6%).



* Joint pain, cholestasis

Figure 3: Perceived side effects among type 2 diabetic patients at the diabetic clinic of JUSH, March, 2011.

From chi-square testing, factors found significantly associated with non-adherence were: depressive symptoms (X^2 =10.295; P =0.001), side effects (X^2 =5.101; P =0.024), diabetes related hospitalization (X^2 =11.167; P =0.001), complexity of regimen (X^2 =11.696; P =0.001), diabetes complications (X^2 =6.866; P =0.009) and fasting blood glucose (X^2 =5.339; P =0.021) (tables 5). Variables related to habits of smoking, chat chewing, alcohol use, patient belief to medication, patient provider relationship and number of medication were excluded from the analysis because this variables did not fulfill the chi-square assumptions.

when the above factors found significantly associated (P<0.05) using chi-square testing was fitted into logistic regression model for univariate analysis, presence of depressive symptoms (COR= 2.528, 95% CI = 1.422-4.496, P =0.002); side effects (COR =1.947, 95% CI =1.087-3.490, P =0.025); complex regimen (COR = 3.286, 95% CI =1.621-6.663, P =0.001); diabetes related hospitalization (COR =2.966, 95% CI =1.540-5.712, P =0.001); presence of diabetes complication (COR =2.609, 95% CI = 1.250-5.445, P =0.011) and fasting blood glucose (FBG) (COR =2.115, 95% CI =1.111-4.027, P =0.023) were also found significantly associated with non-adherence (table 6).

Table 4: Association between socio-demographic variables and non-adherence among type 2 diabetic patients at the diabetic clinic of JUSH, March, 2011.

Variables		N (%)	Non-adherence		Chi-square †	P-value
			Yes [N (%)]	No [N (%)]		
Age	18-30	11 (4.2)	3 (27.3)	8 (72.7)		
	31-59	179 (67.0)	46 (25.7)	133 (74.3)		
	≥60	77 (28.8)	16 (20.8)	61 (79.2)		
	Total	267 (100.0)	65 (24.3)	202 (75.7)	0.761	0.684
Sex	Male	148 (55.4)	35 (23.6)	113 (76.4)		
	Female	119 (44.6)	30 (25.2)	89 (74.8)		
	Total	267 (100.0)	65 (24.3)	202 (75.7)	0.087	0.768
Marital status	Married	230 (86.1)	55 (23.9)	175 (76.1)		
	Single/Divorced/Widowed	37 (13.9)	10 (27.0)	27 (73.0)		
	Total	267 (100.0)	65 (24.3)	202 (75.7)	0.168	0.682
Educational status	Illiterate	72 (27.0)	16 (22.2)	56 (77.8)		
	Primary	104 (39.0)	20 (19.2)	84 (80.8)		
	Secondary	48 (18.0)	15 (31.2)	33 (68.8)		
	Tertiary	43 (16.0)	14 (32.6)	29 (67.4)		
	Total	267 (100.0)	65 (24.3)	202 (75.7)	2.762	0.097
Monthly income (Et.Birr)	<500	178 (66.6)	37 (20.8)	141 (79.2)		
	500-2000	72 (27.0)	23 (31.9)	49 (68.1)		
	>2000	17 (6.4)	5 (29.4)	12 (70.6)		
	Total	267 (100.0)	65 (24.3)	202 (75.7)	2.860	0.091
Family support	Yes	110 (41.2)	24 (21.8)	86 (78.2)		
	No	157 (58.8)	41 (26.1)	116 (73.9)		
	Total	267 (100.0)	65 (24.3)	202 (75.7)	0.648	0.421
Distance from the clinic (km)	<6	134 (50.1)	33 (24.6)	101 (75.4)		
	6-24	45 (16.9)	12 (26.7)	33 (73.3)		
	>24	88 (33.0)	20 (22.7)	68 (77.3)		
	Total	267 (100.0)	65 (24.3)	202 (75.7)	0.082	0.775

* Statistically significant

† Test of association for factors with two categories - general chi-square and for more than two categories - test for linear trend

Table 5: Association between patient, disease and medication related variables and non-adherence among type 2 diabetic patients at the diabetic clinic of JUSH, March, 2011.

Variables		N (%)	Non-adherence		Chi-square †	P-value
			Yes [N (%)]	No [N (%)]		
Depressive symptoms	Yes	88 (33.0)	32 (36.4)	56 (63.6)		
	No	179 (67.0)	33 (18.4)	146 (81.6)		
	Total	267 (100.0)	65 (24.3)	202 (75.7)	10.295	0.001*
Side effects	Yes	81 (30.3)	27 (33.3)	54 (66.7)		
	No	186 (69.7)	38 (20.4)	148 (79.6)		
	Total	267 (100.0)	65 (24.3)	202 (75.7)	5.101	0.024*
Duration of diabetes Rx(yrs)	<1	14 (5.3)	5 (35.7)	9 (64.3)		
	1-5	136 (50.9)	25 (18.4)	111 (81.6)		
	>5	117 (43.8)	35 (29.9)	82 (70.1)		
	Total	267 (100.0)	65 (24.3)	202 (75.7)	1.438	0.231
Duration since last visit	1 month	75 (28.1)	20 (26.7)	55 (73.3)		
	2 months	165 (61.8)	39 (23.6)	126 (76.4)		
	3 months	27 (10.1)	6 (22.2)	21 (77.8)		
	Total	267 (100.0)	65 (24.3)	202 (75.7)	0.310	0.577
Diabetes related hospitalization	Yes	49 (18.4)	21 (42.9)	28 (57.1)		
	No	218 (81.6)	44 (20.2)	174 (79.8)		
	Total	267 (100.0)	65 (24.3)	202 (75.7)	11.167	0.001*
Type of diabetic medications	One oral hypoglycemic	90 (33.7)	19 (21.1)	71 (78.9)		
	Combination oral hypoglycemic	140 (52.4)	34 (24.3)	106 (75.7)		
	Insulin containing combination	37 (13.9)	12 (32.4)	25 (67.6)		
	Total	267 (100.0)	65 (24.3)	202 (75.7)	1.825	0.401
Complexity of regimen	Simple	92 (34.5)	11 (12.0)	81 (88.0)		
	Complex	175 (65.5)	54 (30.9)	121 (69.1)		
	Total	267 (100.0)	65 (24.3)	202 (75.7)	11.696	0.001*
Co-morbidities	Yes	144 (53.9)	38 (26.4)	106 (73.6)		
	No	123 (46.1)	27 (22.0)	96 (78.0)		
	Total	267 (100.0)	65 (24.3)	202 (75.7)	0.709	0.400
Diabetes complications	Yes	192 (71.9)	55 (28.6)	137 (71.4)		
	No	75 (28.1)	10 (13.3)	65 (86.7)		
	Total	267 (100.0)	65 (24.3)	202 (75.7)	6.866	0.009*
Fasting blood glucose (mg/dl)	70-130	94 (35.5)	15 (16.0)	79 (84.0)		
	>130	171 (64.5)	49 (28.7)	122 (71.3)		
	Total	265 (100.0)	64 (24.2)	201 (75.8)	5.339	0.021*

* Statistically significant (P<0.05)

† Test of association for factors with two categories - general chi-square and for more than two categories - test for linear trend

Table 6: Factors associated with non-adherence (Univariate analysis) among type 2 diabetic patients at the diabetic clinic of JUSH, March, 2011.

Variables		Crude Odds Ratio (OR)	95% C.I	P value
Depressive symptoms	Yes	2.528	1.422-4.496	0.002*
	No	1.00		
Side effects	Yes	1.947	1.087-3.490	0.025*
	No	1.00		
Complexity of regimen	Complex	3.286	1.621-6.663	0.001*
	Simple	1.00		
Diabetes complications	Yes	2.609	1.250-5.445	0.011*
	No	1.00		
Fasting blood glucose	70-130	1.00		
	>130	2.115	1.111-4.027	0.023*
Hospitalization	Yes	2.966	1.540-5.712	0.001*
	No	1.00		

* Statistically significant association

When the above significant factors were fitted into logistic regression analysis for multivariate analysis, factors independently associated with non-adherence were presence of depressive symptoms (AOR= 2.404, 95% CI = 1.323-4.366, P =0.004); side effects (AOR =1.868, 95% CI =1.012-3.446, P =0.046); complex regimen (AOR = 3.413, 95% CI =1.652-7.050, P =0.001) and diabetes related hospitalization (AOR = 2.420, 95% CI = 1.174-4.992, P=0.017) (table 7).

Table 7: Factors independently associated with non-adherence (Multivariate analysis) among type 2 diabetic patients at the diabetic clinic of JUSH, March, 2011.

Variables		Adjusted Odds Ratio (OR)	95% C.I	P value
Depressive Symptoms	Yes	2.404	1.323-4.366	0.004*
	No	1.00		
Side effects	Yes	1.868	1.012-3.446	0.046*
	No	1.00		
Complexity of regimen	Complex	3.413	1.652-7.050	0.001*
	Simple	1.00		
Diabetes complications	Yes	1.569	0.701-3.512	0.273
	No	1.00		
Fasting blood glucose	70-130	1.00		
	>130	1.469	0.732-2.949	0.280
Hospitalization	Yes	2.420	1.174-4.992	0.017*
	No	1.00		

*Statistically significant association

7. Discussion

Medication non-adherence is a considerable problem in the management of patients with chronic diseases such as diabetes. Non-adherence accounts for poor glycemic control, substantial worsening of disease and development of complications hence increased rates of hospital admissions, and increased overall health care costs (Kocurek, 2009). In the current study, among the 267 type 2 diabetic patients investigated, 24.3% were found to be non-adherent. The commonest reasons for non-adherence were forgetting to take medication followed by feeling healthy. Factors independently associated with non-adherence were presence of depressive symptoms, side effects, and complexity of regimen. Non-adherence was also found to be associated with poor diabetic outcomes.

Reports show that the prevalence of treatment non-adherence for chronic illnesses such as diabetes generally ranges from 20 to 60% (Bosworth, 2010).The level of non-adherence (24.3%) found in the current study was slightly lower to the result (28.9%) reported in Uganda (Kalyango, *et al*., 2008) but significantly lower compared to the 59% non-adherence level reported in Nigeria (Yusuff, *et al*., 2008). This difference could be due to difference in reported side effects, a major predictor of non-adherence. Higher rate of side effects were reported by Yusuff, *et al* (hypoglycemia in 60.3%) and was the most common reason for non-adherence as this was not the case in this study. However, non-adherence rate in the present study was found to be higher in comparison with the reports of other studies done in Brazil (21.7%) (Gimenes, *et al*., 2009), France (17%) (Moreau, *et al*., 2009), Thailand (7.7%) and (Howteerakul, *et al*., 2007). Such differences might be related to differences in metrics to assess medication non-adherence, variations in methodology, differences in health care setting and socio-economic status.

As described in figure 2 above, the commonly observed reasons for non-adherence in this study were forgetting to take medications (64.6%) and feeling healthy (29.2%). Forgetfulness (49.6%) was also found to be the major reason for non adherence in Nigeria ((Adisa, *et al*., 2009)). The contribution of drug side effects and cost of medication as reason for non-adherence was low in this study as compared to reports of other studies (Yusuff, *et al*., 2008; Adisa, *et al*., 2009). The difference might be due to lower prevalence of hypoglycemic side effect (13.1%) in this study as

compared to 60.3% by Yusuff, *et al*. Poor self monitoring and recording of blood glucose levels might contributed for the lower prevalence of hypoglycemia in this study. Regarding the cost, most of the patients in this study setup had the opportunity to get medications free of cost.

However, it was revealed in this study that patients who experienced side effects to their medication were two times more likely non-adherent as compared to patients without side effects. Other studies are also consistent with this finding. A study from Egypt indicated that patients who experienced drug side effects were associated with poor adherence rate ($P < 0.05$) (Shams, *et al*., 2010). A diabetic cohorts from an urban primary-care clinic, New York City, worrying about side-effects of diabetes medicines predicts poor medication adherence (OR = 3.3; 95% CI =1.3–8.7) (Mann, *et al*., 2009). There was a significant association between the number of tolerability issues and both the likelihood of non-adherence ($r = 0.20$, $p < 0.01$), in a study done by the US National Health and Wellness Survey (Pollack, *et al*., 2010). Each additional tolerability issue was associated with 28% greater likelihood of medication non-adherence.

The most common side effects reported by the current study participants were GI side effects (13.9%), hypoglycemic sign and symptoms (13.1%), headache (5.6%) and weight gain (4.5%). Higher prevalence of side effects was reported from the US National Health and Wellness Survey: signs/symptoms of hypoglycemia (57.2%), constipation/diarrhea (28%), headaches (25.6%), weight gain (22.9%) and water retention (21.0%) (Pollack, *et al*., 2010). Lack of practice with self-monitoring of blood glucose (SMBG) in this study participants and hence unrecognized hypoglycemic signs might contribute for the lower hypoglycemic side effects in our study. This can also substantiated by the higher proportion (64.0%) of patients who had uncontrolled blood glucose (FBG >130mg/dl) as demonstrated in this study.

The current study also demonstrated that depressive symptoms (as measured by the 8-item Patient Health Questionnaire) were strongly associated with medication non-adherence and depressed patients were about three times more likely non-adherent than patients without depressive symptoms. This finding is consistent with studies done in France, where depression was associated with adherence problems [OR= 2.54 95% CI = 1.02–6.33, P = 0.0450] (Moreau, *et al*., 2009). Psychological problems (including stress and depression) were also reported to

affect treatment adherence in patients with type 2 diabetes (Rubin, 2005). Patients with diabetes rarely receive treatments for psychological problems. It is imperative that clinicians should recognize that depression and diabetes related emotional distress (frustration with symptoms and disease management) may lead to poor adherence hence negative clinical or therapeutic outcomes.

In addition to their anti-diabetic medications, diabetic patients have to take many medications to treat diabetes related complications and co-morbidities. Patients on many prescribed drugs (polypharmacy) and complex drug regimens were associated with lower adherence rate ($P < 0.05$) (Shams, *et al*., 2010). There were significant linear trends of poorer adherence with each increase in the daily number of tablets taken ($P = 0.001$) and increase in co-medication ($P = 0.0001$) in a retrospective cohort carried in the Tayside region of Scotland (Donnan, *et al*., 2002). These findings are consistent with our finding where patients on complex and multiple medications were non-adherent as compared to patients on one medication.

Poor adherence to medication seems to be a significant barrier to attain positive clinical or therapeutic outcomes among type 2 diabetic patients. Results of the present study showed that non-adherent patients were associated with presence of diabetes complication, uncontrolled diabetes (FBG >130mg/dl) and increased hospital admission. Previous investigations also show similar findings. Patients with type 2 diabetes who do not obtain at least 80% of their oral antihyperglycemic medications across 1 year were at a higher risk of hospitalization in the following year (odds ratio 2.53; 95% CI 1.38–4.64) (Lau and Nau, 2004). Similarly, a retrospective cohort of patients with diabetes mellitus in a managed care organization of Kaiser Permanente of Colorado (KPCO), non-adherent patients had higher glycosylated hemoglobin and medication non-adherence was significantly associated with increased risks for all cause hospitalization (OR, 1.58; 95% CI, 1.38-1.81; $P < .001$) and for all-cause mortality (OR, 1.81; 95% CI, 1.46-2.23; $P < .001$) (Ho, *et al*., 2006). All these findings evidently indicate that non-adherent patients are at high risk to have poor glycemic control hence, to develop diabetes related complications and increased rates of hospital admissions.

8. Conclusion

In the current study the prevalence of non-adherence to diabetic medications among type 2 diabetic patients was 24%. The commonest reasons for non-adherence were forgetting to take medication followed by feeling healthy. Factors independently associated with non-adherence were presence of depressive symptoms, side effects, and complexity of regimen. Non-adherence was also found to be associated with poor diabetic outcomes (presence of complications, hospitalization and uncontrolled fasting blood glucose).

9. Recommendations

The current study findings implicates the need for more intensive medication adherence monitoring among type 2 diabetic patients with depressive symptoms, side effects, complex and multiple medications and poor diabetic outcomes. Health care providers should spend more time and effort in explaining the importance of optimal medication adherence to these patients during their consultations. Patient education is an integral component of patient management so as to achieve optimal diabetes outcomes. Diabetic patients should aware that they have a lifelong condition that requires their involvement. Strategies to monitor and improve adherence are key components patient care plan. Some strategies that have been well proven to enhance adherence include: using pill boxes or reminder packaging, regular reinforcement and encouraging patients to relate pill taking to daily activities, simplifying treatment regimens by using combination products.

Identifying and treating depression and diabetes-related emotional distress can contribute to improved treatment adherence hence, positive treatment outcomes. Health care providers should identify patients at risk for distress or depression by regularly discussing symptoms with the patient. Practitioners should be cognizant of medication side effects and how this may affect long-term efforts to successfully management of diabetes mellitus. Early identification and management of medication related tolerability issue is important to achieve positive diabetes outcomes. Health care providers should educate their patients regarding side effects in the context of medication benefits and how to manage when potentially severe side effects such as hypoglycemia occurs. Physicians, nurses and pharmacists should strive to strengthen and sustain a good collaborative patient–health care provider relationship as this could enhance patient follow-up, self management practice, and adherence to treatment recommendations.

Recommendations for future works are to use other methods of adherence measure and to conduct on a larger sample population from different clinical settings so as to further investigate the pattern of non-adherence and different factors associated with it among type 2 diabetic patients.

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Annex 1. Data collection tools

Jimma University
College of Public Health and Medical Sciences
Department of Pharmacy
Clinical pharmacy postgraduate program

<Non-adherence to diabetic drug therapy and associated factors among type 2 diabetic patients at the diabetic clinic of Jimma University specialized hospital, southwest Ethiopia>

Name of data collector …….... Date ……Sign ……

Questionnaire

I) Patient socio-demography

1. Patient ID: _____
2. Sex: M □ F □
3. Age (years) _____
4. Marital status: Single □ Married □ Divorced □ Widowed □
5. Educational status: Illiterate □ Primary □
   Secondary □ Tertiary □
6. Monthly income (Birr or kind):_____
7. How many hours/minutes it takes you to reach to this diabetic clinic?
   _____ (hr/min) (specify in km as alternative)
8. Do you have support from family? Yes □ No □
9. Do you smoke cigarette? Yes □ No □
10. Do you chew chat? Yes □ No □
11. Do you drink alcohol? Yes □ No □

II) Patient beliefs about diabetic medications

a. Do you think taking your anti-diabetic medications will help you to stay well?
   Agree □ Neutral □ Disagree □
b. Do you think taking your anti-diabetic medications will keep your diabetes and blood sugar control? Agree □ Neutral □ Disagree □

c. Do you think taking your anti-diabetic medications will reduce your chances of developing complications? Agree □ Neutral □ Disagree □

d. Do you think taking your anti-diabetic medication is important if your blood glucose level is normal? Agree □ Neutral □ Disagree □

e. Do you think your anti-diabetic medications may bring you unpleasant side effects? Agree □ Neutral □ Disagree □

f. Do you think the cost exceeds the benefits you could get from your medications? Agree □ Neutral □ Disagree □

III) Patient-provider relationship

1. Does your doctor communicate you well on your status of glucose control? Yes □ No □
2. Do you participate in decision making while your doctor recommends you to take some treatments? Yes □ No □
3. Does your doctor or pharmacist counsel you well on how to take your medicine? Yes □ No □
4. Are you satisfied with the relationship you have with your doctor or pharmacist? Yes □ No □

IV) Assessment of depressive symptoms

a. Have you been feeling depressed, sad or hopeless? Yes □ no □
b. Have you been bothered by things that usually do not bother you? Yes □ no □
c. Have you had little interest or pleasure in doing things? Yes □ no □
d. Have you had trouble falling or staying asleep or sleeping too much? Yes □ no □
e. Have you had poor appetite or overeating? Yes □ no □
f. Have you been felt tired or having little energy? Yes □ no □
g. Have you had trouble concentrating on doing things? Yes □ no □
h. Have you had felt bad about yourself? Yes □ no □

V) Medication related

1. Have you ever experienced side effects to your diabetic medications? Yes □ No □

   If 'yes' (encircle to all applicable)

a. Gastrointestinal upsets (anorexia, nausea, vomiting, diarrhea and abdominal discomfort)
b. Hypoglycemic symptoms (palpitations, sweating, hunger, sensations of warmth, weakness, fatigue, difficulty of thinking and confusion)
c. Weight gain
d. Others (specify): _____

2. Have you been hospitalized since you started treatments for your diabetes?

(Apart from initial admission of diabetes diagnosis)

Yes □ No □

If 'yes' specify reason for your admission:

_____

3. Duration of diabetes treatment (years/months):_____
4. Duration since last follow up visit (months):_____

VI) Morisky Medication Adherence Scale (MMAS)

1. Have you ever forgotten to take your medicine? Yes □ No □
2. Are you careless at times about taking your medicine? Yes □ No □
3. When you feel better, do you sometimes stop taking your medicine? Yes □ No □
4. Sometimes if you feel worse when you take the medicine, do you stop taking it?

Yes □ No □

[Key: Yes=1, No=0 and sum to get total score]

Adherent (Total score=0) □ Non-adherent (Total score≥1) □

VII) If 'non-adherent', what is/are your reason(s) for not taking your medications as prescribed? (**encircle to all applicable**)

a. I feel as I am healthy
b. I am fed up with taking medications
c. Due to side effects
d. Forgetfulness
e. Cannot afford medications
f. Cannot access medications easily
g. No reason
h. Others (specify): _____

Data abstraction format

1. Current prescribed medications? (include all medications)

   Drug name, dose, frequency, duration of treatment

   a. _____
   b. _____
   c. _____
   d. _____

2. Recorded side effects? Yes □ No □

   If 'yes' specify_____

   _____

3. Co-morbid conditions? Yes □ No □

   If 'yes' (encircle to all applicable)

   a. Hypertension
   b. Dyslipidemia
   c. Others (specify)_____

4. Diabetes related complications? Yes □ No □

   If 'yes' acute complications (**encircle to all applicable**)

   a. Diabetes ketoacidosis
   b. hyperosmolar hyperglycemic state

   Chronic complications (**encircle to all applicable**)

   a. Neuropathy
   b. Retinopathy
   c. Nephropathy
   d. Ischemic heart disease
   e. Myocardial infarction
   f. Others (specify)_____
   g. Stroke
   h. Peripheral arterial disease
   i. Impotence
   j. foot ulcer/infection

5. Glycemic level: Last readings of FBG (mg/dl) _____date _____

   Last reading of HbA1c (%) _____date _____

Amharic version of the questionnaire

I. የታካሚው መለያና ማህበራዊ ሁኔታዎች

1. የታካሚው መለያ ቁጥር _____
2. ፆታ: ወ □ ሴ □
3. ዕድሜ: _____
4. የትዳር ሁኔታ: ያላገባ □ ያገባ □ የተፋታ/ች □ የሞተባት/ችበት □
5. የትምህርት ደረጃ ፤ ያልተማረ □ አንደኛ ደረጃ □ ሁለተኛ ደረጃ □ ዩንቨርሲቲ/ኮሌጅ □
6. ወርሐዊ ገቢ (ብር/መጠን)፤_____
7. እዚህ ክሊኒክ ለመድረስ ስንት ሰአት ወይም ደቂቃ ይፈጅብዎታል? _____
8. ከቤተሰብ እርዳታ ያገኛሉ? አዎ □ አይደለም □
9. ሲጋራ ያጨሳሉ? አዎ □ አይደለም □
10. ጫት ይቅማሉ? አዎ □ አይደለም □
11. አልኮሆል መጠጥ ይጠጣሉ ? አዎ □ አይደለም □

II. ታካሚዎች ስለ ስኳር በሽታ መድሀኒቶች ያላቸው እምነትና

1. የስኳር መድሀኒት መውሰድዎ ጤናማ ሆኖ ለመኖር ያግዘኛል ብለው ያምናሉ?
   አዎ □ አላውቅም □ አላምንም □
2. የስኳር መድሀኒት መውሰድዎ ህመምዎንና የደምዎን የስኳር መጠን ለመቆጣጠር ይጠቅማል ብለው ያምናሉ?
   አዎ □ አላውቅም □ አላምንም □
3. የስኳር መድሀኒት መውሰድዎ ከስኳር በሽታ ጋር ተያያዥ የሆኑ ህመሞችን ለመቀነስ ይረዳል ብለው ያምናሉ?
   አዎ □ አላውቅም □ አላምንም □
4. የደምዎን የስኳር መጠን በደምብ ከተቆጣጠሩት መድሀኒትዎን መወሰድ አለበኝ ብለው ያስባሉ?
   አዎ □ አላውቅም □ አላስብም □
5. የስኳር በሽታ መድሀኒቶችዎን መውሰድ ላልተፈለገ የመድሀኒት የጐንዮሽ ተፅእኖ ያጋልጠኛል ብለው ያስባሉ?
   አዎ □ አላውቅም □ አላስብም □
6. የመድሀኒትዎ ወጪ ከመድሀኒቱ ከሚያገኙት ጥቅም ይበልጣል ብለው ያስባሉ?
   አዎ □ አላውቅም □ አላስብም □

III. **ታካሚዎች ከጤና ባለሞያ ያላቸው ግንኙነት**

1. ሀኪምዎ የደምዎ የስኳር መጠን ያለበትን ደረጃ ይነግርዎታል ? አዎ □ አይደለም □

2. ሀኪምዎ መድሀኒት በሚያዝልዎት ጊዜ በውሳኔው እርስዎ ተሳትፎ ያድጋሉ? አዎ □ አይደለም □

3. ሀኪምዎ ወይም የፋርማሲው ባለሞያ መድሀኒትዎ እንዴት መውሰድ እንዳለበዎት ይነግረዎታል?

አዎ □ አይደለም □

4. ከሀኪምዎ ወይም ከፋርማሲው ባለሞያው ጋር ያለዎት ግኑኝነት አጥጋቢ ነው? አዎ □ አይደለም □

IV. የድብርት ምልክቶች አሰሳ

1. የድብርት ስሜት፣ የማዘንና ተስፋ የመቁረጥ ስሜት ተሰምቶዎት ያውቃል? አዎ □ አይደለም □
2. በፊት የማያሳስብዎት ነገር ላይ ብዙ አሰበው ወይም ተጨንቀው ያውቃሉ? አዎ □ አይደለም □
3. በነገሮች ላይ ደስታ የማጣት ወይም አለመደሰት ስሜት ተሰምቶዎት ያውቃል? አዎ □ አይደለም □
4. የእንቅልፍ ችግር ወይም ብዙ የመተኛት ችግር ኖሮዎት ያውቃል? አዎ □ አይደለም □
5. የምግብ ፍላጎት ማጣት ወይም ብዙ የመብላት ችግር ኖሮዎት ያውቃል? አዎ □ አይደለም □
6. የድካም ስሜት ወይም አቅም የማጣት ችግር ኖሮዎት ያውቃል? አዎ □ አይደለም □
7. በነገሮች ላይ ተረጋጋግቶ የመስራት/የማድረግ ችግር ኖሮዎት ያውቃል? አዎ □ አይደለም □
8. ስለራስዎ መጥፎ ስሜት ተሰምቶት ያውቃል? አዎ □ አይደለም □

V. ስለ መድሀኒት የተመለከተ

1. ከሚወስዱት/ዷቸው የስኳር መድሀኒት/ቶች ጋር የተያያዘ የጎንዮሽ ተጽእኖ ወይም ህመም ኖሮት ያውቃል?

   አዎ □ አይደለም □

   መልስዎ አዎ ከሆነ ምን ነበርዎት፤ **(የሚሆኑት ሁሉም ያክብቡ)**

   ሀ. ሆድ የማመም፣ የማስታወክ፣ የማሰመለስ፣ የማስቀመጥ

   ለ. የልብ ትርታ መጨመር፣ የማላብ፣ የራብ ስሜት፣ የድካም ስሜት፣ ራስ የመሳት

   ሐ. ክብደት መጨመር

   መ. ሌላ ካለ (ጥቀስ): _____

2. የስኳር መድሀኒት ከጀመሩ በኃላ ሆስፒታል ተኝተው ያውቃሉ ? አዎ □ አይደለም □

   አዎ ከሆነ ምክንያቱ ይጠቀስ: _____

3. ለስኳርዎ መድሀኒት ከጀመሩ ስንት አመት ሆንዎት: _____

4. በየስንት ጊዜ ነው ክትትል የሚያደርጉት: _____

VI. የስኳር መድሀኒት አወሳሰድ አሰሳ

1. የስኳር መድሀኒትዎን ሳይወስዱ ረስተው ያውቃሉ? አዎ □ አይደለም □
2. የስኳር መድሀኒትዎ አወሳሰድ ላይ ግድ የለሽ ሁነው ያውቃሉ? አዎ □ አይደለም □
3. ህመምዎ ሲሻልዎት መድሀኒትዎን መውሰድ አቁመው ያውቃሉ? አዎ □ አይደለም □
4. አንዳንድ ጊዜ ህመምዎ ከባሰብዎት መድሀኒትዎን መውሰድ ያቆማሉ? አዎ □ አይደለም □

[**መፍቻ፤** አዎ= 1 አይደለም= 0 ፤ የአራቱ ድምር ለማግኘት]

መድሀኒት በትክክል የሚወስድ (ጠቅላላ ድምር = 0) □ **መድሀኒት በትክክል የማይወስድ (ጠቅላላ ድምር ≥ 1)** □

VII. መድሀኒት በትክክል የማይወስድ ከሆነ፤

መድሀኒትዎን በትክክል የማይወስዱበት ምክንያት ምንድ ነው? **(የሚሆኑት ሁሉም ያክብቡ)**

1. የተሻለኝ ስለመሰለኝ ነው
2. ሁሌ መድሀኒት መውሰድ ስለሰለቸኝ ነው
3. ከመድሀኒቱ ጋር የተያያዘ የጎንዮሽ ተጽእኖ ስለሚያመኝ ነው
4. ስለምረሳው ነው
5. መድሀኒት መግዛት ስለማልችል ነው
6. መድሀኒት በቅርብ ማግኘት ስለማልችል ነው
7. ምክንያት የለኝም
8. ሌላ ካለ (ጥቀስ):_____

Afan oromo version of the questionnaire

I. Haala Hawaasummaa fi bakka jireenyaa dhukkubsataa

1. Lakkoofsa waraqaa eenyumma: _____
2. Saala: Dhiiraa □ Dubartii □
3. Umrii (Waggaadhaan): _____
4. Haala fudhaaf heerumma: kan hin fuune □ kan fuudhe □ kan hiike □ kan dhiirsi/nii tin irraa du'e □
5. Haala barnoota: kan hin baranne □ Sad. 1^{ftaa} □ Sad. 2^{ffaa} □ College fi universitii □
6. Galli ji'aan argamu (qarshiin ykn kan biroo): _____
7. Kiliinikii waldhaansa dhibee sukkaraa kana ga'uuf daqiqaa ykn sa'aatii meeqaa isii irraa fudhata: _____ (sa'ati/daqiqaa)
8. Maatii irraa qarqaarsa qabdaa? Eeyyee □ Miti □
9. Sigaaraa ni xuuxaa? Eeyyee □ Miti □
10. Caatiihoo ni qamaataa? Eeyyee □ Miti □
11. Alkoolii ni dugdhaa? Eeyyee □ Miti □

II. Itti amantummaa fi ilaalchaa dhukkubsataan waa'ee qoricha dhibee sukkaaraa irratti qabu

a. Qoricha dhibee farra sukkaaraa fudhachuun haala gaariin jiraachuuf sifayyada jettee ni yaaddaa? sirri □ hin beeku □ sirri miti □
b. Qoricha farra dhibee sukkaraa fudhachuun dhibichaa fi sukkaara dhiiga keessa jiruu of jala ni olcha jettee ni yaadhaa? sirri □ hin beeku □ sirri miti □
c. Qoricha farra dhibee sukkaaraa fudhachuun dhiibbaa yhn walxaxxinsa dhibee sukkaaraa irraan dhufu ni hir'isa jettee ni yaaddaa? sirri □ hin beeku □ sirri miti □
d. Ergaa hangi sukkaaraa dhigaa kee kessaa erga sirraa'e booda qoricha fudhachuun gaarii dha sitti fakkaataa? sirri □ hin beeku □ sirri miti □
e. Qoricha kana fudhachuun waan hin barbaachisne ni fida jettee ni yaaddaa? sirri □ hin beeku □ sirri miti □
f. Gatiin qoricha kanna bu'aa irra argatu ni caala jettee yaaddaa? sirri □ hin beeku □ sirri miti □

III. Walitti dhufeenya dhukubsataa fiqarqaaraa isaa qaban

1. Waa'ee sukkaaraa dhigaa kee keessa jiru ilaalchisee Doktorrn' kee sirritti si wajjiin mari'atee jiraa? Eeyyee □ Miti □
2. Yammu doktorri kee dawaa si ajaju, ati wanti keessa seentee itti hirmaatte qabdaa? Eeyyee □ Miti □
3. Daktoraa moo abbaa qondaala qorichaattu waa'ee dawaaa kana sirritti sitti humee? Eeyyee □ Miti □
4. Walitti dhufeenya doktoraa fi faarmasisti waliin qabdu baay'ee sigamachiiseeraa? Eeyyee □ Miti □

IV. Maadaalli mallatoolee dunququu

a. Mallatoo keen akka dunquqa'uu, gadduu yku abdi kuta chuu sitti daga'ameeraa? Eeyyee □ Miti □
b. Wanti dura si hin cinqine si cinquu egaleeraa? Eeyyee □ Miti □
c. Wanta nama gamachiisu sigammachiisu didee jiraa? Eeyyee □ Miti □
d. Rakkini hirriba (sitti baay 'isuu, ykn hir'aachuun) siqunnameeraa? Eeyyee □ Miti □
e. Fedhiin nyaataa kee dabalee yokin hir'atee jiraa? Eeyyee □ Miti □
f. dadhabiin ykn hir'in human sitti dhagamaa jiraa? Eeyyee □ Miti □
g. Wanta akka TV ykn waa dubbisuu irratti rakkinii xiyyeefannoo siqunnameeraa? Eeyyee □ Miti □
h. Of jubbiinsi sitti dhaga 'ameeraa? Eeyyee □ Miti □

V. Dhibichaa fi qoricha ilaalchisee

1. Dawaa farra dhibee sukkaaraa irraa miidhaan siqunname ni jiraa?
   Eeyyee □ Miti □
   Yoo, eeyyee jette (kan armaan gadii keessa filidhuu itti marii)
   a. Mallattolee garaa keessa kan akka, lollogisuu, haqisiisuu ykn baasaa
   b. Mallatoolee yammu sukkaarri dhiqa keessa gad bu'u mul'atan kan akka beela'uu, dadhabuu, haruu, fuursuu fi kankana fafakaatu.
   c. ulfaatin qamaa dabaluu
   d. Kan biraa: _____

2. Erga qoricha egaltee as hospitaala ceestee beektaa (kan jalqaba jemmu dhibeen kun sitti himamee as)? Eeyyee □ Miti □

   Yoo, eyyee jette, sababa isaa: _____

3. Eerga yaala egaltee waggaa meeqa? _____
4. Erga tanaan dura as dhuftee ji'a meequa ta'a? _____

VI. Madaalli qaricha seeraan fudhachuu ilaalu

1. Qoricha kee fudhachuu dagattee beektaa? Eeyyee □ Miti □
2. Qoricha kee fudhachu irratti dhima dhiboofaatee beektaa? Eeyyee □ Miti □
3. Yammu sitti wayyaa'u, yeroo tokko tokko qoricha fudhachuu dhiistee beektaa? Eeyyee □ Miti □
4. Qoricha osoo fudhattu, yemmu dhibeen sijabaatu, qoricho fudhachu dhistee beektaa? Eeyyee □ Miti □

   [furtuu: Eeyyee =1, miti =0, ida'ama isaa argachuf walitti ida'i]

   Qoricha seeraan fudhata (Ida'ama =0)□

   Qoricha seeraan ala fudhatta (Ida'ama >0)□

VII. Yoo, qoricha seeraan ala fudhatta ta'ee, sababni isaa maaliidha (kan ta'u hundaa itti mari)

a. Fayyummaa waan natty dhaqa'amufi
b. Qoricha fudhachuu waan na muffisiiseefi
c. Miidhaa qorichi fiduu irra kan ka'ee
d. Dagachuudhaan
e. Qoricha bitachuu waan hindandeenyeef
f. Sababa hin qabu
g. Kan biraa:_____

Annex 2. Preliminary Eligibility Screening Slip

<Non-adherence to diabetic drug therapy and associated factors among type 2 diabetic patients at the diabetic clinic of Jimma University specialized hospital, southwest Ethiopia>

S.N	Screening criteria	Indicators (encircle)	
1.	Type 2 diabetic patient	Yes	No
2.	Type 1 diabetic patient	No	Yes
3.	Newly diagnosed	No	Yes
4.	Duration of diabetic treatment	≥ 3 months	< 3 months
5.	Age (yrs)	≥ 18	< 18
6.	Pregnancy condition (if female)	No	Yes
7.	Physical condition of the patient	Well and conscious	Acutely ill and mentally impaired

Recommendation**:** (Mark √)

Eligible ☐ Not Eligible ☐

Completed by: _____signature_____

Annex 3. Informed consent

<Non-adherence to diabetic drug therapy and associated factors among type 2 diabetic patients at the diabetic clinic of Jimma University specialized hospital, southwest Ethiopia>

1. Information sheet

You are being invited to participate in a research. The purpose of conducting the study is to understand how diabetic patients are adhering to their medication and to know the barriers they have in adhering medications. Findings obtained from the study will help to identify patients who need intervention to improve adherence, and to develop better strategies to solve adherence problems for the future. You are chosen randomly, and you are one of those who fulfill the criteria for our study. You are requested for interview for about 20 minutes and your medical record will be reviewed. Your participation in the study is entirely voluntary. If you decide to take part you are still free to withdraw at any time and without giving a reason. A decision not to take part or to withdraw at any time from the study, will not affect the services you receive at the clinic.

Your personal information will not be shared with anyone. The information you give us and obtained from your medical record will be kept confidential. Any information collected about you will have a code number instead of your name. Only the study team members will know what your number is and we will lock that information up. Your participation will help to develop better strategies to support your adherence and will also benefit society and future generations. You will be given 5 birr to compensate the time you spent and for your participation in the study. There is no any anticipated harm to you because you participated in the study.

We would greatly appreciate your truthful and keen participation in responding to this questionnaire.

Amharic version of the informed consent

የተከበሩ ተሳታፊዎችን ለጥናት ፈልገንዎት ነው፡፡ የጥናቱ አላማ የስኳር ህመም ታካሚዎች የመድሀኒት አወሳሰዳቸው ለማጥናትና ለማወቅ እንዲሁም አወሳሰድ ላይ ያላቸው ችግር ለማጥናት ነው፡፡ የጥናቱ ውጤት መድሀኒት አወሳሰድ ችግር ያለባቸው ታካሚዎቸ ለመርዳትና ለወደፊት የተሻለ ህክምናና ክትትል እንዲደረግ ያግዛል፡፡ እንደእድል ነው የመረጥንዎት፡ እርስዎ ለጥናቱ መስፈርት ከሚያሟሉ ተሳታፊዎች አንዱ ነዎት፡፡ የምንፈልግዎት ለሀያ ደቂቃ ቃለ መጠይቅና የህክምና ካርድዎ ለማሰስ ነው፡፡ እዚ ጥናት ላይ የሚሳተፉት በእርስዎ በጎ ፍቃደኝነት ነው፡፡ ከጥናቱ ያለምክንያት በማነኛው ጊዜ አቋርጠው መሄድ ከፈለጉ ይችላሉ፡፡ በጥናቱ አለመሳተፍ በክሊኒኩ የሚያገኙትን የህክምና አገልግሎት አያግድዎትም፡፡

ከእርዎ የምንወስደው መረጃ ለማንም አናሳይም፡ አንሰጥም፡፡ መረጃዎ በምስጢር የተጠበቀ ነው፡፡ የምንወስደው መረጃ ሁሉ በመለያ ቁጥር የተለየና፤ ስምዎ የማይጻፍ መሆኑን እንገልፅልዎታለን፡፡ ተሳትፎዎ መድሀኒት አወሳሰድዎ ለመደገፍ ብሎም ለህብረተሰቡና ለቀጣዩ ትውልድ ይጠቅማል፡፡ ለተሳፎዎና ከኛጋር ለሚያሳልፉት ጊዜ ለማካካስ 5 ብር ይሰጥዎታል፡፡ጥናቱ ላይ በመሳተፍዎ ምንም ጉዳት አይደርስብዎትም፡፡

በጥናቱ ላይ በመሳተፍ በጎ ፈቃደኝነትዎና ቅንነትዎን በማድነቅ፤ ለዚህ መጠይቅ ሲመሉስልን ምስጋናችን የላቀ ነው፡፡

Afan oromo version of the informed consent

Isin qoranno kana irratti hirmaa chuudhaaf afeeramtan jirtan. Sababni qorannoo kanaa immo haala dhukkubsatootoni dhibee sukkaraa qoricha isaanii itti fudhatani fi wanta qorich seeraan fudhachuu isaan dhuwwu beekuuf qarqaraa. Bu'aan qarannicha irraa argamuus dhukubsatonni dhibeekana qoricha seeraan akka fudhatanii fi karoora isaanii baasuuf faaydaa olaanaa qaba. Isin namoota filatamaa 294 keessa tokko yoo taatan, daqiqaa 20f erga waliin haasofne booda, kaardii keessanii ni laalla. Itti hirmaadhuuf erga murteessitee booda, keessa bahuus ni dandeeta. Yoo baates, bayuun kee bu'aa ati kana irraa argatuu hin hir'isu.

Deebiin nuti sirraa argannu, nama biraatti hin himamu. Deebiin saas, Maqaa keetiin osoo hin taanee, lakkofsaa koodin bakka bu'ama. Hirmaannaan kee si'if bu'aa baay'ees qabaachuu baatuus, hirmaannaan kee nu'ufi dhalaata itti aanuuf baay'ee gariidha. Yenoo kee gubdee nu waahii abitti hirmaachu keef qarshi 5 ni argatta.

Amma qoranno kanatti hirmmaatu kee murteesitee? Wanti ati nuti himtu dhugaa ta'u isaa itti amannatiin, hirmaachuu keetiif baay'ee itti gamanna.

Research paper endorsement form to be filled before submission to Department of Pharmacy, College of Public Health and Medical Sciences, Jimma University

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Here with our signature, we declare that this research Paper was done under our advisorship and we have approved that this is the final paper to be submitted.

Name of advisors	**Signature**
Dawit Tesfaye, MD, Internist	
Jemal Hussien, B.Pharm, MSc.	

Here with my signature, I declare that this research Paper has been examined by me and I have checked that the student has incorporated the comments forwarded during examination.

Name of examiner	**Signature**
Elias Ali Yesuf, MD	

Here with my signature, I declare that this research Paper was done by me as a principal investigator and I assure that this is the final paper to be submitted.

Name of principal investigator	**Signature**
Gebrehiwot Teklay, B.Pharm	