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## EFFECT OF MEDICATIONS-RELATED BELIEFS ON ADHERENCE TO TREATMENT OF TYPE II DIABETES MELLITUS IN A PRIMARY HEALTHCARE SETTING, ADDIS ABABA, ETHIOPIA

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Medication Adherence, Medication Beliefs, Type 2 Diabetes Mellitus, Addis Ababa, Ethiopia.

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**ABSTRACT:** Studies reported from Ethiopia depict poor health outcomes and management of diabetes cases and low patients' adherence to recommended regimens including medications. Among factors determining adherence to medications that are amenable to interventions are patient perceptions to their recommended medications. This study thus aimed to assess adherence to anti-diabetic medications and determinant factors including medication related beliefs among type 2 diabetic patients attending their treatment in primary healthcare centers of Addis Ababa, Ethiopia using standardized measures. **Methodology:** A facility-based cross-sectional study design was followed to assess study participants recruited from among type 2 diabetic patients attending their treatment in three health centers in Kirkos Sub City, Addis Ababa from April to June, 2013. For the assessment interviewer administered structured questionnaires based on standardized measures such as the 8-item Morisk's Medication Adherence Scale (MMAS) and the specific Belief about Medications Questionnaire (BMQ) were used. **Result:** A total of 155 study participants, all of whom were on oral hypoglycemic agents were involved in the study among whom 53.5% were male and 49.1% had maximum educational status of just being able to read and write. The findings into the medication adherence of the study participants indicated a mean MMAS score of  $4.9 \pm 2.3$  indicative of low adherence. The linear multiple regression model showed the male sex and concern about medications to have negative associations on patients' medication adherence. This might indicate the need for healthcare providers to assess medication-related beliefs and address safety concerns that patients may have.

**INTRODUCTION:** Diabetes mellitus is one the major health problems affecting the world today. Latest figures depict 387 million adult global population to be living with disease with 225 million increase expected by the year 2035.

The corresponding figures for sub-Saharan Africa and Ethiopia respectively for adult diabetes cases are 21.5 million and 2.14 million, the large majority being of type 2. International Diabetes Federation (IDF) also reported that diabetes to be responsible for the deaths of more than 4.9 million people globally with the highest mortality rate from African region <sup>1</sup>.

Other studies have further indicated high prevalence of complications among diabetics in sub-Saharan Africa such as retinopathy, micro-albuminuria, gangrene, sepsis associated with diabetic foot ulcer disease and trauma to the hand <sup>2</sup>.

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Studies from Ethiopia indicate that the majority of patients to have poor health outcomes. For example, studies depict that patients treated in public health facilities in different parts of Ethiopia had blood glucose and blood pressure levels above recommended levels and had experienced high levels of micro- and macro-vascular diabetes-related complications<sup>3-8</sup>. A review study on the epidemiology of diabetes in Ethiopia also reported high levels of diabetic foot and other skin infections as well as high levels of hypercholesterolemia and hypertriglyceridemia among diabetics in different parts of the country<sup>8</sup>.

The majority of patients in one of the studies also required hospital admissions due to uncontrolled diabetes<sup>3</sup> which in turn was associated to increased expenditures<sup>9</sup>. Recent assessments on diabetic patients' medication-taking behavior in hospitals in different parts of Ethiopia have reported unacceptably low levels of adherence to recommended medication regimens which have been implicated for the poor glycemic control<sup>5, 10, 11</sup>.

A number of studies have been done on medication adherence and the factors affecting it in relation to diabetes and other chronic illnesses. While a number of different types of tools are reportedly used to assess adherence self-report measures are among the most widely used. This is due in part to their feasibility in clinical practice and research but also for their ability to depict a reasonable picture of adherence albeit an overestimate compared with some of measures such as electronic measures<sup>12</sup>. Morisky's Medication Adherence Scale (MMAS) is among the most widely used self-reported methods used for different conditions and for which validity and reliability tests have been done in different languages<sup>13, 14</sup>.

Morisky's scale has been reportedly used by different studies in different settings, languages and different illness conditions including diabetes. Studies utilizing it have also been reported from Ethiopia that have assessed adherence for different chronic conditions. Both the 4-item and 8-item scales have been used to assess self-reported adherences to medications used in different conditions such as diabetes<sup>10, 11</sup>, hypertension<sup>15-17</sup>,

psychiatry<sup>18, 19</sup>, tuberculosis<sup>20</sup>, HIV/AIDS<sup>21</sup>. Among the factors associated with adherence identified by the above studies include patient-centered factors such as sex, age, place of residence, educational level, occupational status, forgetfulness, irregular follow up, social drug use, drinking alcohol; psychological factors such as knowledge about illness and treatment, perception about severity, knowledge about benefits of compliance; therapy related factors such as experience of side-effects, pill burden, complexity of drug regimen, duration of maintenance therapy; disease-related factors such as comorbid conditions, presence of related complications, depressive symptoms, spot blood pressure; social and economic related factors such as poor social and family support, being busy; health system factors such as distance from hospital, perceived accessibility, perceived waiting time, perceived professional care and overall patient satisfaction<sup>11, 15-17, 19-22</sup>.

Among the factors which have reportedly led patients to intentionally non-adhere to provider recommendations and that are widely believed to be amenable to interventions are the psychological factors such as patient perceptions about their treatment<sup>23</sup>. A number of studies have reported about how patients' perceptions about necessity and concerns about the safety of their medications have impacted their medication-taking behaviors. Such studies have used a widely used tool known as 'Beliefs about Medicines Questionnaire' (BMQ) which has been found to be a valid and reliable tool in different languages and settings.

The conceptual model which is also termed as the 'Necessity-Concerns Framework' has been used to explain patients' adherence to medications of chronic illnesses such as HIV/AIDS, diabetes, schizophrenia, chronic kidney disease, rheumatoid arthritis and hypertension. In general studies using this framework have reported low adherence to be associated with stronger perceptions about safety concerns of medications and low perceptions about the necessity of treatment<sup>24, 25</sup>. Only one study was identified in online searches that has reported use of BMQ from Ethiopia that assessed the medication-related beliefs of type 2 diabetes patients in the south-western part of Ethiopia<sup>11</sup>.

The findings of this study however did not indicate the outcome of the assessment with regards to the necessity or concerns' belief of the study participants nor did they relate it to the measured adherence. The present study thus aimed to assess the socio-demographic and medication related beliefs determinants for adherence to type 2 diabetic medications in primary healthcare centers of Addis Ababa, Ethiopia using standardized measures.

### **Methodology:**

The study was conducted in Kirkos sub-city, one of the ten sub-cities of Addis Ababa located in the center and also popularly known as home to the most economically disadvantaged population. Addis Ababa is the political and commercial capital and the largest urban center of Ethiopia. According to the latest figures, Addis Ababa is home to 3.27million population of which Kirkos Sub-City contributes 264hundred thousand<sup>26</sup>. The official language and most widely used language in Addis Ababa and Ethiopia is Amharic.

Three of the primary health centers of Kirkos Sub-City, namely Kirkos, Meshualekia and Kazanchis Health Centers were purposively selected among the six, given that the remaining three health centers were newly established and catering to few patients at the time of the study. A health center is expected to serve 40 thousand population in its catchment area according to the recent guideline. Chronic illness care which includes diabetes care is one of the services the Health Centers provides to the population.

A facility based cross sectional study was done using interviewer administered structured questionnaires for type 2 diabetes mellitus patients who visited the Chronic Care Clinic during the study period which was from April –June 2013. The source population were all diabetes patients who were on follow up at the three health centers in Kirkos Sub City. Consecutive diabetes patients who came for their clinic appointments and who fulfilled the inclusion and exclusion criteria were selected as study participants. The inclusion criteria was diagnosis of type 2 diabetes mellitus, follow up of treatment at the respective health center at the time of study, prescription of oral hypoglycemic

medication for at least 6 months, age greater than or equal to 18 years and ability to understand the Amharic language. Patients who were not willing to participate in the study, not responsible for their own care and with hearing impairments were excluded from the study.

The single proportion formula was used to calculate the sample size of 155 study participants that were recruited from the three health centers in Kirkos Sub-City. The sample size was calculated considering proportions from previous studies on medication adherence to oral hypoglycemic agents in urban centers of Ethiopia. Using a margin of error of 0.05 and 90% confidence interval, a sample size of 262 respectively was obtained and further consideration was made for a 10% non-response rate, which resulted in the number of diabetes patients to be included in the survey to then be 289. The total population of diabetes patients in the selected health centers was considered 'small' (< 10,000) which led to sample size reduction to come up with the final sample size of 155. This figure was apportioned to the three health centers based on their patient populations. Accordingly, 64, 51 and 54 questionnaires were distributed to Kirkos, Kazanchis and Meshualekia Health Centers respectively.

Data collection was carried out using interviewer administered questionnaire that included the 8-Item Morisky's Medication Adherence Scale (8-MMAS)<sup>13</sup> and the specific Beliefs about Medicines Questionnaire (BMQ) -Specific<sup>24</sup> both of which have been widely validated in different settings and different languages especially for the assessment of patients' adherence in managing chronic conditions. Morisky's Medication Adherence Scale is an 8 item questionnaire which self-report scale for assessment of non-adherent behavior with 7 of them being yes/no questions and the 8<sup>th</sup> question requiring a 5-point Likert type response. The Beliefs about Medicines Questionnaire (BMQ) - Specific is a tool for assessing beliefs which patients commonly hold about their prescribed medication<sup>24</sup>. BMQ – Specific consists of ten-item scales presented as 5-point Likert type scale. This scale assesses patients' beliefs about the necessity of their medications for controlling their disease and their concerns about potential adverse

consequences of taking it. Studies using the BMQ-Specific sub-scales have shown that respondents with stronger beliefs about the necessity of their medication and fewer concerns about their medication (as measured by the BMQ) are more likely to use their medicines as recommended by the prescriber<sup>25</sup>.

The variable of the study included: independent variables such as socio-economic characteristics (age, marital status, religious affiliation, sex, educational status, employment status and monthly income); clinical status (diabetes duration, family history) and behavioral variables (BMQ – necessity and concerns) and medication adherence as the dependent variable. Data was collected using structured, translated and pretested questionnaires and before starting data collection the questioners were duplicated and data collectors were selected using different criteria then training was given to the data collectors about the questioner and how they should collect the data's.

To ensure the creditability of the data was cleaned every day and also double checking was done by randomly selecting the collected data. The collected data was cleared, coded and then entered into IBM SPSS version 20 software. Descriptive statistics was used to present the data as appropriate. Cronbach's alpha was used to indicate the internal consistency of the items in the scale. The value of Cronbach's alpha greater than 0.7 was considered to be acceptable<sup>27</sup>. Further, standard linear regression analysis model was constructed using medication adherence as dependent variable. A p-value of 0.05 or less was considered to indicate statistical significance.

Collected data was collected using established and validated tools. The tools were translated into Amharic and then back-translated to check for consistency. Training was given to the data collectors which was followed by regular supervision for the duration of the data collection to check among other things for completeness, clarity and accuracy. The study protocol including the methodology and information and consent form was approved by the Department of Pharmaceutics and Social Pharmacy, School of Pharmacy, Addis Ababa University. The Department then sent a support letter to the respective health centers which gave permission for the study and then forwarded to the chronic care clinic. The interview conducted in Amharic was carried out after obtaining informed verbal consent from the patients selected for inclusion in the study.

### Findings:

**Socio-demographic characteristics of participants:** A total of 155 diabetes patients on oral hypoglycemic agents were involved in this study and their socio-demographic characteristics are shown in table 1. Among the total of 155 respondents 83 (53.5%) were male, 76(49.1%) of the respondents had a maximum educational status of just being able to read and write, 63 (40.7%) were in the age group of 60-69 years, 90 (58.1%) were Orthodox Christian and 103 (66.5%) of respondents were married, 73 (47.1%) were unemployed and majority of the study participants 92 (59.3%) had monthly income less than1050 ETB. Seventy one (51%) of the study participants have had their disease for less than 5 years and 101 (65.2%) of them had reported negative family history of diabetes.

**TABLE 1: SOCIO DEMOGRAPHIC DATA OF DIABETES PATIENTS IN KIRKOS SUB CITY HEALTH CENTERS (n=155)**

Socio demographic variables		No (%)
Sex	Female	72(46.5)
	Male	83(53.5)
Age	30-39	1 (0.7)
	40-49	34 (21.9)
	50-59	55 (35.5)
	60-69	49 (31.6)
	70-79	16(10.3)
Religion	Orthodox	90(58.1)
	Muslim	33(21.3)
	Protestant	27(17.4)
	Others	5(3.2)
Marital status	Single	9(5.8)
	Married	103(66.5)
	Divorced	17(11.0)

Level of education	Widowed	26(16.8)
	Cannotread and write	30(19.4)
	Readonly	10(6.5)
	Readand write	36(23.2)
	1-6 grade	27 (17.4)
	7-12 grade	32 (20.6)
Monthly income	Diplomaand above	20 (12.9)
	< 350	47 (30.3)
	350-750	20(12.9)
	750-1050	25(16.1)
Work status	>1050	63(40.7)
	Unemployed	73(47.1)
	Government	38(24.5)
	Private	33(21.3)
	Self-employed	9(5.8)
Duration of diabetes	Others	2(1.3)
	1-5 years	79(51.0)
	6-10 years	28(18.1)
Family history of diabetes	>10 years	48(31.0)
	Yes	54(34.8)
	No	101(65.2)

**Belief about medication:**

Regarding BMQ-Specific, participants’ perception about their anti-diabetic drug is with highest mean and SD of 3.85 (0.89) and 4.26 (0.73) of BMQ

concern and necessity respectively as shown in **Table 2**. The internal reliability of each of the scales was acceptable with Cronbach alpha greater than 0.7.

**TABLE 2: SPECIFIC BELIEF ABOUT STUDY PARTICIPANTS’ PERCEPTIONS ON ANTI-DIABETIC MEDICINES (n=155)**

	Mean	SD
<b>Specific concern perception</b>		
Having to take this anti-diabetic medicine worries me	3.42	1.068
I sometimes worry about becoming too dependent on my anti- diabetic medicines	3.85	0.891
I sometimes worry about the long term effects of my anti-diabetic medicines	3.70	0.981
My anti-diabetic medicines disrupt my life	3.46	1.158
My anti-diabetic medicines are a mystery to me	2.87	1.188
Possible scale range = 5-25. Total scale score (mean ±SD) = 17.3±3.8. Range 10-25. Cronbach’s alpha = 0.76		
<b>Specific necessity perception</b>		
My health, at present, depends on anti-diabetic medicines	4.03	0.781
Without anti-diabetic medicines, I would be very ill	4.26	0.73
My anti-diabetic medicines protect me from becoming worse	4.11	0.887
My health in the future will depend on anti-diabetic medicines	3.86	1.099
My life would be impossible without anti-diabetic medicines	3.99	0.936

Possible scale range = 5-25. Total scale score (mean ±SD) = 20.3±3.3. Range 10-25. Cronbach’s alpha = 0.78

**Adherence to prescribed medication:**

The findings into the medication adherence of the study participants indicated a mean MMAS score of 4.9±2.3 indicative of low adherence (**Table 3**). The proportion of study participants who reported non-adherent behavior were 64.5% and 56.8% with regards to the questions, “Have you ever cut back or stopped taking your medication without telling your doctor because you felt worse when you took it?” and “Taking medication every day is a real inconvenience for some people? Do you ever feel

hassled about sticking to your anti-diabetes treatment plan?” respectively. Considering the overall MMAS scores, it was found that 79 (51.0%) of the study participants had a total score of 0-5classified as low adherence to their prescribed anti-diabetic medicines(**Fig.1**). This study also revealed that the Amharic version of the MMAS scale used for the present study to be have acceptable internal consistency with Cronbach’s alpha of 0.8.

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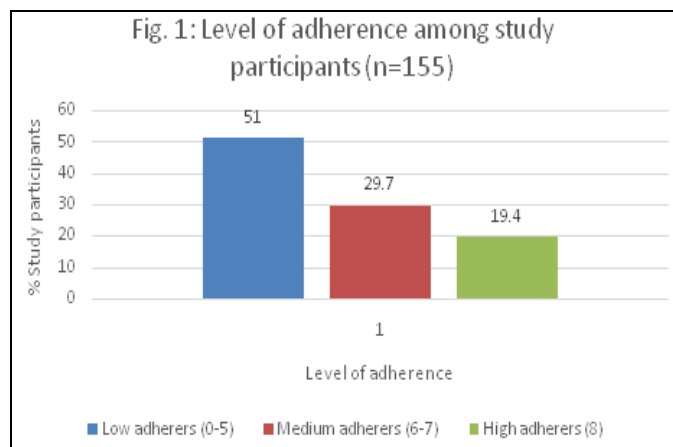
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**TABLE 3: MORISKY'S MEDICATION ADHERENCE SCALE FOR STUDY PARTICIPANTS (N=155)**

S. No	Morisky's medication adherence scale	Correct response <sup>a,b</sup>	N (%)
1	Do you sometimes forget to take your anti-diabetics medication? <sup>a</sup>	No	68 (43.9)
2	Over the past 2 weeks, were there any days when you did not take your anti-diabetics medication? <sup>a</sup>	No	103 (66.5)
3	Have you ever cut back or stopped taking your medication without telling your doctor because you felt worse when you took it? <sup>a</sup>	No	100 (64.5)
4	When you travel or leave home, do you sometimes forget to bring along your medications? <sup>a</sup>	No	89 (57.4)
5	Did you take your anti-diabetic medicine yesterday? <sup>a</sup>	Yes	143 (92.3)
6	When you feel like your diabetes is under control, do you sometimes stop taking your medicine? <sup>a</sup>	No	128 (82.6)
7	Taking medication every day is a real inconvenience for some people? Do you ever feel hassled about sticking to your anti-diabetes treatment plan? <sup>a</sup>	No	88 (56.8)
8	How often do you have difficulty remembering to take all your anti-diabetes medication? <sup>b</sup>	Never	42 (27.1)

<sup>a</sup>Possible response: yes/no; correct response = 1 point; incorrect response = 0 points

<sup>b</sup>Possible responses: never/rarely (1 point); once in a while, sometimes, usually, always (0 points). Possible scale range = 0-8. Total scale score (mean  $\pm$ SD) =  $4.9 \pm 2.3$ . Range 1-8. Cronbach's alpha = 0.803



**FIG.1: LEVEL OF ADHERENCE AMONG STUDY PARTICIPANTS (n=155)**

The linear multiple regression model showed two of the independent variables, sex and BMQ concern to be significant predictors of medication adherence (**Table 4**). Specifically, the variable of male sex and concern about medicines (BMQ – concern) were found to have a negative effect on patients' medication adherence.

**TABLE 4: ASSOCIATION BETWEEN SOCIO DEMOGRAPHIC VARIABLES, BELIEFS ABOUT MEDICINES AND MEDICATION ADHERENCE IN THE TOTAL SAMPLE**

Dependent variable	Independent variables	Beta	p-value
Medication adherence	Age	.033	.067
	Monthly income	.041	.819
	Religion	.005	.982
	Sex	1.085	.004*
	Family history	-.531	.174
	Work status	.003	.995
	Diabetes duration	.405	.101
	Education level	.152	.280
	Marital status	-.057	.725
	Mean of BMQS concerns	-.174	.008*
	Mean of BMQS necessity	-.052	.477

\*P value < 0.05

**DISCUSSION:** The findings revealed that the study participants had what can be considered low level of adherence with more than half (51%) reporting low adherence to their medications while 29.7% and 19.4% respectively were either

moderately adherent or highly adherent. The level of non-adherence reported in the present study is higher than the two studies reported from Ethiopia. One of the studies used the 8-item Morisky scale and reported low adherence for only 25.4% of the study participants and medium and high adherence respectively for 28.7% and 45.9% of the study participants<sup>10</sup>. This study also reported patients on noninsulin regimen to be more likely to report poor adherence. It was also evident from this study by Abebe et al (2014) that better glycemic control was achieved by those who reported better medication adherence which could serve as further support for the validity of the Morisky scale.

The other study which used the 4-item Morisky scale reported a 24.3% prevalence for low adherence<sup>11</sup>. This study further reported that medication non-adherence was highly likely to result in diabetes-related hospitalization. On the other hand, the adherence level in the present study is lower when compared to another study from India where 74% of the participants had poor adherence to the medication with a 3.57 mean score<sup>28</sup>. This study further reported that patients on oral hypoglycemic agents had poor adherence compared to their counterparts. The reports by Abebe et al (2014) and Sankar et al (2013) attributed the lower adherence level for those on oral therapy to the fact that this group of patients may be more likely to be asymptomatic and also consider the illness to be less serious than those on insulin. The lower adherence level reported in the present study where all participants were on oral hypoglycemic agents may be partly explained by this explanation.

According to the findings of this study, beliefs about safety concerns of anti-diabetic medicines and male sex were found to be significant predictors for non-adherence. The association of sex with adherence has in fact been found to be ambivalent in different studies with some associating it to better adherence, others such as the present one relating it to lower adherence and still no significant association in many of the studies<sup>29</sup>. According to the review made by Lin et al (2008), sex may not be a good predictor of adherence. Nevertheless, among studies that related sex to adherence is one reported locally from north-western Ethiopia which reported significant

association of the male sex with adherence to anti-hypertensive medication<sup>15</sup>. Plausible reasons for less adherence among males could be their being burdened with outdoor activities which could make them forget to take their medications and alcoholic drinking that is more common among the male.

With regards to the specific belief about study participants' perceptions on anti-diabetic medications, concern about safety of the medications was found to be a significant predictor for adherence as would be expected from the 'Necessity-Concerns Framework'<sup>25</sup>. Accordingly, the low levels of adherence to anti-diabetes medication could be partly explained by the concerns the study participants expressed towards their medications. It was however safety concern but not necessity beliefs that was found to predict the level of adherence to medications similar to other studies that reported significant association of concerns to medications with adherence<sup>30-32</sup>.

Specific belief about necessity for anti-diabetic medications was not a significant predictor for adherence despite the fact that the total scale score for belief about the necessity was higher compared to that about the concern and that would lead one to expect higher levels of adherence which was not the case. While there could be a number of reasons for these, one could be that patients may have concerns that go beyond side effects such as the unavailability of medicines in the health facilities or about the high cost of medications that may be indeed be concerns for this study participants as also reported in other studies including from Ethiopian settings<sup>5, 25</sup>. A couple of studies have also reported the presence of side effects and complexity of the regimen<sup>11</sup> and poor wealth status and dissatisfaction with clinic services<sup>10</sup> to associate with poor adherence to diabetes medications.

On the other hand, patients may have beliefs about the necessity of the medications that they may relate to perceived severity of their condition but may not believe that strict adherence is required especially when symptoms are absent<sup>5, 25</sup>. Such beliefs are not unexpected in this group of participants where most are of socio-economic status and thus besides being unable to afford the

cost of treatment. Most in relation may have low health literacy and low biomedical knowledge which may be further reason for research that explores and assesses about illness perceptions and their possible influence on medication adherence.

The findings of this study reveal about the important role that safety concerns have on patients' adherence to their medications. This would require the need for providers initially assess medication-related beliefs and address safety concerns that patients may have.

This may have to be done not only at the initial prescribing stage but also during the use by the patient to assess the occurrence of side-effects or any other concerns and address them. Given the low socio-economic status of the patients especially those treated in the public health facilities, affordability concerns and those related to the low health literacy may also have to be discussed on and addressed as part of efforts to improve adherence to recommended regimens. With regards to necessity to medications, assessment should be made in a more comprehensive manner that may go beyond the 'Necessity-Concerns Framework' and include issues related to the illness perceptions that may allow better understanding about patients' perceptions including on the timeline (acute/chronic nature) and symptom of diabetes.

#### **Strengths and limitations of the study:**

The strengths of the present study were use of contextually adopted standardized and translated questionnaire which can contribute for future studies. Limitations were smaller sample size and study setting in health centers in one part of the city only which could limit its representativeness. The cross-sectional study design of the method didn't allow for determination of the causal relationship between variables. Importantly, this being a health facility-based study and that in the public sector may not be representative for those not on regular medical follow-up and those following treatment in the private sector.

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