ADDIS ABABA UNIVERSITY

SCHOOL OF PHARMACY

COLLEGE OF HEALTH SCIENCES

DEPARTMENT OF PHARMACEUTICS AND SOCIAL PHARMACY

PREVALENCE OF DELAYED INITIATION OF INSULIN AND THE ASSOCIATED FACTORS AMONG PATIENTS WITH TYPE 2 DIABETES MELLITUS AT THE DIABETES CLINIC OF TIKUR ANBESSA SPECIALIZED HOSPITAL

BY:

ELHAM RESHID

July, 2017

Addis Ababa, Ethiopia

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A THESIS SUBMITTED TO THE SCHOOL OF GRADUATE STUDIES OF ADDIS ABABA UNIVERESITY IN PARTIAL FULFILLMENT OF THE REQUIREMENT FOR THE DEGREE OF MASTER OF SCIENCE IN PHARMACOEPIDEMIOLOGY AND SOCIAL PHARMACY

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This is to certify that the thesis prepared by Elham Reshid Jemal, entitled: Prevalence of Delayed Initiation of Insulin and the Associated Factors Among Patients with Type 2 Diabetes Mellitus at the Diabetes Clinic of Tikur Anbessa Specialized Hospital and submitted in partial fulfillment of the requirements for the Degree of Master of Science in Pharmacoepidemilogy and Social Pharmacy complies with the regulations of the University and meets the accepted standards with respect to originality and quality.

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LIST OF ACRONYMS AND ABBREVAITIONS

ADA	American Diabetes Association
BP	Blood Pressure
DAWN	Diabetes Attitude Wish and Need
DM	Diabetes Mellitus
EASD	European Association for the Study of Diabetes
EDA	Ethiopian Diabetes Association
FMHACA	Food Medicine Healthcare Administration and Control Authority
FPG	Fasting Plasma Glucose
Hg A1C	Hemoglobin A1C
IDF	International Diabetes Federation
MDI	Multiple Dose Injection
OAM	Oral Anti-hyperglycemic Medications
OGTT	Oral Glucose Tolerance Test
T2DM	Type 2 Diabetes Mellitus
TASH	Tikur Anbessa Specialized Hospital

GLOSSARY OF LOCAL TERMS

***Idir*:** A traditional social institution to support each other in times of need, in most cases funerals

***Iqub*:** A traditional saving institution

***Kebele*:** The smallest administrative structure of the country's political organization. It is currently being changed to *woreda*

***Woreda*:** It is a district which is an administrative division of an area.

ABSTRACT

Prevalence of Delayed initiation of insulin and its associated factors among patients with type 2 diabetes at the diabetes clinic of Tikur Anbessa Specialized Hospital.

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Introduction: Type 2 diabetes mellitus prevalence is much more common than type 1 diabetes where metformin remains to be the first line medication. However, it is recommended to initiate insulin when oral therapy fails which is inconsistent due to different factors to result in delay. Failure to achieve glycemic control due to delayed insulin initiation result in different complications. Both the prevalence and associated factors need to be studied to avoid complications. There is no such study conducted in the current setting as well.

Objectives: The aim of the study was to assess the prevalence of delayed insulin initiation among patients with type 2 diabetes being managed in the Diabetes Clinic of Tikur Anbessa Specialized Hospital and explore the associated factors.

Methods: Both quantitative and qualitative data were collected from January 1, 2017 to March 30, 2017 G.C. using data abstraction form and a semi structured interview guide, respectively. For the quantitative part, data entry and analysis was held using Epi Info and SPSS version 20 software's, respectively. Thematic analysis was used for the qualitative finding.

Result: The prevalence of delayed initiation of insulin in patients with type 2 diabetes mellitus at the diabetes clinic was found to be 64.2%. Contributing factors were identified. Patient factors included beliefs about the necessity of insulin and concerns related to starting insulin. Physician factors included perceived patient's situation regarding anticipated side effects and other patient factors and lack of clinical competency. Health institution factors included inadequate laboratory set up and absence of contextual guidelines for diabetes management including insulin initiation.

Conclusion and recommendations: The prevalence of delayed insulin initiation was found to be 64.2% and factors included patient, physician, and health institution. Solutions included strengthening the diabetes health education program and focusing on task shifting.

Key words: Delay in insulin initiation, Ethiopia, Tikur Anbessa Specialized Hospital, Type 2 Diabetes Mellitus

1. INTRODUCTION

Type 2 Diabetes Mellitus (T2DM) which accounts 90-95% of the population is a condition presented with limited production of insulin (relative insulin deficiency) coupled with an insulin resistance state where Oral Anti hyperglycemic Medication (OAMs) will be used as a first line therapy. Although metformin remains the first line agent, guidelines including the American Diabetes Association (ADA) recommend insulin therapy when glycemic control is inadequate with OAMs (ADA, 2017). However, the time to initiation of insulin remains inconsistent owing, in large part, to patient, and healthcare provider factors which presents both behavioral (lifestyle) and therapeutic challenge to timely initiation of insulin in those patients (Owens, 2013).

According to the International Diabetes Federation (IDF) report, Ethiopia is among the most populous sub-Saharan African countries standing only fourth by the number of diabetic population in the region with an estimated national prevalence rate of 2.9% in 2015. T2DM is the commonest type in the country which were being diagnosed and treated with in different health sectors of the country (IDF, 2015).

The diabetes clinic at Tikur Anbessa Specialized Hospital (TASH) is the biggest well-organized diabetes clinic in the country which runs on its own separate building staffed by several endocrinologist and endocrinology fellows. Based on the available evidences, there was no such study conducted at the clinic setting on the same subject matter and the study is the first one to be conducted in its kind. Considering this, both quantitative and qualitative study was conducted in the current study setting with the aim of assessing the prevalence of delayed insulin initiation and factors associated with it in patients with type 2 diabetes.

1.1. BACKGROUND

According to the definition by the ADA, Diabetes Mellitus (DM) is defined as a group of metabolic diseases characterized by high level of glucose in the blood as a result of flaws in insulin secretion, insulin action, or both. Mainly, there are four types of diabetes; type 1 DM, T2DM, gestational DM, and specific types of diabetes due to other causes. The difference between the first two lies over the fact that there is complete destruction of beta cells in the

former while there is a limited beta cell function from the latter one. The pancreatic beta cells in the islets of Langerhans are responsible for the secretion of insulin (ADA, 2017).

Different measures were used to assess the level of blood glucose in the body and hence, diabetes. Diabetes may be diagnosed based on plasma glucose criteria; either the fasting plasma glucose (FPG) or the 2-hr plasma glucose value after a 75-g oral glucose tolerance test (OGTT) or on the Hemoglobin A1C (Hg A1C) criteria. The Hg A1C has several advantages over the FPG and OGTT, including greater convenience (fasting not required), greater pre-analytical stability, and less day-to-day perturbations during stress and illness which is balanced by its greater cost and limited availability in developing countries. The A1C level of $\geq$6% and a FPG test of $\geq$126 mg/dl [7.0 mmol/L] are considered to be diagnostics of DM (ADA, 2017).In 2012, the ADA in conjunction with the European Association for the Study of Diabetes (EASD), suggested less stringent goals for HgA1c levels (7.5% to 8.0%) for patients with a history of severe hypoglycemia, a limited life expectancy, advanced complications, or extensive comorbid conditions, or for those who have difficulty attaining glycemic control (Owens, 2013).

Management of T2DM consists of interventions designed to involve the physical activity levels and food intake of an individual. However, current treatment recommendations now also include initiation of pharmacotherapy at the time of diagnosis (Inzucchi. *et al*., 2012). Metformin remains to be the most widely used first-line therapy (ADA, 2017). However, depending on the agent used and the baseline A1C level, the A1C will decrease by about 0.5% to 1.5% with monotherapy (Petznick, 2011). With timely adjustments and/or addition of OAMs, the target A1C level should be attainable within three to six months. However, when glycemic control is not achieved with maximum recommended or tolerated doses, the ADA and the EASD recommend initiation of insulin therapy to prevent microvascular and macrovascular complications (Nathan. *et al.,* 2009). Initiation of insulin should also be considered in patients with newly diagnosed type 2 diabetes who are symptomatic and/or have A1C $\geq$10% and/or FPG level$\geq$300 mg/dL (ADA, 2017).

In patients with T2DM, the treatment goal is to preserve the degeneration of beta cells for better glycemic control. Insulin resistance, glucotoxicity, lipotoxicity, inflammation, and obesity are the known factors that are thought to promote beta cell loss. Thus, insulin has been known for

nearly 40 years to improve beta cell function as determined by an enhanced insulin response to glucose (Lovre and Fonseca, 2015). Furthermore, suppression of hepatic glucose production was observed with insulin therapy, resulting in near normalization of basal hepatic glucose production (Petznick, 2013).

Insulin has also shown a better result over other OAMs considering glycemic control and prevention of microvascular complication. In a study done on 39 patients given intensive insulin therapy using Multiple Daily Injections (MDI) over 2–3 weeks resulted in 44% of people maintaining glycemic control for up to 1 year with diet therapy alone. When MDI was compared with treatment with OAMs over 12 months, improvements in HgA1c levels and higher proportions of individuals achieving HbA1c targets were observed with the intensive MDI insulin therapy (Chen. *et al*., 2008).

Another recent study, by Harrison *et al*., conducted on 58 treatment-naive individuals with newly diagnosed T2DM, demonstrated the long-term benefits of early intensive therapy with premixed insulin on beta cell function. Following initial treatment with insulin plus metformin for 3 months, beta cell function was preserved for 3.5 years, regardless of whether subjects continued treatment with insulin plus metformin or switched to triple oral therapy with metformin, glyburide, and pioglitazone (Harrison. *et al*., 2012).

On the contrary, poorly controlled DM is known to result in serious complications affecting several vital organs and systems. The diverse diabetes related complications could be microvascular diseases including retinopathy, nephropathy, neuropathy or macrovascular diseases including coronary artery disease, cerebrovascular disease, peripheral artery disease, and other complications such as psychosocial problems and dental diseases (ADA, 2017).

1.2. STATEMENT OF THE PROBLEM

Diabetes Mellitus is one of the most common non communicable diseases affecting a significant number of populations throughout the world (ADA, 2017). According to IDF report, approximately five million people aged between 20 and 79 years died from diabetes in 2015 which is equivalent to one death every six seconds and higher than the combined number of deaths from the infectious diseases (1.5 million deaths from HIV/AIDS, 1.5 million from

tuberculosis and 0.6 million from malaria in 2013). DM has also become a major health problem of public health importance in developing countries which resulted from the combined effect of globalization and epidemiological transition among others (IDF, 2015).

In Africa, an estimated 14.2 million adults aged 20-79 years have diabetes representing regional prevalence of 2.1-6.7%. Ethiopia is among African countries with the highest numbers of people with diabetes standing fourth position. The prevalence of diabetes was estimated to be 2% in the year 2010 which has reached 2.9% in 2015 (IDF, 2015). However, the researches done in different parts of the country reveal a higher prevalence. A study done by Addis Continental Institute of Public Health in 2010 at the employees of the Commercial Bank of Ethiopia and teachers in public schools found a prevalence rate of 4.5%. A research done at the north western part of Ethiopia also showed a prevalence of 5.1% and 2.1 % for urban and rural dwellers, respectively (Abebe. *et al.,* 2014). The predominant type of DM in Ethiopia (and the TASH) is T2DM similar to the overall global picture (Gizaw. *et al*., 2015; Owens, 2013).

Although metformin remains to be the first line therapy for T2DM, guidelines recommend initiation of insulin whenever there is an uncontrolled glycemic level on optimal OAM therapy (ADA, 2017). However, the time to introduction of insulin remains to be contentious and inconsistent pertaining to different factors as patient, physician, and health institution factors. The overall clinical goal in managing T2DM is related to maintaining the blood glucose level as nearly normal as possible. Thus, failure to achieve glycemic control in those patients with failure of commencing timely insulin will result in different diabetes related complications (Lovre and Fonseca, 2015).

Accordingly, delay in insulin therapy was reported to result in compromised control of blood glucose level in which hyperglycemia is a major predictor of the development of diabetes late complications of both microvascular and macrovascular events (Owens, 2013). Evidence shows that nearly one-third of Ethiopian patients with diabetes face one or the other form of acute complications and approximately half face at least one chronic complication. According to a systematic review conducted in Ethiopia, the prevalence of neuropathy, retinopathy, and nephropathy was estimated to be approximately 35%, 25%, and 15%, respectively (Nigatu, 2012).

In a similar study at TASH (current study setting), it was found that the main causes of admission for T2DM were diabetic foot ulcer (39%) and cardiovascular disease (21%). Hypertension, neuropathy, nephropathy, retinopathy and diabetic foot ulcers accounted for 85% of the 756 existing complications. Overall inpatient mortality was 21% and of the 89 deaths, 77 occurred in patients with type 2 diabetes (Gizaw. *et al*., 2015). This shows the extent of the problem in the study setting which was also reported worldwide. According to a report by IDF, the global health expenditure to prevent and treat diabetes and its complications was estimated to range from $673 billion to $1,197 billion in 2015 and is extrapolated to exceed $ 802 billion to $1,452 billion in today's dollar by 2040 (IDF, 2015).

Tikur Anbessa Specialized Hospital is an important part of Ethiopia's health system and provides complex curative care and is considered as the highest referral medical care facility in the country (TASH, 2015). Under the hospital is the biggest well-organized diabetes clinic in the country which runs on its own separate building staffed by several endocrinologist and endocrinology fellows. To the best of evidences at hand, however, there was no study done in Ethiopia or the hospital, particularly at the diabetes clinic of TASH regarding the prevalence of delayed initiation of insulin and associated factors in patients with T2DM.

1.3. RATIONALE OF THE RESEARCH

The aim of advocating timely initiation of insulin is to have glycemic control and decrease diverse microvascular and macrovascular complications. Estimating the prevalence of delayed initiation and exploring the factors will help to cut short the consequences from those complications which are burden to the patient with regard to morbidity and health costs. And, the impact of such studies is tremendous in resource limited countries like Ethiopia to have a cost effective health care system.

Thus, the current study will help to capture modifiable factors which can be intervened accordingly to help strengthen patient outcome in the clinic or in the country in general. Moreover, the output of the study will further serve as a reference for auxiliary relevant studies.

1.4. LITERATURE REVIEW

1.4.1. PREVALENCE OF DELAYED INITIATION OF INSULIN

The prevalence of delayed initiation of insulin due to patient's refusal has been increasing from time to time as shown by different research works. According to a research done in Malaysia, the prevalence of insulin therapy refusal was found to be 74.2% from the response taken from 461 patients (Tan. *et al.,* 2015). Similarly, there was a research done across eight western nations (France, Germany, United Kingdom, Italy, the Netherlands, Spain, Sweden, and the United States of America) to assess patient's willingness to commence insulin therapy. It was found that a total of 17.2% reported they would be unwilling to start insulin (the Psychological resistance group), while 34.7% were ambivalent and 48.1% indicated they would be willing to do so. There were marked differences by country with insulin resistance ranging from 5.9% (Spain) to 37.3% (Italy) (Polonsky. *et al*., 2011). This findings were supported by other researches where refusal to insulin therapy by patients were found to be 42.5% and 28.2% in the studies done in Bangladeshi patients in East London and in some American states, respectively (Polosky. *et al.,* 2005; Khan. *et al.,* 2008).

1.4.2. FACTORS ASSOCIATED WITH DELAYED INITIATION OF INSULIN

Because of the progressive nature of T2DM, there is a gradual decline in the effectiveness of OAMs over time, reflecting an ongoing attenuation in insulin secretary function. However, different factors contribute to delayed initiation of insulin and these factors are usually patient and/or physician related and sometimes health institution related (Peyrot. *et al.,*2005; Peyrot *et al.,*2010; Owens, 2013).

Interpersonal communication between patient and physician was found to be one of the main determinants (Funnell, 2006; Tan. *et al*., 2011; Owens, 2013). One of the researches which determined the quality of medical relationships between healthcare providers and patients, large majority of patients (88.8%) rated the quality of their relationships with their providers as good. Most health care providers, however, reported that they needed a better understanding of the psychosocial consequences of diabetes (69.8%) and the various ethnic cultures with whom they

work (78.8%). Better patient-provider collaboration was associated with more favorable ratings on all outcomes including fewer complications (Funnell, 2006).

Healthcare provider's factors were also found to be different as reviewed from distinct literatures done on the topic to describe physician's inertia (Peyrot. *et al*., 2010; Polonsky. *et al*., 2011; Lee. *et al*., 2012). Accordingly, it was found that physician's failure to initiate insulin therapy was partly attributed to the perceived concerns of patients, including the development of hypoglycemia and the pain associated with both injections and blood tests (Haque. *et al.,* 2005; Polinski. *et al.,*2013); however, one of the data showed that only less than 20% of patients are truly unwilling to start insulin therapy (Polonsky. *et al*., 2011).

In addition, healthcare providers show negative attitudes towards insulin therapy and the 'legacy effect' of old insulin guidelines also prevails (Lee. *et al*., 2012). Thus, healthcare provider's attitude along with the experience with insulin therapy is a possible factor for delayed initiation of insulin (Peyrot. *et al.,* 2005; Peyrot. *et al*., 2010; Tan. *et al*., 2011). According to one study, the different experience level of healthcare providers is one factor where 43.4% of the healthcare providers preferred to delay initiation of medications until absolutely necessary, but specialists and opinion leaders were less likely than nurses and general practitioners to delay insulin (Peyrot. *et al*., 2010). Lack of knowledge and experience with the use of guidelines related to insulin therapy between physician and patients also contribute to delayed initiation of insulin (Haque. *et al.,* 2005; Ng. *et al.,*2015).

On the other side, patient factors to delayed insulin commencement includes refusal to acknowledge the need for insulin therapy, its perception as a social stigma, an inconvenient mode of treatment or punishment for failure, fear of needles, side effects and complications, negative impact on social life and job, low efficacy of insulin, and reliance on others to take insulin (Polosky. *et al.,* 2005; Peyrot. *et al.,* 2005; Khan. *et al.,* 2008; Karter. *et al.,* 2010; Tan. *et al*., 2011; Ng. *et al.,*2015).Thus, patients are highly hesitant to start insulin therapy even if they require it (Polosky. *et al.,* 2005; Peyrot.*et al*., 2010). In the Diabetes Awareness Wishes and Needs (DAWN) survey also, almost half of the patients believed that they were given insulin therapy because they had somehow "failed", and they believed that the insulin therapy was their punishment. Socioeconomic problem by the patient is also another factor (Haque. *et al.,* 2005).

Moreover, patients' factors includes culture-specific barriers such as the religious purity of insulin, preferred use of complementary medication and perceived lethality of insulin therapy (Khan. *et al.*, 2008; Karter. *et al*., 2010; Lee. *et al*., 2012). There is also a concern over the permanence of insulin therapy, that once it has been initiated the patient will remain on insulin for life. Some people with diabetes think that initiation of insulin denotes a "worsening" of their condition and that they have somehow failed in managing the disease (Peyrot. *et al.*, 2005; Polosky. *et al.*, 2005; Kunt and Snoek, 2009).

The above factors are also described in a quantitative study from other researches below. Among non-adherent patients (prescribed with insulin but not dispensed or refused), the most commonly cited reasons for failing to initiate insulin included patients plan to change health behaviors instead of starting insulin (25%), injection phobia (13%), negative impact on work (9%), concerns about long-term medication use (9%), inconvenience (6%), and not believing insulin was needed (6%). Patients refused to start insulin therapy believed that taking insulin can cause blindness (20%), renal failure (32%), amputations (15%), heart attacks or strokes (19%), and early death (19%) (Karter. *et al*., 2010).

Patients also rated the efficacy of insulin therapy as low, with only 26.9% of those not taking insulin reporting that insulin would help them to manage their diabetes better (Funnell, 2006).

According to Haque et al and Ng et al, however, health institution factors for delayed initiation of insulin includes time barrier (long appointment periods), financial constraints, lack of health educational materials, accessibility of insulin, lack of continuity of care, and language barriers (Haque. *et al.*, 2005; Ng. *et al.*,2015).

Although all factors have its own contribution to delayed initiation of insulin, sometimes the relationship among these factors is what plays a major role. Lack of guideline in the institution, for instance, might not have a direct effect on delayed initiation of insulin but the fact that the physician do not have a uniform guideline result in postponed decision and thus, delay. The presence of legacy effect of insulin guideline will also have an impact on the physician resisting proper changes to timely initiation of insulin (Ng. *et al.*,2015). On the same token, the fact that the physician does not communicate well on the course of the disease and the inevitable need for insulin is a problem since the patient could not understand the necessity of insulin and refuses

insulin therapy (Funnell, 2006; Ng. *et al.*,2015). Perceived patient concern by the physician is also one factor for the physician to postpone and delay insulin therapy (Polinski. *et al.*,2013). Likewise, lack of continuity of care in the same could be a factor to refuse insulin by patients due to lack of trust they acquired from visiting different physicians at different appointments (Ng. *et al.*,2015).

1.4.3. SUMMARY

The earlier studies done to assess prevalence on the same topics (Polosky. *et al.*, 2005; Khan. *et al.*, 2008; Polonsky. *et al*., 2011; Tan. *et al.*, 2015) focused on examining patient refusal or patient's psychological resistance to insulin therapy. However, the current study examined the prevalence of delayed initiation of insulin which could be due to the patient, the physician inertia, or the health institution factor. Thus, the present study aimed on focusing on a relatively broader topic which was the overall prevalence of delayed initiation of insulin at the study setting.

As explained earlier, factors associated with delayed initiation of insulin were also a collection of patient, healthcare providers, and health institutions factors (Peyrot. *et al*., 2010; Polonsky. *et al*., 2011; Lee. *et al*., 2012; Ng. *et al.*, 2015). Some of the factors are directly linked to the insulin delay but some factors have indirect relationships as elucidated in earlier studies (Tan. *et al*., 2011; Ng. *et al.*, 2015). Though these factors are multifarious, they are unique to each clinical setting which needs separate study. There is a gap of such study in the Ethiopia and the current study setting was considered to fill up this gap.

1.5. CONCEPTUAL FRAMEWORK

As illustrated in the figure below, factors associated with delayed initiation of insulin were a collection of patient, healthcare providers, and health institutions factor (Polonsky. *et al*., 2011; Lee. *et al*., 2012; Peyrot. *et al*., 2010; Ng. *et al.*, 2015). Individual or a linked association between different factors contributes to delayed initiation of insulin (Tan. *et al*., 2011; Ng. *et al.*, 2015).

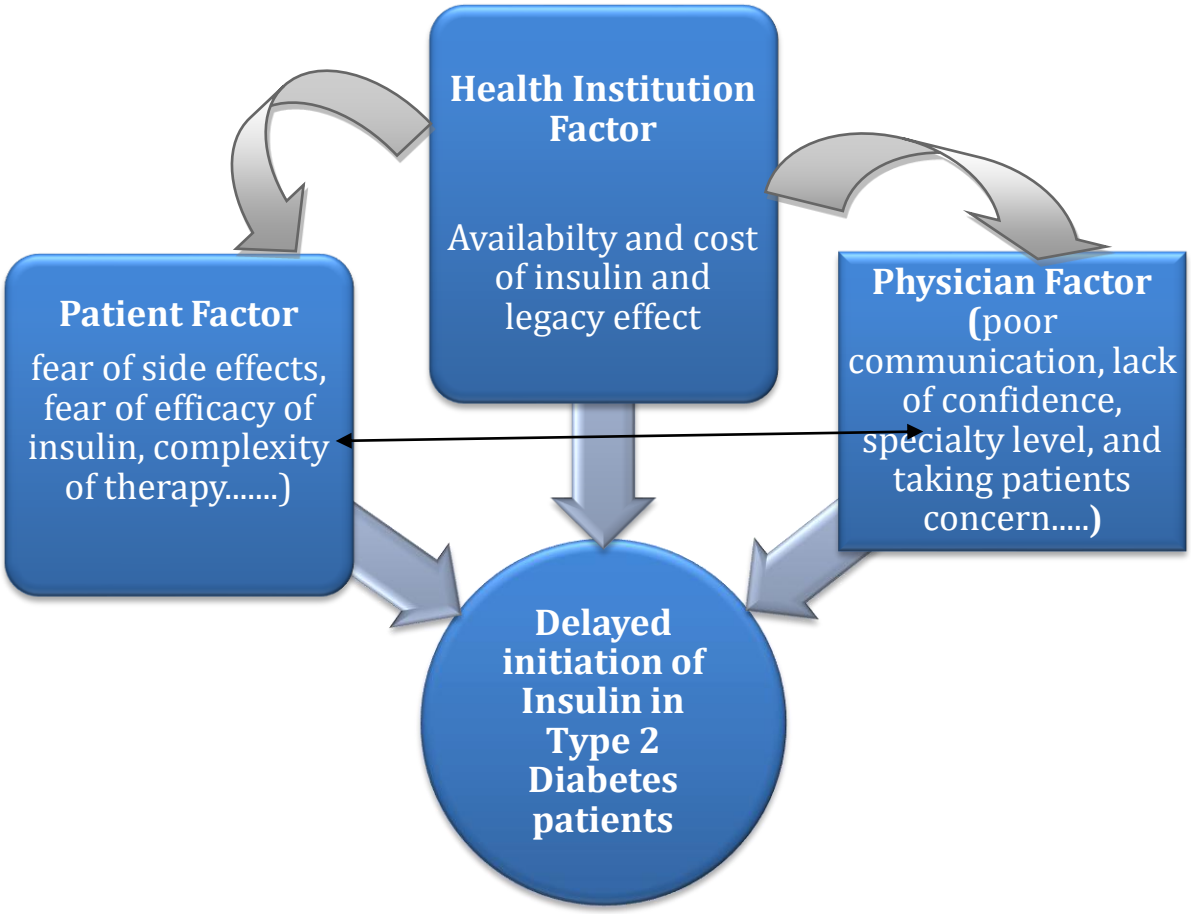

Figure 1: Conceptual Framework of the study

2. OBJECTIVES OF THE STUDY

2.1. GENERAL OBJECTIVE

- To assess the prevalence of delayed initiation of insulin and identify factors related to it among patients with T2DM at the diabetes clinic of TASH, Addis Ababa, Ethiopia.

2.2. SPECIFIC OBJECTIVES

- To determine the prevalence of delayed initiation of insulin in patients with T2DM at the diabetes clinic of TASH, Addis Ababa, Ethiopia.
- To explore factors associated with delayed insulin initiation in patients with T2DM at the diabetes clinic of TASH, Addis Ababa, Ethiopia.

3. METHODS

3.1. STUDY SETTING AND STUDY PERIOD

Data was collected from January 1, 2017 to March 30, 2017 at the card room (Outpatient department) and diabetes clinic of TASH. TASH is a teaching hospital of Addis Ababa University under the College of Health Sciences which started providing services starting from around 1973. Originally it was built to accommodate 500 beds and currently has more than 600 beds (TASH, 2015).

The hospital is an important part of Ethiopia's health system and provides complex curative care and is considered as the highest referral medical care facility in the country. The hospital has more than 1700 medical and non-medical staff and offers inpatient, outpatient and emergency services in about 20 specialty clinics and units (TASH, 2015).

TASH serves about 250,000 patients per year in its outpatient department and about 24,000 in the inpatient and emergency departments. Recently, the hospital has reorganized its services in to seven core services; one of which is the outpatient service (TASH, 2015).

The diabetic clinic serving only the outpatient wing was first established in 1994. It gives service to patients with diabetes (both adult and pediatric), acute and chronic diabetes complications, and other endocrine disorders. It provides service to around on average 340 patients per week. Its clinical staffs include five senior physicians/consultants (endocrinologists), two internists attending endocrinology fellowship program, five residents in the Internal Medicine specialty program who are entrusted to take the primary role in managing patients while serving their month long attachment, and five nurses. There is a pharmacy at the clinic which constituted three pharmacists (P.C, 2016).

3.2. STUDY DESIGN

This research employed a mixed but sequential explanatory study design. For the quantitative study, a cross sectional study design was conducted where patients chart was reviewed retrospectively through the data collection period (January 1- March 30, 2017) to obtain the prevalence of delayed initiation of insulin. In addition, a qualitative interview approach was

employed using semi structured interview guides with flexible probing techniques to explore factors associated with delayed initiation of insulin at the current study setting.

3.3. SOURCE AND STUDY POPULATION, SAMPLING, AND ELIGIBILITY CRITERIA

3.3.1. SOURCE AND STUDY POPULATION

The source population for both quantitative and qualitative study was patients with type 2 diabetes aged 18 and above of both sexes who were being followed at the diabetes clinic of TASH from the year 2001 E.C.

The study populations for the quantitative part was patients with type 2 diabetes aged 18 and above of both sexes who were being followed in the study period at the outpatient diabetes clinic of TASH.

For the qualitative part, physicians (endocrinologists and internists attending the endocrinology fellowship program and selected residents), nurses, and pharmacists working in the diabetes clinic at the time of data collection were included to gather health care providers' and health institution factors. Patients' who initiated insulin albeit late or refused to start the medication (insulin) were involved in the study to identify patient and health institution related factors.

3.3.2. SAMPLING AND SAMPLE SIZE

Quantitative study

The sample size for the study was determined using single proportion population sample size formula. With the absence of data on the prevalence of delayed initiation of insulin, an estimate prevalence of 50% was used for the current study. Thus, the P value used in the calculation was 0.5 with a margin of error of 5%.

$$n = \frac{(1.96)^2 \times (0.50\ (1-0.50))}{(0.05)^2} = 385$$

The sample size needed based on the calculation was 385. The data collection was conducted consecutively until the sample size was reached.

Qualitative study

The study employed purposive sampling method. Patients who have had a history of delayed initiation of insulin at the diabetes clinic were purposively selected by reviewing their chart to be included in the study. Both patients who already started and yet not shifted to insulin, fifteen in number, were included in the study. The interview continued until point of saturation where new data provide no further points in reference to the research objectives and the available literatures. At first, saturation was reached with interviewing twelve patients but three more patients were added to see if any new data can be established. However, there was no new finding and the interview was finalized with the fifteenth patient. In addition, senior physicians, pharmacists and nurses were interviewed as key informants. Pharmacists with a prolonged experiences at the outpatient pharmacies and the clinic were selected out for interview. In general, three endocrinologists, two internists attending the endocrinology fellowship program, two pharmacists, and three nurses from the diabetic clinic were interviewed. To gather responses from the perspective of junior doctors, two senior residents working at the diabetes clinic were also interviewed.

3.3.3. ELIGIBILITY CRITERIA

All type 2 diabetes patients aged 18 and above who were on follow up with oral medications at the diabetic clinics and switched to insulin or supposed to switch to insulin during the study period were included in the study.

The study excluded patient charts with incomplete information regarding their oral hypoglycemic medications and their insulin initiation status. Patients with a history of gestational diabetes were also excluded.

Patients who were healthcare providers were not included in the study as it may impart information bias to the study. Responses from patient healthcare providers was assumed to be different and sharpened positively due to their presence at the service area in contrary to the other interviewed patients. Patients who were unable to provide information due to medical

conditions or others were excluded from the study. Those patients and healthcare providers who were unwilling and those patients who could not speak Amharic but other native language were also excluded from the interview.

3.4. DATA COLLECTION PROCEDURE

3.4.1. DATA COLLECTION INSTRUMENTS

Quantitative Study

For the quantitative study, a data abstraction form was employed (Annex III). The form included different questions to obtain the presence of delayed initiation of insulin, socio-demographic profiles and clinical information of the participants with delayed initiation of insulin.

Qualitative Study

A semi-structured interview guide was used to conduct the qualitative study (Annex-I). The consent form and the interview questions were translated to the local language (Amharic) by the principal investigator (Annex-II) to make it convenient to the patient and back translated to English to ensure the consistency of the questions. Back translation was done by colleagues under the field of Pharmacy and Medical Doctor. Thus, local language (Amharic) was used to interview all participants to have a uniform and convenient response from all healthcare professionals and patients. The interview guide had two sections for which the first included questions about the socio-demographic and background profile of the study participants while the second one included questions on factors related to delayed initiation of insulin. It included questions to select out factors from the patient, physician, and health institution and explore the interpersonal communication approach between the patient and the physician.

3.4.2. DATA COLLECTION PROCEDURE

Quantitative study

The data collection procedure started with selecting out patient's chart numbers recorded in the health management information system record of the diabetes clinic. Selected patient card numbers were given to the assigned person at the outpatient department card room of the

hospital. Thus, data was collected at the card room by the principal investigator through reviewing patients' chart retrospectively during the data collection period. In addition, patient charts that were available at the diabetes clinic when the patient comes on their appointment date were reviewed. After data collection, each data collected was checked on the day of the data collection for completeness of information. Moreover, data quality was checked up for completeness before data entry.

Qualitative study

Data was collected through interviewing patients and healthcare providers at interviewee's convenient place which was outside the diabetes clinic/hospital for most of them. The interview was held in Amharic to better comprehend the responses. The interview was audio taped and field notes were taken at each session as a reference for the transcription. The responsible person for data collection and transcription was the principal investigator.

3.5. DATA ENTRY AND ANALYSIS

For the quantitative study, each questionnaire form was checked for completeness and codes were given during data collection. Data entry and analysis was made using Epi info version 7 and SPSS version 20 software's, respectively. Descriptive analysis was employed to assess the prevalence and characterize patients with delayed initiation of insulin.

However, the qualitative study first accompanied a process of preliminary analysis to get a sense of the collected data through transcription and translation. Accordingly, the preliminary data from the audiotape and field notes which were in Amharic was transcribed. Sections of original transcripts and key quotes which were considered to be illustrative of the emerging themes were translated to English to facilitate discussion with the full research team. However, the process of data collection, transcription, and analysis was done simultaneously to allow a room for flexibility of the interview questions and hence, point of saturation. Finally, the data was analyzed using thematic analysis approach (Virginia and Victoria, 2006). At first, open coding was followed where each distinct code was developed into subthemes and then themes considering the research objectives. While developing in this procedure of open coding at the beginning and later to themes, supervisors and other colleagues were approached for discussion.

However, previous research works (Tan. *et al*., 2011; Ng. *et al.,* 2015) were reviewed and applied as a reference while rearranging subthemes under themes.

3.6. QUALITY ASSURANCE METHODS

Quantitative study

A pre-test was done by the principal investigator at the diabetes clinic on patients with diabetes of age 18 and above who are eligible for the study to modify and ensure the validity of the questionnaire from selected thirty patient charts. After the pre-test, certain modifications considering the information on patient chart were made to the instrument. The modification included physician's recommendation as one question in the data collection tool which was observed from some patient charts. In addition, delayed initiation of insulin was checked considering three consecutive visits to the diabetes clinic but how frequent and in what gap those three visits should be was defined later after the pre-test. Thus, a minimum of six month duration was considered after that.

Qualitative Study

To ensure validity of data gathered, different data collection methods were applied as a triangulation mechanism. Data collected through both quantitative and qualitative methods were cross checked. After data collection, the validity was first checked through member checking where the preliminary analysis from the data collected was shared to some proportion of the study participants. Preliminary findings were made available to three physicians, one nurse and five patients. The findings that were disseminated to the healthcare professionals were brought back after feedback. However, the findings from the patient were discussed in person to agree on the responses. In doing so, the accurateness in disseminating the information gathered was validated. Accordingly, corrections were made taking the responses into account. The themes were also put to discussion among investigators of different background. The research included a physician and academicians as investigators in addition to the main researcher.

Employing reflexivity in this study, clarifying the researcher's position, any biases that might impact the overall design, collection, analysis, and interpretation of the study have been clearly

stated. Further, to ensure reliability, the research obtained a detailed field note by employing a good quality tape for recording and by transcribing the tape.

3.7. ETHICAL CONSIDERATIONS

Approval to conduct the current research was obtained from Addis Ababa University, School of Pharmacy Ethics Review Committee. An official letter from School of Pharmacy, Department of Pharmaceutics and Social Pharmacy was also written to the Head of Department of Internal Medicine where the diabetes clinic is housed to obtain support during data collection. The research protocol was also approved by the Ethics Review Committee of Internal Medicine Department.

Before data collection, all participants were provided with information regarding the purpose of the study and what is expected from them. They were informed that participation is voluntary and withdrawal from the study at any point is possible. Participants were assured of anonymity and that their answers would remain confidential. They were also reassured that the report of the findings would not identify them and only the aggregate data would be reported. Finally informed oral consent was taken from every participant. The audio record from the interview remained only in the hands of the principal investigator.

3.8. OPERATIONAL DEFINITIONS

Diagnostic Criteria: FPG level was used as a diagnostic criterion for delayed initiation of insulin considering it was the only option for the current setting.

Delayed initiation of insulin: It includes patients who were on maximum dose of two OAMs and failed to achieve optimum FPG level but not prescribed with insulin (ADA, 2017) after three consecutive visits to the clinic of a minimum of six month duration. Or patients who refused to take when prescribed in the third visit.

Maximum dose of OAMs: The maximum dose taken for glibenclamide and metformin was 20 mg and 2000 mg a day, respectively (ADA, 2017).

Average FPG or Blood Pressure (BP): It specifies the average of the three consecutive visits of a minimum of six month duration at the time of delayed initiation of insulin.

BP measurement classification: The classification is based on the eighth Joint National Committee (JNC) where patients are classified into BP measurements under 140/90mmHg and over 140/90mmHg (James. *et al.*, 2014).

Co-morbid/ Complications and concurrent medications: It specifies the medical condition or concurrent medications that were used at the time of delayed initiation of insulin.

3.9. RESEARCHER'S POSITION AND REFLEXIVITY

Stating researcher's position and reflexivity is crucial in understanding the epistemological and personal conviction of the individual researcher, which in turn influences the research finding (Hsiung, 2008). In doing so, the following circumstances are believed to have had an impact on the research, though utmost care has been taken to avoid any bias that may have resulted from this.

The research being a healthcare provider, a pharmacist, has been seen both as an opportunity and impediment in the research. The researcher was working previously as a pharmacist at the drug information center of TASH. This may have imparted effect on the research as the researcher might unknowingly overlooked some health institution factors in the overall process of the research. However, being a previous employee provided an already established network of informants, health care providers where communication was smooth as a result. On the contrary, additional effort was required from the researcher to understand patient's view and experiences. The researcher is currently a pharmacist at the drug information center of a chain community pharmacy doing her Master's degree. Nonetheless, patients were, in some cases, willing to share their secret and provide detailed explanation on their situation with the expectation that the pharmacist would give them a solution. Knowing that the researcher was a pharmacist (the researcher first approached as a student doing her Master's degree but some insisted on knowing the profession) and not a physician enabled patients to discuss on their reservations towards the therapy and physicians' communication with them. Most participants had questions regarding the research and other factors in which they showed interest to discuss on their social life requirements and stresses they have back at home, mentioning its effect on the disease's status. For some, the interview presented a dialogue about their illness and medication. Some patient's used the chance to talk about their concerns and complaints, thinking the researcher have a

medical background. However, all of the responses were made after the interview was completed in order not to create bias to the study findings.

In designing the research, the researcher's inadequate training in qualitative research method had been difficult to come around. The researcher only took a course which covered introduction to qualitative study design and methods as part of fulfilling the Master's program from Addis Ababa University, School of Pharmacy. To minimize its impact on the overall research design, the researcher had to extensively explore and familiarize herself to the concept of qualitative research. In the process of data collection, the researcher assessed interview guides used and screened out questions which were vague, inappropriate, and senseless to some of the participants. Thus, it was important to revise and modify the interview guides.

The researcher is female and Amharic speaker, which also had an impact, among other factors, on data collection. While this created a common ground for some to discuss freely in interviews, others distanced themselves in discussing of their situation. Female patients were more open to discuss in details about their social activities. Study participants who did not speak Amharic were not included in the study for reasons of communication barriers.

4. RESEARCH FINDINGS

4.1. PREVALENCE OF DELAYED INITIATION OF INSULIN AND CHARACTERISTICS' OF THE PATIENTS

A total of 385 patient charts were reviewed to assess the prevalence of delayed initiation of insulin in patients with type 2 diabetes at the diabetic clinic of TASH. Among these, 247 (64.2%) of them were found to have delayed initiation of insulin in their course of treatment. Those patients were left with a combination of OAMs of maximum dose despite not achieving optimum FPG levels when they should have been shifted to insulin therapy.

Out of those with delayed initiation of insulin, 142 (57.5%) patients were female with the majority 213 (86.2%) of the patients residing in Addis Ababa. The mean age of those with delayed initiation of insulin was found to be 52±10.80 years with the majority 79 (32%) of the patients aged 46-55 years. The average of the three consecutive measurements of FPG at the time of delay among the majority 113 (45.7%) of the patients were found to be in the range of 181-230 mg/dl. The mean FPG measurement was found to be 215±44.15mg/dl. The BP measurements of majority 162 (65.6%) of patients with delayed initiation of insulin were found to be below 140/90mmHg (See table 8.1).

The study also found that hypertension 143 (57.9%) and dyslipidemia 58 (23.5%) to be the major comorbid conditions prevalent among patients with delayed initiation of insulin, followed by neuropathy 39 (15.8%) and retinopathy 28 (11.3%) (Figure 1). Accordingly, majority of the patient with delayed initiation of insulin were found to use cardiovascular medicines under the category of angiotensin converting enzyme inhibitors 111 (44.9%), statins 86 (34.8%), anti-platelet agent 73 (29.6%), calcium channel blockers 40 (16.2%), diuretics 36 (14.6%), and beta blockers 25 (10.1%) (Table 8.2).

Table 8.1: Socio-demographic characteristics and FPG and BP measurements in patients with delayed initiation of insulin at the diabetic clinic of TASH, Addis Ababa, Ethiopia, 2017 (N=247)

Variables		N (%)	Mean ± Standard Deviation (Range)
Sex	Male	105 (42.5%)	
	Female	142 (57.5%)	
Age Group	35-45 years	78 (31.6%)	52.2 ±10.80 years
	46-55 years	79 (32%)	(35-83 years)
	56-65 years	62 (25.1%)	
	>65 years	28 (11.3%)	
Fasting Plasma	131-180 mg/dl	64 (25.9%)	
Glucose	181-230 mg/dl	113 (45.7%)	215 ±44.15mg/dl
	231-280 mg/dl	40 (16.5%)	(133-336mg/dl)
	>280 mg/dl	30 (12.1%)	
Blood Pressure	<140/90 mmHg	162 (65.6%)	
	≥140/90 mmHg	85 (34.4%)	

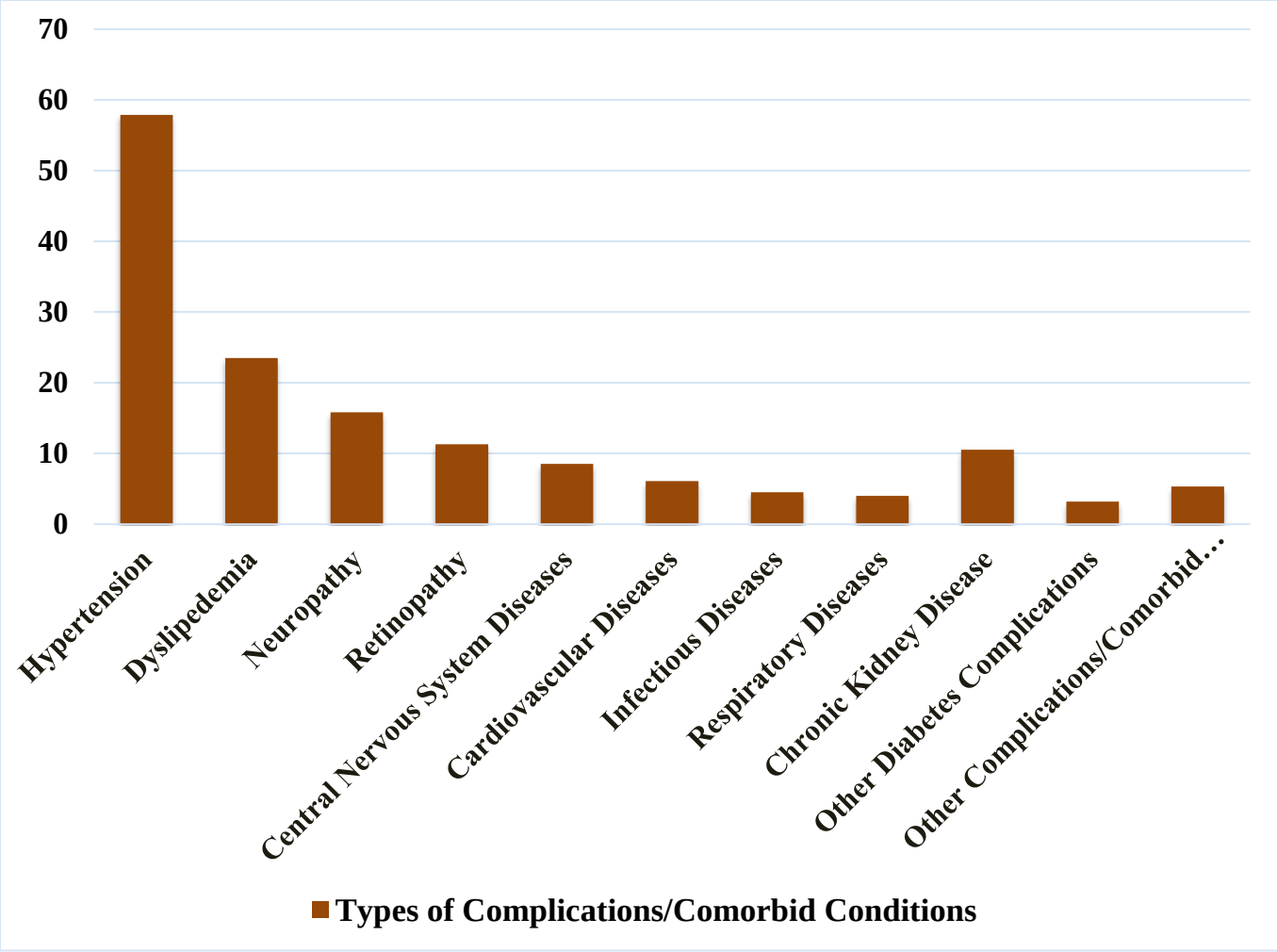

Figure 2: Complications/comorbid conditions of patients with delayed initiation of insulin at the diabetes clinic of TASH, Addis Ababa, Ethiopia, 2017

*includes musculoskeletal diseases (gout, osteoarthritis and rheumatoid arthritis), hematological conditions (chronic idiopathic thrombocytopenic purpura and 2^0 polycythemia), benign prostatic hyperplasia, and hepatobiliary disorders (cholestasis). Other diabetes complications include erectile dysfunction, dermatological condition (dermpathy), dental diseases (dental carrier), and diabetic ketoacidosis. Cardiovascular diseases include hypertensive heart disease, ischemic heart disease, chronic rheumatoid valvular heart disease, peripheral artery disease, and dilated cardiomyopathy. Central nervous system diseases include stroke, seizure/epilepsy, right hemiparesis, schizophrenia, sciatic pain, chronic lower back pain, degenerative spondylitis, and multiple central nerve palsy. Respiratory diseases include chronic obstructive pulmonary disease and asthma. Infectious diseases include retroviral infection, urinary tract infections, liver infection (hepatitis), gastrointestinal infections (tapeworm), and dental and dermal infections (periodontitis and dermatitis). And, chronic kidney disease includes nephropathy.

NB: The percentage of all disease conditions does not add up to 100% due to the multiple response effect.

Table 8.2: Concurrent medications taken by patients with delayed initiation of insulin at the diabetic clinic of TASH, Addis Ababa, Ethiopia, 2017. (N=247)

Concurrent Medications Used	**N (%)**
Cardiovascular Medications (70%)	
Angiotensin converting enzyme inhibitors	111 (44.9%)
Statins	86 (34.8%)
Antiplatelet agent (Aspirin)	73 (29.6%)
Calcium channel blockers	40 (16.2%)
Diuretics	36 (14.6%)
Beta blockers	25 (10.1%)
Central Nervous System Medications (16.6%)	
Analgesics	10 (4%)
Antidepressants (amitriptyline)	32 (13%)
Anticonvulsant	4 (1.6%)
Vitamins and Hormonal Medications (4.5%)	
Corticosteroid preparations (only prednisolone)	6 (2.4%)
Vitamin B combination (Neurobion)	7 (2.8%)
Gastrointestinal Medications (10%)	
Antacid/proton pump inhibitor (Omeprazole)	10 (4%)
Anti-infective Medications (2.4%)	
Antibiotics	5 (2%)
Antiviral	4 (1.6%)
Others*(4.5%)	
	11 (4.5%)

*includes medicines for disease of the respiratory disease (Salbutamol and Dextromethorphan), medicine for rheumatic disease (Allopurinol), and medicine for erectile dysfunction (Sildenafil citrate).

NB: The tabulated numbers do not add up to 100% since it was a multiple response question where each could have more than one answers.

The present study also found that there was physician's recommendation to start insulin therapy only in 102 (41.3%) of the patients with delayed initiation of insulin based on what is documented in the patient charts. Among these, 23 (22.5%) of the patients rejected insulin therapy until the completion of the current study. Yet, only 37 (25.5%) of the patients for whom there was no timely physician's recommendation evidence have started insulin therapy albeit late than it was supposed to be recommended. And, 108 (74.5%) of those with no physician's recommendation did not start insulin therapy at all until the completion of the study.

Overall, 116 (47%) of the patients started on insulin therapy while 131 (53%) of the patients did not start insulin at all. Of those with insulin therapy, 55 (22.3%) and 61 (24.7%) of the patients were put on bed time and on a twice a day regimen of Neutral Protamine Hagedorn (NPH) insulin therapy, respectively (Table 8.3).

Table 8.3: Physician's recommendation to start insulin therapy along with their insulin therapy status at the diabetes clinic of TASH, Addis Ababa, Ethiopia, 2017

		Started Insulin		
		Yes	**No**	**Total**
Physician's recommendation	**No**	37 (25.5%)	108 (74.5%)	145 (58.7%)
	Yes	79 (75.4%)	23 (22.5%)	102 (41.3%)
	Total	116 (47%)	131 (53%)	247 (100%)

4.2. FACTORS TO DELAYED INITIATION OF INSULIN

4.2.1. SOCIO-DEMOGRAPHIC CHARACTERISTICS OF STUDY PARTICIPANTS

The purpose of gathering qualitative data for this research was to explore factors associated with delayed initiation of insulin in patients with T2DM. Overall, 27 patients with type 2 diabetes and healthcare providers participated in the study, out of the 30 approached. The patient study participants were 15, most of whom were in the age range of 40-50 years old, female and with duration of illness less than 5 years (Table 8.5). The provider participants, 12 in number were mostly had practice experiences of less than 5 years and had entry-level professional degree although for the medical doctors they were in the process of undergoing their internal medicine residency training (Table 8.4)

Table 8.4: Profiles of the healthcare providers interviewed at the Diabetes Clinic of TASH, Addis Ababa, Ethiopia, 2017. (N=12)

Sociodemographic and background profiles	**Number**
Sex	
Male	5
Female	7
Year of practice at the diabetes clinic	
< 5 years	7
5-10 years	4
>10 years	1
Type of profession	
Physician	7
Nurse	3
Pharmacist	2
Academic qualification	
Doctor of Medicine/ Bachelor's Degree	7
Internal Medicine Specialty (CSIM)	2
Endocrinology Sub-specialty certificate	3

Table 8.5: Profiles of the patient participants with delayed initiation of insulin interviewed at the diabetes clinic of TASH, Addis Ababa, Ethiopia, 2017. (N=15)

Sociodemographic and other characteristics of Patients	**Number**
Age	
30-40	3
41-50	6
51-60	3
Above 60	3
Gender	
Male	5
Female	10
Religion	
Orthodox Christian	13
Muslim	2
Educational level	
No formal education (can't write or ready/ can read and write)	4
Primary level education (1-8th grade)	4
Secondary level education (9-12th grade)	4
Diploma/Certificate	3
Type of Job	
House wife	8
Pensioner	1
Guard	2
Merchant	3
Company Driver	1
Duration of Illness	
< 5 years	5
5-10 years	4
10-15 years	2
>15 years	4
Initiated Insulin	
Yes	6
No	9
Source of payment of medication	
Self-Paying	9
Government- Paying	6

4.2.2. PROCESS OF INITIATION OF INSULIN

At the diabetes clinic, the healthcare providers were found to be involved at different capacities. Initiation of insulin is a process held by the physician who decides which patient starts insulin therapy. Nurses were found to be involved in provision of diabetes related health education at the waiting area and a one to one diabetes education and counseling that includes injection techniques demonstrations to the patients who once decided to start insulin therapy, as supported by all healthcare professionals and some patients. A nurse and a physician mentioned that pharmacists who are working at the drug information center of the hospital but not at the clinic were found to participate in imparting diabetes health educations in an irregular manner.

The clinic uses the treatment guideline by the ADA, EASD, and IDF as a general practice but adopted to local situations of a resource limited setting. However, the process of initiation of insulin was not found to be uniform and in line with the guideline used by the clinic. This has been strengthened by one physician that:-

> *The process of initiation is not as it is expected to be. There is delayed initiation of insulin and I don't believe that there is proper initiation of insulin.* Physician, Male (M)

Overall, three main themes emerged from the current study to discuss the factors contributing to delayed initiation of insulin; patient related factors, physician related factors, and health institution factors. In view of those, eleven subthemes came into sight and are reported below accordingly. Factors related to the health care providers are entirely explained as physician's factor according to the findings of the study.

4.2.3. PATIENTS RELATED FACTORS

In the interviews held with the physician, nurse, and patient participants, it was found that patients are not willing to start insulin therapy in most cases and patients need to give it a thought and discussion with friends, families, and relatives. Accordingly, they postpone their decisions for consecutive appointments. Three subthemes emerged under the patient factor; namely, perceived adherence problems to prescribed insulin therapy, beliefs about the necessity of insulin, and concerns relating to starting insulin.

Perceived adherence problems to prescribed insulin therapy

As stated by few patients, the adherence problem they encountered with OAMs due to religious and stressful conditions at home or work was put as a reason to resist transition to insulin. Patients believe that insulin won't have any additional effect considering their adherence problem considering their situations. In addition, few patients stated that they intended to correct their adherence problem with OAMs before deciding to shift to insulin. This was supported by the following responses.

> *I also think I have adherence problem and I don't think taking insulin will make any difference taking my life style into consideration. I would be happy if I can see it with oral medications of more doses.* Patient, Female (F), 41 years (yrs.) old

> *I know where I went wrong, I was doing prohibited and wrong things in the past few months […] I did not even take my medicines as advised (properly) or followed proper meal. So, I am deciding to quit those unnecessary and wrong behaviors instead of shifting to insulin therapy.* Patient, M, 51 yrs. old

As it was reported by one of the physicians and few patients, for some, patients complain about their stressful conditions as a reason to be passive about their disease condition or OAMs and thus, they think the same goes to insulin and resist the therapy. This was supported as follows.

> *I have some problems at home, kind of an argument in my family due to inheritance issue and that is also the other thing which affects my health. I am not taking my medicine properly. What difference does it make to start insulin considering my problem?* Patient, F, 68 yrs. old

Beliefs about the necessity of insulin

As mentioned by a physician and a patient, patients believe that both OAMs and insulin therapy are the same with regard to efficacy except that insulin needs complicated management and monitoring. Thus, patients don't see the necessity of transferring to insulin. This has been reinforced by the following.

> *I have one question though. Does taking insulin really change the blood glucose level better than the oral medications? I am taking the tablets and I think I am not sick and I*

do not think I need to be shifted to insulin as long as I am walking healthy. Patient, F, 41 yrs. old

Don't you think my glucose level will lower down with the oral medications? I do not think insulin will be different than the tablets with regard to the efficacy. Patient, M, 44 yrs. old

Moreover, patients lack awareness on the natural course of the disease where insulin therapy is necessary in the eventual process of the disease. Rather, patients believe insulin prescription is when their diabetes reaches advanced level as forwarded from a patient and a physician as follows.

They think like their disease has advanced when they are prescribed with insulin. Physician, M

May be the disease reached advanced stage […] my glucose level has been increasing. Patient, M, 54 yrs. old

Almost all patients, however, mentioned that the rise in their blood glucose level was the reason to shift to insulin therapy as supported by the following response.

The blood sugar level can't be lowered with oral medications. Mine reaches up to 246 mg/dl when I was taking oral medication and the lower range is 140mg/dl. But, the average is around 200mg/dl. I believe that is a reason I was told to shift to insulin. Patient, F, 41 yrs. old

However, the present study has observed belief towards the necessity of insulin in patients who already started insulin. In fact, they promote timely initiation of insulin therapy as prescribed. This was witnessed by few physicians as well as some patients. This was strengthened by the following statements from a patient and physician.

I found insulin to be a good medicine now […] I advise others to start insulin as soon as they are told. If I started insulin the day I was told, I wouldn't have faced such problem with my kidney [I am having kidney problem due to the diabetes]. Patient, F, 41 yrs. old

But, from my experience, I have seen that most patients are willing to accept if we can get time to counsel them […] they mostly regret the fact that they were not convinced enough to start earlier. Physician, F

Concerns related to starting insulin

Fear of side effects and complications

According to health care providers and few patients, fear of side effects like hypoglycemia and weight gain were reported to be among reasons for patients' to resist insulin treatment. As put in the following quote, one of the patients also explained her fear of weight gain came true after she was prescribed with insulin.

I also heard that insulin results in weight gain and I proved that right when I am taking it now. Patient, F, 40 yrs. old

Moreover, patients think insulin result in complications and are thus, lethal, as supported by few patients and some physicians. Patients usually perceive complications as part of taking the insulin but not part of the disease process. This statement was supported by the following.

I know of a patient who died as a result of infection that occurred from insulin at the injection sites. I still have a concern of infection and then death. Patient, F, 41 yrs. old

I heard that insulin result in complications and then death. Patient, F, 49 yrs. old

Patients say that my relative died taking the medicine, false misconception's, most commonly, further complications taking insulin, complication as part of the insulin not on the disease. Physician, F

Fear of injections

Patients past exposure to any type of injection and have undergone some forms of blood taking at regular levels resulted in fear of injection. Majority of the patients, all physicians, and nurses reported a fear of the overall concept of needle while few of the physicians stated patients have a fear from associating the thickness of insulin syringes with other conventional syringes used in injection of other medicines or donation of blood. This has been supported by the following responses from a patient and physician, respectively.

I have a fear of needle. I even have a fear to take dust out of my eye or take a splinter out from my hands leave alone to inject myself with needle. Patient, F, 41 yrs. old

The first thing is fear of injection as part of being human. Second, they don't understand the thickness or type of the insulin syringe which is different than the conventional syringes used to draw blood or inject other medicines. Physician, M

However, few patients mentioned no fear of injection at all as reported as follows.

I like injection better than swallowing tablets and I do not have problem with that. I am taking the tablet since it is must but I still don't like it. Patient, F, 70 yrs. old

Few of the physicians, nurses, and patients acknowledged that patient's fear also resides on the fact that the injection is going to be a lifelong thing where the patient is expected to bear the pain for the rest of his/her life. This was strengthened by a response from a nurse below.

[…] Normally, patients prefer being cured and expect being healthy immediately after having the proper treatment. And, the idea of taking insulin on injection form for the rest of their lives becomes a tough decision and patients show loss of hope. Nurse, F

I just could not imagine injecting myself every day. The tablet is okay to take but it is hard to imagine the injection every day. Patient, M, 44 yrs. old

Poor socioeconomic conditions

As stated by few patients, a nurse, a pharmacist, and a physician, some patients can't afford to buy insulin. Pharmacist informants noted that, the combined price of two generic OAMs (glibenclamide and metformin) is less than vials of insulin for an average monthly consumption considering the price of the pharmacy at the diabetes clinic. This was supported by a response from the pharmacist as follows.

Definitely, insulin is expensive. It depends on the brand you are buying actually. For example, the oral medication cost them a maximum of 60 birr when they take 2 tablet 2 times a day but when we come to insulin taking the average usage of 50 unit per day, they need 2 vials which is around 112 birr. It actually is more than this since we only considered with the average usage. Physician, F

Most of the self-paying patients who have to buy the medication out of pocket fell under this category where they think shifting to insulin might result in incurring additional cost. To enroll into the free government medical service, a patient is required to bring letter from *Kebele/Woreda* every four months or every year indicating they are unable to pay for their medication. Given the bureaucracy and time required to process such letters, few patients find it hard to provide support letter from the *Kebele/Woreda* every month they show up to the clinic despite the presence of the service. This also hinders timely initiation of insulin as strengthened by the following response from a patient.

> *The hospital requires letter from Kebele every month and I could not renew my ID for a free service at Tikur Anbessa Hospital and that is my problem not to start insulin. You don't always go to Kebele begging that you cannot afford and it is difficult. I cannot afford medicines and it is going to be more expensive with insulin.* Patient, F, 48 yrs. old

One of the patients has also mentioned that he already bought the earlier prescribed OAMs in bulk and he needs to stick with the oral medication until the next refill. The patient said he can't afford buying medicines anytime and it is a waste to discard the medicines and buy insulin with limited income.

However, on the contrary to the argument over expensive insulin vial cost, one patient regarded shifting to insulin therapy as cost effective. This is due to brand OAMs available in the market which was found to exceed the price of insulin from the same market.

The expensive transportation cost for those patients coming from far away residences from the treatment site for follow ups was also mentioned to hinder insulin commencement as reported by a physician and a patient. Insulin requires close monitoring and repeated visits which the patient might not comply due to unaffordable transportation cost. This was witnessed by a statement from the patient as follows.

> *I believe it is expensive. The transportation fee has increased now by the way. I am only planning to check and control my diabetes level when I return home, Addis Ababa. I am working in the rural area.* Physician, M

Perceived difficulty in insulin administration and loss of independence/reliance on others

As supported by some patients and almost all healthcare providers, older patients with visual impairments or/and those patients who cannot read or write were found to have difficulty of handling the technique of insulin injection at home. Few patients who refused to start insulin until the end of the study period do not even have someone at home who would inject them. This was reinforced by the following point from a patient.

> *But, it would be impossible for me to take it with the prescribed dose […] what if I take it with the wrong dose than the prescribed one and that might kill me…That is my problem. I am illiterate and can't read or write well…..*Patient, F, 70 yrs. old

Another participant also mentioned the following point.

> *Even, some of them are frail to inject themselves despite the fact that they can read and write. I remember from my experience where patients in the same neighborhood were injecting each other with only the same dose that one patient was prescribed with.* Nurse, F

Few patients also mentioned lack of trust where same patients who are dependent on their caregivers for administration foresaw future inconvenience if caregiver support becomes diminished or compromised due to different changes. This was strengthened by the following statements from the informants.

> *I don't trust myself with anyone […] you can't trust anyone; I should prepare and do it myself but my eye sights are getting weak. For example: this girl is a student and it might get late until she comes home and inject me.* Patient, F, 68 yrs. old

Not amenable to religious healing (e.g. holy water use) and practices (e.g. fasting)

The first reason is that patients put down "holy water" as an alternative means to lower down their glucose level instead of shifting to insulin therapy as mentioned by one of the patients as follows.

> *I said to the doctor "I need some time". I am trying to lower the blood glucose level with "holly water". I believe it is better to lower it down with this instead of going to insulin.* Patient, F, 50 yrs. old

The second reason is the interference of shifting to insulin therapy with the fasting seasons according to the patients. As explained by few patients among Orthodox Christians, patients heard that insulin requires having proper meal and they do not think they are capable of avoiding the fasting season. It was also noted that they become negligent of their medication during such seasons where they are overwhelmed with the overall religious practices. And, they think the situation will get worse with insulin which needs regular meal. This is more evident among patients of old age who are daily observant of religious practices and ceremonies. This was strengthened as follows.

> *I do not take my medication regularly. I go to church early in the morning and go to "mass" services. The "mass" ends around 9 am and the medicine should be taken by then. So, this is one problem for me which will be worse if I start insulin.* Patient, F, 68 yrs. old

Similarly, one of the Muslim patients mentioned of religious obligation, the fasting season of Ramadan in particular, interfering with insulin intake.

> *I also had a fear it will be a problem in the fasting season.* Patient, F, 40 yrs. old

In addition, one patient explained that fasting decreases the blood glucose level and thus, prefer it instead of following a proper meal and uninterrupted medication schedule.

> *I am fasting […] even, the fasting decreases the glucose level and it is good.* Patient, F, 70 yrs. old

One of the patients also reported on the belief where mixing religious practices, such as drinking or bathing with holy water and performing "Holy Communion", with OAMs does not get along with her religious belief. And, she thought the same will happen if she starts insulin therapy.

> *Religious leaders actually insist that we should take our medicines properly even if we are taking "holly water" or doing the "Holy Communion" procedure. But, I believe it is not right. It is my belief that restricts me from taking the medicines during those procedures. I don't want to mix the medicine with the body and blood of Christ. What happens if I start insulin?* Patient, F, 68 yrs. Old

Social factors

Social factors are believed to be among the factors that affects medication intake of patients.

Insulin was found to be related to stigma in the society as mentioned by only one physician. Hence, patients are not willing to inject themselves when they are at work or when they are invited to weddings or friends or relatives house thinking their friends or colleagues will stigmatize them for depending on needle every day. This fear of stigma prevents patients from taking insulin injections at public and in general at any place.

In addition, patients are busy with social engagements like weddings, funerals, "*Idir*", and "*Iqub*". Some patients reported that insulin needs refrigeration and is not convenient to carry when moving from place to places on these occasions. Thus, patients resist insulin prescription considering their anticipated fear of managing these situations. This was supported by the following statement.

> *It even gets late when taking the tablet, I don't follow it properly. I might have to go somewhere early in the morning [friend's house or relative or some things I wish to accomplish]. So I take the meal and then the medicine sequentially at once thinking that it might get late by the time I get home. That is because of my tight schedule and it will be worse with insulin. Insulin needs refrigeration to carry it with me and I am not expected to take it with the meal at once, right? I need to wait some minute. So, it will be difficult.*
> Patient, F, 41 yrs. old

Other than this, entertaining guests coming to their house was found to keep patients busy as mentioned by one patient. Patients think insulin takes time to inject and it is against the norm to stand up from the conversation having the guest sitting at home. There are norms and values in the society which hinders individuals to act differently, as mentioned by a patient. Thus, there is a fear of accepting insulin therapy in the face of the present issues they have had encountered. The following statement witnesses these.

> *I may have a wedding, a funeral, or a guest might come to my place unexpectedly. Some might come to my house to seek for advice. In such cases, I cannot interrupt my conversation to take insulin since it takes time. It is against our culture to get up from a*

conversation. So, I do not think I can do that for the sake of taking insulin. Patient, F, 68 yrs. old

Few physicians and a patient also mentioned that insulin interferes with their job. Their job does not permit them to have regular meal or take insulin regularly. In addition, one of the patients mentioned that insulin is stored in the refrigerator and it will be difficult to comply to the schedule since he cannot carry the medicine at times of busy work schedules from place to place.

…One, we go out early in the morning […] I have disorganized schedule […] I stay far-away for work and do not live with my family. You don't get breakfast as you want [may be I will skip food or the company prepares prohibited foods for diabetes and I cannot eat,] it is difficult. I don't follow proper meal. And, this will be a problem if I start insulin. Patient, M, 54 yrs. old

Some patients say it is hard to control their meal pattern or their job doesn't allow regular meal. Physician, F

Perceived resistance to insulin

Resistance to the medication is another concern related to insulin therapy. It is believed that patients with diabetes will through time develop resistance to insulin like the oral medications have failed to help over time. This was a response proposed by the following patient.

The main reason is that I had a fear thinking what if my body adapts to the insulin as well? It should not be stopped right? It means I am going to stop the medication if my body adapts to it and it will have no alternative medicine. That is my fear. What am I going to take after that? Patient, M, 60 yrs. old

4.2.4. PHYSICIANS RELATED FACTORS

Some physicians mentioned physician's inertia to result in delayed initiation of insulin where he/she is resistant to take actions in those patients who require insulin therapy. Two subthemes to include perceived patient's situation and lack of clinical competency emerged under this theme.

Perceived Patient's Situation

As mentioned by few physicians, side effects patients anticipate to occur creates sense of fear among physicians to initiate insulin therapy. The physician fears that the patient will resist or go through unexpected events, such as hypoglycemia and weight gain or might disappear from follow up if prescribed with insulin therapy.

Similarly, few physicians also reported that some patients with memory problems or patients who cannot be able to read or write may come to the clinic and they suggested that it is difficult to initiate insulin therapy for those patients. This was supported by the following response.

> *Some patients have dementia and can't remember what they are taking. It is risky to start insulin with those patients.* Physician, M

If the patient is unable to understand the procedure for insulin intake or is unable to administer insulin, physicians show reservation in proposing initiation of insulin therapy as mentioned by a physician as follows.

> *We don't tend to initiate as well if the patient doesn't fit for insulin, doesn't have assistance, or have visual impairment [...] patient may have forgetting problem.* Physician, M

Moreover, few physicians also mentioned patient's difficulties adhering to the maximum dose regimen which makes them hesitant to prescribe insulin therapy. The low socioeconomic status of some patients also does not allow them to have proper meals at regular interval which is necessary to take their medicine as mentioned by few nurses and physicians. As a result, healthcare providers have indicated that a fear of hypoglycemia might result if the patient can't get proper meal while taking insulin and this affected their prescription of insulin therapy. This was reinforced by a response below.

> *[…] .For example, I had a conversation with one patient yesterday who was telling me that the only food that he can get every day is bread and tea. So, I had to tell him on how to take the bread with portions in a way that doesn't affect his blood sugar level. So, how are you going to prescribe insulin to this patient if he has to take? It is difficult.* Physician, M

Lack of clinical competency

All physicians stated that they are ready to initiate any eligible patient on insulin therapy. However, some physicians reported that some residents are not ready or confident enough to put patients on insulin, as reported by almost all physicians and a nurse. Under this subtheme are factors like lack of expertise and experience, lack of motivation and confidence, and lack of communication skill.

Lack of expertise and experience

As stated by all physicians and few nurses, the residents' lack of expertise or the lingering experience to put some patients on insulin and titrate it accordingly was found to be a reason for delayed initiation. One of the physicians also mentioned that some residents are not comfortable or familiar to communicate with patients on the appropriate pattern of insulin initiation and titration. This was strengthened by responses below.

> *There might be limited knowledge/experience on the indications. There is also lack of experience on the target FPG numbers and insulin initiation.* Physician, M

Lack of motivation and confidence

According to a physician informant, lack of motivation among some residents who rotate frequently as part of their residency program and avoiding responsibility was found to be among the reasons to delay insulin initiation. Few physicians and nurses mentioned lack of confidence among residents who are at the front lines to diagnose and treat diabetic patients as a reason to delay insulin. This was strengthened by the following statements.

> *To actually tell the truth, practically, residents are coming to diabetes clinic for short period of time as part of their rotation and they don't want to take the responsibility to initiate insulin therapy in this time. They just want to see and send the patient with the present medication he/she is taking.* Physician, M

One of the physicians also stated the following.

> *Lack of confidence by residents might be a reason for delay. They have guidelines and pocket cards to refer and they know the theory. But, it needs consulting and confidence when changing the theory to practice.* Physician, M

However, the fact that the residents are in academic institution was mentioned by a physician as a good opportunity.

Lack of communication skill

Most physicians and few nurses indicated that lack of communication skill among physicians to interact with patients regarding the disease and the medications. Residents lack the confidence and the appropriate approach to communicate with patients. Likewise, this was supported by the residents as the communication system is not good and needs to be strengthened. There was also a complaint from a patient on the improper communication from some senior physicians.

The communication in most cases follow a paternalistic approach where the physician dictates the patient instead of taking time to gather and provide information from and to the patient as mentioned by some patients and few physicians. The physicians do not take time to explain about insulin when they prescribe it to patients. And, patients will be left with dilemmas regarding the new treatment until they decide to be part of it and be given counseling by the nurses. This was mentioned by all patients and nurse and almost all physicians and is strengthened by the response below.

> *[…] while initiating insulin therapy, I do a simple run down on the symptoms they will encounter and on how to treat the hypoglycemia. But, the details are given by nurses.* Physician, F

A patient also witnessed the following statement.

> *Some of the doctors take time to explain and some do not even listen of what you complaining let alone explaining the situation […] the second ones just write your results and he/she doesn't take your points into consideration. Personality of doctors matters. The first doctor I have seen was so good to explain on initiation of insulin and titrate my dose and the second replaced physician was so fast that I couldn't catch her advises.* Patient, F, 41 yrs. old

Some physicians and few nurses also mentioned that physicians fail to communicate well on the course the disease and the inevitable need to take insulin. They don't sensitize patients from the beginning on the necessity of insulin, which leaves false misconceptions on the patient side.

In addition, insulin is considered to be prescribed as a punishment for patients who are unable to manage their blood glucose level. This was supported by one physician and a patient as follows where physicians frame insulin as a penalty for failing to control their disease with OAMs.

> *The physician tells the patient that he/she will start him on insulin if the patient doesn't behave with oral medications and other factors to be considered. This means the physician is not telling the patient as insulin is imminent on the course of treatment but insulin is a punishment.* Physician, F

> *The physician used to tell me that I should behave with oral medications and otherwise it will be changed to the injection. May be he wants me to behave and do things right but he was trying to scare me with the injection thing at the same time.* Patient, F, 38 yrs. old

4.2.5. HEALTH INSTITUTION RELATED FACTORS

Under this theme, six subthemes emerged, namely; inadequate laboratory set up, lack of continuity of care, absence of guidelines for diabetes management including insulin initiation, lack of health educational resources, inadequate staff for diabetes care and education, and time barrier.

Inadequate laboratory set up

The absence of a well-designed laboratory set up in the hospital was found to be another factor to compromise timely initiation of insulin at the diabetic clinic.

The first reason was found to be the disorganized and time taking laboratory system to provide FPG results within a day. Results are provided within days, which forces patients with emergency situation to wait for the result after a day or two or they need to do FPG test outside the hospital. This was described as a factor to delay the patient care system and delayed insulin initiation.

In addition, Hg A1C test is not available at the hospital laboratory. The test, according to physicians interviewed, is not accessible and affordable to patients. This forces the physicians to only use FPG results to make decisions of initiating insulin therapy. Physicians, thus, demand series results of records of results to decide on whether to shift to insulin therapy despite the present indications. This delay and postpone initiation of insulin as FPG was not found to be the reliable test for a confident decision as reported as follows.

> *We advise them to take a couple of records at home for the next appointment. Hemoglobin A1C is expensive for most of the patients and we usually rely on FPG. Still most of the patients can't afford to go and check their FPG. So, what you base yourself is on the thing you can have as evidence in your hand.* Physician, M

Another healthcare provider also witnessed this.

> *There is also problem with laboratory set ups; we don't have hemoglobin A1C level in our set up.* Physician, M

Lack of Continuity of Care

As mentioned by few physician informants, the care system at the diabetic clinic lack continuity, and this was seen as a challenge to initiate insulin in a timely manner. Coming to contact with different physicians at different times and appointment dates, patients show lack of trust and frustration against the physician prescribing the insulin therapy. Rotation of residents every month together with long appointment dates has been given as a reason why patients see different physicians on their appointment dates. This requires patients to explain their situation every time they visit the clinic. This was noted by a nurse and a patient interviewed as follows.

> *[…] patients want to see the same doctor every time they come for clinic visit. It is mostly the new doctor which tells the patient to start insulin and they lack trust to accept the new doctors' recommendation. They complain of the fact that they are not checked by the same doctor and the fact that the doctor asks the patient every time they come to visit.* Nurse, F

> *Since I started my follow up here, I was being checked up by different doctors. And, some of them are young and I am sure they are taught well to do that and I have no problem*

with their knowledge. But we see different face of doctors each time we come for clinic visit and it is difficult to consult the same doctor at different visits. Patient, F, 68 yrs. old

Absence of guidelines for diabetes management including insulin initiation

It was also mentioned that the available guidelines for physicians to start a single patient on insulin are adopted mainly from the ADA guideline and few physician mentioned that it does not get along with the context of the clinic or the country. The treatment guidelines and titration system used in the diabetic center were designed for developed countries while the system operates in the context of developing country in which the setup is different in both. This was supported by the following statement.

I can't say the treatment approach is uniform and that is one factor. Besides, we don't have our national guideline and we are using developed countries guideline which doesn't fit to our setting and that is one factor as well not to have non-uniform treatment approach. Physician, M

Flyers and guidelines should be prepared considering our setting, most of them are westernized….that result in non-uniform treatment practice. Physician, F

Lack of health educational resources

Few physicians and a nurse described on absence of enough teaching and learning materials prepared for the patient in local language (Amharic and others) on the general concept of diabetes and insulin as well. This was also backed up by one of the patient where he mentioned lack of those resources for the patient to understand in his own terms. This was endorsed by the following statements.

There are no teaching and education materials. There should be posters and video materials. Physician, M

In my follow up at this clinic thus far, I have never encountered a patient education material prepared in Amharic. I bought one prepared material today in years. And, attention should be given to assist the patient. Patient, F, 38 yrs. old

Besides, it was found that the overall health education is not done regularly as mentioned by few physicians. This statement was strengthened by the following point.

[…] now we are giving the health education haphazardly even if it is expected to run regularly. Physician, F

Inadequate staff for diabetes care and education

The major problem related to the system mentioned by most of the physicians and a nurse is the small number of nurses. Physicians mentioned that nurses are necessary to have a regular health education system and counseling sessions about insulin at the diabetic clinic but their low number resulted in irregular schedules at the setting. This was supported by the following statement.

Nurses are leaving the clinic for further education or personal reasons. And there is shortage of nurses in our setting. Sometimes, we are only two nurses to fulfill the overall activities. It is tough. Nurse, F

It was also mentioned by one of the physicians that nurses should have been helpful in dose titration of insulin if there number was large.

Now we are giving the health education haphazardly even if it was expected to have regularly. If the number of the nurses were adequate [titration shouldn't have been my work and the health education could have been regular]. Physician, F

However, the fact that the available nurse staffs are knowledgeable and experienced was mentioned by one physician as a good opportunity to have a positive interaction with patients.

The number of the residents was also found to be small and not proportional to the high patient flow as suggested by few physicians. This can also be a factor for delayed initiation of insulin where residents send patients with the same medicine again and again for the sake of using the available brief time, prescribing the same medication given by the previous doctor who treated the patient. This was supported by responses from patients as follows.

The interaction with the physicians is short since the number of physicians does not carry the number of patient. I was also telling the nurse why there is no practice of full diagnosis of the body. That is my problem [I don't like when they just give us medicines and send us home instead of full checkup]. Patient, F, 68 yrs. old

The replaced doctor only writes down the medications that the previous doctor wrote and that is a problem. The physician is thinking about the patient load but not on prolonged stay with certain patient. The number of the physicians is small compared to the patient. Patient, M, 80 yrs. old

Time barrier

Under this subtheme are factors of high patient load resulting inkling appointment periods and extra time required to address insulin dose adjustment.

High patient load and Long appointment Periods

Follow up appointments are prolonged in the diabetes clinic which can extend up to six months. This was found to be one of the factors associated with delayed initiation of insulin. High patient flow was mentioned by all health care providers to result in long appointment periods. Following this it was difficult to follow a patient in short visits and timely prescribe insulin therapy. This was witnessed by the following statements from healthcare professionals.

In my earlier year of experiences, the number of patient seen per day was 25 and now the number is high since they cannot shift to Minilk and Ras Desta Hospital as Tikur Anbessa is known to have better supply of medicines. Nurse, F

The appointment system is a big problem to initiate, titrate, and monitor the patient. Physician, M

Few of the physicians also mentioned that it was found to be difficult to initiate a certain patient on insulin and titrate it accordingly since the appointment system does not allow short visits and checkups. The above statement was strengthened by the following responses.

The appointment system is one factor. The physician has a fear of initiating insulin therapy thinking that it is impossible to see the patient in a short day appointment and follow him accordingly […] The system does not allow appointing the patient whenever you want and that is a challenge to the physician to start insulin. Physician, F

However, few physicians reported that the appointment system could not be an excuse to delay insulin initiation as the nurses are willing to give short visits whenever it is needed. This was stated by a physician as follows.

> *The appointment system is a burden. But, we insist the patient to communicate us privately if necessary […] and I don't think it is a problem.* Physician, M

5. DISCUSSION

This study was conducted to assess the prevalence of delayed initiation of insulin and explore factors related to it at the diabetes clinic of TASH. The study found that 64.2% of the patients had delayed initiation of insulin. Factors included patient, physician, and health institution. The main findings under patient factor included the concerns about insulin including fear of injection, not amenable to religious practices, and perceived difficulty of insulin administration. Physician factors incorporated physician's inertia where lack of clinical competency takes the priority. Health institution factors included inadequate laboratory set up and time barrier.

From the present study, the overall prevalence of delayed initiation of insulin was found to be 64.2% resulting mainly from patient and physician factors such as refusal to start insulin by the patient and physician inertia to commence insulin therapy based on what is documented from patient's chart. However, the majority 145 (58.7%) of the delay was found to be due to absence of physician's recommendation. Only 22.5% of the patients who were seen at the diabetes clinic and had physician's recommendation refused to start insulin therapy. This percentage is lower than other studies done in different countries where the percentage of insulin refusal ranges from 28.2% to 74.2% (Polosky. *et al.*, 2005; Khan. *et al.*, 2008; Tan. *et al.*, 2015). However, the overall prevalence of delayed initiation of insulin is significant in the current study setting.

The end result of such a problem is hyperglycemia which is a major predictor of diabetes related complications. And, complications results in different economic burden which can be reviewed in three ways (IDF, 2006). The first is the direct cost to the patient or a family due to further costs from complications. According to one study, the median direct cost of diabetes in Addis Ababa in the year 2015 was found to be 459 birr, of which 58.9% of it was related to the medical cost (Tseto, 2015). And, the cost is high in developing countries like Ethiopia where around 85% of the expenditure is out-of-pocket expenses from the patients (IDF, 2015). The second is related to loss of productivity from diabetes where the economic loss was estimated to be $11,814,852,255 for group 3 (<2000 gross national income per capita) countries including Ethiopia (Kirigia. *et al.*, 2009). The last is the monetary value lost due to disabilities or death from diabetes where estimates from IDF showed that 23 million years of life are lost each year to the disability and reduced quality of life caused by diabetes complications which are particularly

high in poor and middle income countries (IDF, 2006). Thus, the intervention towards minimizing factors related to delayed initiation of insulin should be given priority in a country like Ethiopia where there is limited resources.

One major factor to resist insulin therapy which is attached to the patient and playing a major role is related to concerns they have regarding insulin. The top concern mentioned was fear of injection coupled with the fact that it is a lifelong treatment. This was also in line with other findings of other researches done both in Ethiopia and elsewhere (Karter. *et al.,* 2010; Polinski. *et al.,* 2013; Habte *et al.,* 2017). A research done by Habte et al (2017) reported fear of injection as a reason for patient's low adherence to the insulin they were prescribed. The benefits of insulin interms of increasing vitality and decreasing the risk of complications must be emphasized along with imparting the relative less pain with insulin syringe compared to conventional syringes. This should be done at times of health education program or at the time of one to one counselling. The involvement of 'expert patients' who have had positive experiences of insulin initiation and the injection techniques may increase the possibility of patients commencing insulin therapy (Khan. *et al.,* 2008).

Another patient concern stated was the effect of religious practices and beliefs to start insulin therapy. Few patients from the Orthodox religion believe that fasting or drinking "holy water" is more effective than insulin therapy and being involved in the religious practices (taking holly water and performing "Mass") is more appealing to treat their disease than shifting to insulin. In addition, patient's are reluctant about their medicine when they are engaged with these practices and think it would be worse with insulin. Similarly, another study in Ethiopia identified religious practices as barriers to anti-diabetis medications' adherence (Habte *et al.,* 2017). The involvement of religious leaders to tackle religious concerns will improve patient's adherence as tried in the case of HIV/AIDS where religious leaders endorsed and encouraged the use of anti-HIV medications to patients while safely practicing their religious believes (Kloos *et al.,* 2013).

Perceived difficulty in insulin administration and loss of independence/reliance on others was among the reason for delayed initiation of insulin in the current study. This is consistent to what was documented by Lee et al (2012) where low self-efficacy presented a problem for those who cannot inject themselves or do not have someone to inject them. The involvement of family

members or care givers for the overall diabetes care or the health education session might provide substantial result.

Considering almost all patient factors discussed, they indicate the necessity of strengthening awareness program in the patient side. The present study also found that those patients who already had started insulin showed good perception about insulin. Yet, the health education program at the diabetes clinic was found to be poor where the low number of nurses was mentioned as a top reason. One method to strengthen the education will be by increasing their number. However, involving trained nurse educators would play an important role in the current setting as physicians usually refer patients to the nurses for education and instruction after prescribing insulin. This was also reported in another study that trained diabetes nurse educators can help patients to overcome psychological insulin resistance, and thus, fill the gap (Tan. *et al*., 2011; Lee. *et al*., 2012). Moreover, the nurses should work collaboratively with pharmacist to capitalize on the education regarding insulin therapy and to focus on continued diabetes treatment and care. The impact of health education whether given in groups or in one-to-one basis is tremendous which was also stressed from a research by Habte et al (2017). However, it is highly important to take into consideration of patients' religious and socio-economic background.

Quite the reverse, however, was the absence of physician's recommendation to result in delayed initiation according to the finding from quantitative study. This might reveal physician's inertia but the finding from the qualitative findings also showed that health institution factors can also play role towards physician's decision and thus delay in insulin initiation. The findings from the quantitative study was also supported by the qualitative finding where physician's inertia is one factor for delayed initiation of insulin as mentioned by other similar studies as well (Tan. *et al*., 2011; Lee. *et al*., 2012; Polinski. *et al.*, 2013).

Lack of experience and motivation as part of physician's inertia was a finding from the current research. A systematic review done by Polinski et al (2013) also showed that about one-half (49%) of the respondents reported that physicians lack experience with available types of insulin and that educating patients regarding progression would take too much time (Polinski. *et al.*,2013). From the current study, limited experience was a key problem attached to the residents who are mostly staying at the diabetic clinic for one month. The study also found that they are

not motivated to start patients on insulin therapy. Thus, the decision would be referred for another residents to come for attachment or to the endocrinologists as also described by Lee et al (2012).

However, the other important issue raised during the study period was the type of communication which was reported to be weak and unilateral, in most cases. Although the low educational level of some patients might not allow proper interaction, the high patient flow in the system was found to affect the communication between the providers and the patients. However, the inherent low communication skill among the residents is something that needs to be strengthened in the course of interaction with patients. The physician should develop skills through different on job trainings, seminars, and courses to create a habit to gather information from the patient and provide or sensitize the patients about the course of treatment, including insulin throughout the interaction with patient.

The problem of high patient flow and long appointment periods which affected the communication process was also a case accounted in a research done in Cape Town that poorly managed appointment systems and long waiting times as a result of excessive patient loads contributed to lack of continuity of care and other problems (Haque. *et al.,* 2005). The diabetes clinic is operating under the teaching and referral hospital where plenty of patients are being referred and followed in the clinic by a referral system. Patients are mostly being treated in this clinic than going to other primary healthcare and private hospitals. The reasons to this effect could be due to uninterrupted supply of insulin in the current study setting, lack of well organized health center to titrate and mange patients with insulin, and also the low socioeconimc status of the patients who can only afford public medical services. However, the hospital along with the relevant bodies should put efforts towards adjusting the referral system by creating a path to refer patients back to the health center where they referred from. In addition, task shifting from physicians to trained nurse educators and/or pharmacists regarding dose titration might allow a room to strengthen the interaction between the patient and the physician.

Another major interaction between the institution and physician inertia which might be unique to this study was the use of FPG instead of Hg A1C. It is not in line with several guidelines including that by ADA which recommend to use Hg A1C (ADA, 2017). Thus, the decision of the physician's will be postponed and thus, delayed since series of FPG results are acquired from

the patient. This is also magnified by the long patient appointment system where single result of patient's measurement taken before the appointment dates. The physician might not be certain about a single result and send the patient home with another 3 or 6 month appointment. Thus, it results in postponed decision by the physician which in turn, results in delayed initiation of insulin. Thus, either there has to be such guidelines with local context or the system should thrive to create a well-designed system to use the available guidelines from developed countries.

Overall, the study showed the relationship among different factors which indicated a combined intervention needed to work from the perspectives of patient, physician and health care institution to tackle the current study problem.

6. STRENGTH AND LIMITATION OF THE STUDY

The strength of the study was the fact that is done on a relatively well designed setting of the hospital, the diabetic clinic which made the qualitative data collection process very smooth. The fact that the clinic uses a health management information system record made it possible to have a sampling frame from which patient chart numbers were easily picked. Thus, the system allowed easy selection of patients charts from the card room of the outpatient department.

However, one factor which limited the scope of the study was the use of FPG test as measuring criteria to classify patients with delayed initiation of insulin. The current study used what is best to use in the available setting but that might affect the results of the study in certain ways as FPG is not the best indicator of the overall glycemic state. The other limitation was the use of patient chart system to collect data. The poor organizations of charts made it difficult to have sequential history of the patient and compromised the concentration and time of data collection. Moreover, some of the patient charts were not found from the card room at time of data collection. Even for those with available chart, old cards were lost and only the history of the present few months were found. The study aimed at assessing the prevalence of delayed insulin initiation and some patients card were lost at time of data collection where it was difficult to obtain when the patient started insulin or to point out for how long the patient stayed with oral medications. The fact that the hospital is a tertiary and referral hospital, most patients did their first diagnosis elsewhere and it was difficult to have an overall history of the patient. Likewise, it was difficult to identify some variables and determine associations due to limited and interrupted information from the patient chart which narrowed the scope of the study.

Moreover, there could be an information bias from interviewing few patients and all healthcare providers at the diabetes clinic of TASH. Few patients were interviewed at the diabetes clinic (health institution) where the characteristics/behaviors of the patient is considered to be changed and thus, their response. The healthcare professionals might have also introduced information bias while interviewed at the very duty they were engaged. For the patient, a separate room was used to minimize bias but it was impossible to avoid bias when it comes to healthcare providers.

Finally, the fact that the researcher was a former employee of the hospital might have impacted the results of the study where she unknowingly overlooked some health institution factors.

7. CONCLUSION

According to the current study, the prevalence of delayed initiation of insulin at the diabetic clinic was found to be 64.2%. However, the majority of the delay was found to be due to absence of physician's recommendation with only 22.5% of the patients refusing insulin therapy. Factors explored from the study was from three perspectives; namely, patients, physicians, and health institution. Patient factors pointed out from the present studies were perceived adherence problems to insulin, beliefs about the necessity of insulin, and concerns related to starting insulin. Concerns of the patient towards insulin therapy have been decreasing and belief about the necessity of insulin increased in those patients who already started insulin therapy. Concerns about insulin included its interference with social and religious activities, perceived adherence problem, and perceived difficulty in insulin administration and loss of independence/reliance on others. Physician's factors were found to be related to physician's inertia where perceived patients situation and lack of clinical competency were found to contribute. However, health institution factors were found to be lack of health educational resources, absence of guidelines for diabetes management including insulin initiation, inadequate staff for diabetes care and education, inadequate laboratory set up, and time barrier.

8. RECOMMENDATION

The present study tried to assess the prevalence of delayed initiation of insulin and explore factors associated with it. The following recommendations were pointed out from the outputs of the present study.

- The diabetes health education program at the clinic should be continuous and regular to allow a room for creating awareness on the patient side. The impact of the education should also be assessed and evaluated continuously.
- Diabetes care related patient counseling tips, references or reading materials should be prepared in lay man terms considering the background and context of the patient. The materials should be disseminated to reach the patient.
- All healthcare professionals at the clinic should sensitize on the significance of EDA membership and group education forum conducted by the association as a stage of experience sharing with other patients with diabetes which will improve the perception of the patient.
- There should be task shifting at the clinic to balance the small number of health care professionals. The number of nurses should be raised to have continuous and regular health education program at the clinic. The clinic should also engage pharmacists on one-to-one counseling sessions and/or diabetes health education sessions to assist on the titration of insulin therapy and its adherence.
- A laboratory set up which delivers instant FPG measurement services to the patient should be designed.
- The diabetes clinic should prepare local or national guidelines for the overall diabetes management and care of patients at the clinic.
- The hospital along with the relevant bodies should put efforts towards adjusting the referral system.

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ANNEXES

ANNEX I: IN-DEPTH INTERVIEW

Addis Ababa University
College of health sciences
School of pharmacy
Department of pharmaceutics and social pharmacy

Consent form for in-depth interview

Introduction

This in-depth interview is prepared to explore factors associated with it in patients with type 2 diabetes at the Diabetes Clinic of Tikur Anbessa Specialized Hospital. I am postgraduate pharmacy students conducting a study on the aforementioned research topic. The research could mainly serve for the clinic to identify for modifiable factors and intervene accordingly for a better patient outcome. For the purpose of obtaining the necessary in information I am delivering self-structured interview guide. The interview will take 15-30 minutes of your time and the interview will be held at your convenient location.

Your participation is purely voluntary and information you provide will be kept completely confidential. Direct quotes might be taken from your response to be used in written and verbal reports of the paper but your name will never be written and aggregate responses from different respondents will only be identified only by codes. However, tape recorder may be used during the interview.

Your honest response to the question is of paramount importance for the successful completion of the study. There is no right or wrong answer and you can have clarification for any doubt regarding the questions.

Are you willing to respond to the questions? Yes/No

I. Interview guide for the Physician

Part one: Socio-demographic characteristic of respondents

1. Sex Male ☐ Female ☐
2. Age: _____
3. Your present position: _____
4. Date of interview: _____
5. Venue: _____
6. Years of working experience in present position: _____

Part two: Questions based on research topic

1. General introduction
    - ❖ What are your experiences like in initiating diabetic patients on insulin therapy?

_____
_____
_____
_____
_____
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2. Organization and support
    - ❖ How is the process of initiating insulin therapy like in your area of work?
    - ❖ Can you discuss the organizational support provided to help you to initiate insulin therapy in diabetic patients?
    - ❖ What are the concerns/issues that you have come across with respect to the setting or the hospital that might result in delayed initiation of insulin?

_____
_____
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3. Patient attitudes and beliefs
    - ❖ In your experience, what are the issues or concerns verbalized by patients when they were initiated with insulin therapy?
4. Provider's clinical competency
    - ❖ How do you assess that patients are suitable or are ready to initiate insulin therapy?
    - ❖ What personal concerns do you have in initiating insulin therapy?
    - ❖ How do you feel about your readiness in initiating insulin therapy?
    - ❖ Do you think the physician can be put as a factor to delay insulin initiation? How?

_____
_____
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_____

5. Possible solutions
    - ❖ In recognizing some of the potential issues that patients and you may have, what would you propose to help improve patients' acceptance and success in insulin therapy?

_____
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Any recommendations you have on the topic?

_____
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_____

If you have further points or comments to add, i will be appreciating.

_____
_____

Thank you for your cooperation!!!

II. Interview guide for the Nurse

Part one: Socio-demographic characteristic of respondents

1. Sex Male ☐ Female ☐
2. Age: _____
3. Your present position: _____
4. Date of interview: _____
5. Venue: _____
6. Years of working experience in present position: _____

Part two: Questions based on research topic

7. General introduction
   - ❖ What are your experiences with physicians in initiating diabetic patients on insulin therapy?

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8. Organization and support
   - ❖ How is the process of initiating insulin therapy like in your area of work?
   - ❖ Can you discuss the organizational support provided to help initiate insulin therapy in diabetic patients?
   - ❖ What are the concerns/issues that you have come across with respect to the setting or the hospital that might result in delayed initiation of insulin?

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9. Patient attitudes and beliefs
    - ❖ In your experience, what are the issues or concerns verbalized by patients when they were initiated with insulin therapy?
10. Provider's clinical competency
    - ❖ What personal concerns do you have when physicians initiate insulin therapy?
    - ❖ How do you feel about the physicians' readiness in initiating insulin therapy?
    - ❖ Do you think the physician can be put as a factor to delay insulin initiation? How?

_____
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11. Possible solutions
    - ❖ In recognizing some of the potential issues that patients and physicians may have, what would you propose to help improve patients' acceptance and success in insulin therapy?

_____
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Any recommendations you have on the topic?

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If you have further points or comments to add, I will be appreciating.

_____
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Thank you for your cooperation!!!

III. Interview guide for the Patient

Part one: Socio-demographic characteristic of respondents

1. Sex Male ☐ Female ☐
2. Age: _____
3. Level of education: _____
4. Date of interview: _____
5. Venue: _____

Part two: Questions based on research topic

6. General introduction
   - ❖ Can you share with me how the use of insulin injection was first discussed with you?
   - ❖ What do you think are the reasons you were asked to start on insulin?

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7. Patient's health beliefs and attitudes
   - ❖ Can you share with me the reasons why have you rejected the physician's suggestion to start insulin?
   - ❖ Many patients verbalize fears that starting on insulin will bring about a lot of inconveniences and changes. What do you think of this?
   - ❖ If you were to start on insulin injections, what sort of adjustments/difficulties do you think you would encounter?

_____
_____

8. Is there any problem you observed from the physician to hinder you to start insulin on time?

_____

9. How about problems you encountered at the clinic or the hospital which affected your decision to start insulin therapy on time?

_____

10. Coping and support
    - ❖ If you were to start on insulin injections, how do you think you would have coped with these changes?
    - ❖ What sort of adjustments or changes in lifestyle would you anticipate?
    - ❖ What type of support or assistance would you like to help you get started on insulin therapy?

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Any recommendations you have on the topic?

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If you have further points or comments to add, I will be appreciating.

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Thank you for your cooperation!!!

ANNEX II: AMHARIC VERSION OF THE INTERVIEW GUIDE

አዲስ አበባ ዩኒቨርስቲ

ጤና ሳይንስ ኮሌጅ

የፋርማሲ ትምህርት ቤት

የፋርማሲውቲክስና የሶሻል ፋርማሲ ዲፓርትመንት

የቃለ መጠይቅ ፎርም

መግቢያ

እኔ ኢልሃም ረሺድ በድህረ ምረቃ የሁለተኛ ዓመት የፋርምሲ ተማሪ ስሆን የመመረቂያ ፅሁፌን በሁለተኛው አይነት የስኳር ህሙማን ላይ እየሰራሁ እገኛለሁ;; የሁለተኛው የስኳር አይነት የታመሙ ሰዎች በጊዜ ሂደት በአፍ ከሚወሰዱ እንክብሎች ወደ ኢንሱሊን እንደሚተላለፉ እርግጥ ነው;; ነገር ግን ከሃኪሙም ሆነ ከህመምተኛው በሚከሰቱ የተለያዩ ምክንያቶች ኢንሱሊን መጀመር ካለበት ጊዜ የመዘግየት ሁኔታ ይከሰታል፡፡ የእኔም የጥናት ፅሁፍ በዚህ ላይ ያተኮረ ሲሆን የዚህ ጥናት ዋና አላማም ሊቀረፉ የሚችሉ ችግሮች ለይቶ በማውጣት በክሊኒኩ ውስጥ የተሻለ የጤና አቅርቦት እንዲጎለብት ለማድረግ ነው፡፡ ስለሆነም ይህንን አርዕስት በተመለከተ መረጃ ለመሰብሰብ ይጠቅም ዘንድ ከታች የሚገኘውን ቃለመጠይቅ አዘጋጅቻለው፡፡

በዚህ ጥናት በመሳተፍዎ በእርስዎ ጤና፣ አካልና ስነልቦና ላይ የሚደርስ ምንም አይነት ጉዳት አይኖርም፡፡ የእርስዎ ተሳትፎ ግን ወደ ፊት የሚሰጠውን የስኳር ህክምና በይበልጥ ለማሻሻል ይረዳል፡፡ ጥናቱ ሙሉ በሙሉ በፈቃደኝነት ላይ የተመሰረተ ሲሆን ከእርስዎ የሚገኘው መረጃ በሚስጢር የሚያዝ ይሆናል፡ ፡ መረጃ በሚሰበሰብበትም ጊዜ የእርስዎን ስምም ሆነእርስዎን ሊያመላክቱ የሚችሉ ነገሮች አይካተቱም፡፡ በጥናቱ የመሳተፍ ወይም ያለመሳተፍ የእርስዎ ምርጫ ሲሆን በጥናቱ መሃል አቋርጠው የመውጣት መብትዎም የተጠበቀ ነው፡፡ ለቃለመጠይቁየሚሰጧቸውምላሾችሁሉበሚስጥርየተጠበቁሲሆኑከአኔውጪማንምሰውየሰጡኝንመረጃሊያገኘውአይችልም፡፡ መረጃ ሙሉ በሙሉ ለመመዝገብ ግን በቃለ-መጠይቁ ጊዜ የድምፅ መቅጃ መሳሪያ መጠቀም ያስፈልጋል፡፡

ይህንን ፅሁፍ በተመለከተ ትክክል ወይም የተሳሳተ የሚባል መልስ የለም፡፡ ነገር ግን የእርስዎ ሀቀኛ የሆነ መልስ ለፅሁፉ እውነተኛነት እና በስኬት መጠናቀቅ ትልቅ ሚና ስላለው እነዲተባበሩኝ በትህትና እጠይቃለው፡፡ በቃለ መጠይቁ ጊዜ ግልፅ ያልሆነልዎት ጥያቄ ካለ እንዲብራራልዎት የመጠየቅ መብት አለዎት፡፡ ቃለ መጠይቁ ከ 15-30 ደቂቃ የሚፈጅ ሲሆን በመረጡት ቦታ ሊካሄድ ይችላል፡፡

በመቀጠልም እርስዎ ፍቃደኛ ከሆኑ መጀመር እንችላለን፡፡ አዎ/አይደለም

ለሃኪም የተዘጋጀ ቃለ መጠይቅ ፎርም

ክፍል 1: መግቢያ

1. ፆታ፡ ወንድ/ሴት ☐ ☐
2. እድሜ: _____
3. አሁን ያሉበት የስራ መደብ: _____
4. የቃለ መጠይቁ ቀን: _____
5. ቦታ: _____
6. የስራ ዓመት ልምድ (አሁን ባሉበት ቦታ): _____

ክፍል 2: ጥናቱን የተመለከቱ ጥያቄዎች

7. አጠቃላይ መግቢያ
    - ❖ የስኳር ህመምተኞችን ኢንሱሊን የማስጀመር ልምድዎ ምን ይመስላል?

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8. አደረጃጀት እና ድጋፍ
    - ❖ በሥራ ቦታዎ ላይ ኢንሱሊን የማስጀመር ሂደት ምን ይመስላል?
    - ❖ ኢንሱሊንን ለማስጀመር ከሆስፒታሉ የሚያገኙት እገዛ ወይም ድጋፍ ካለ ሊያስረዱኝ ይችላሉ?
    - ❖ በዚህ ሆስፒታል ወይም ክሊኒክ ውስጥ ኢንሱሊን በጊዜው እንዳይጀመር ሊያደርጉ የሚችሉ ያጋጠምዎት ችግሮች ምንድን ናቸው?

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9. የ ህመምተኛው አመለካከትና እምነት

- በእርስዎ የሥራ ቆይታ ውስጥ ኢንሱሊንን ከማስጀመር ጋር ተያይዘው ከታካሚው የሚነሱ ጉዳዮች ወይም ቅሬታዎች ምንድን ናቸው?

10. የሃኪሙ የሥራ ብቃት
    - ኢንሱሊንን በሚያስጀምሩበት ወቅት፣ አንድ ህመምተኛ ለኢንሱሊን ዝግጁ እንደሆነ ወይም ኢንሱሊን እንደሚያስፈልገው በምን መስፈርት ነው የሚያረጋግጡት?
    - ኢንሱሊን ለማስጀመር ያልዎት ቅሬታ ምንድን ነው?
    - ኢንሱሊንን ለማስጀመር ምን ያህል ዝግጁ ነኝ ብለው ያስባሉ?
    - ኢንሱሊን በጊዜው እንዳይጀመር ሀኪሙ እንደ ምክንያት ሊነሳ ይችላል? እንዴት?

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11. ሁነኛ መፍትሄዎች
    - ከላይ ያወራነውን ጉዳዮች ወይም ቅራኔዎች አስመልከተው እንዲሁም ከህመምተኛው የሚመጡትን ከማገናዘብ አንፃር፣ የታካሚውን የመቀበል አቅም ለማሻሻልና የኢንሱሊን ህክምና ውጤታማ ለማድረግ ሊያቀርቡት የሚችሉት መፍትሄ ይኖራል?

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በመጨረሻም በተጠቀሰው አርዕስት ላይ ተጨማሪ ሀሳብ ወይም አስተያየት ካለዎት እርስዎ መቀጠል ይችላሉ

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ለትብብርዎ አመሰግናለሁ!!!

ለነርሰ የተዘጋጀ ቃለ መጠይቅ ፎርም

ክፍል ፡ መግቢያ

1. ፆታ፡ ወንድ/ሴት
2. እድሜ: _____
3. አሁን ያሉበት የስራ መደብ: _____
4. የ ቃለ መጠይቁ ቀን: _____
5. ቦታ: _____
6. የስራ ዓመት ልምድ (አሁን ባሉበት ቦታ): _____

ክፍል 2: ጥናቱን የተመለከቱ ጥያቄዎች

7. አጠቃላይ መግቢያ
   - ❖ የስኳር ህመምተኞችን ኢንሱሊን ለማስጀመር ከሃኪሙ ጋር ያለዎት ልምድ ምን ይመስላል?

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12. አደረጃጀት እና ድጋፍ
    - ❖ በሥራ ቦታዎ ላይ ኢንሱሊን የማስጀመር ሂደት ምን ይመስላል?
    - ❖ ኢንሱሊንን ለማስጀመር የሚያገኙት ድርጅታዊ እገዛ ወይም ድጋፍ ካለ ሊያስረዱኝ ይችላሉ?
    - ❖ በዚህ ሆስፒታል ወይም ክሊኒክ ውስጥ ኢንሱሊን በጊዜው እንዳይጀመር ሊያደርጉ የሚችሉ ያጋጠምዎት ችግሮች ምንድን ናቸው?

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13. የህመምተኛው አመለካከትና እምነት

- በእርስዎ የሥራ ቆይታ ውስጥ ኢንሱሊንን ከማስጀመር ጋር ተያይዘው ከታካሚው የሚነሱ ጉዳዮች ወይም ቅሬታዎች ምንድን ናቸው?

14. የሃኪሙ የ ሥራ ብቃት
    - ሃኪሙ ኢንሱሊን በሚያስጀምርበት ወቅት የተመለከቷቸው ችግሮች ወይም ቅሬታዎች ምንድን ናቸው?
    - ሃኪሙ ኢንሱሊንን ለማስጀመር ምን ያህል ዝግጁ ነው ብለው ያስባሉ?
    - ኢንሱሊን በጊዜው እንዳይጀመር ሀኪሙ እንደ ምክንያት ሊነሳ ይችላል? እንዴት?

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15. ሁነኛ መፍትሄዎች
    - ከላይ ያወራነውን ችግሮች ወይም ቅራኔዎች አስመልከተው እንዲሁም ከህመምተኛው የሚመጡትን ከማገናዘብ አንፃር፣ የታካሚውን የመቀበል አቅም ለማሻሻልና የኢንሱሊን ህክምና ውጤታማ ለማድረግ ሊያቀርቡት የሚችሉት መፍትሄ ይኖራል?

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በመጨረሻም በተጠቀሰው አርዕስት ላይ ተጨማሪ ሀሳብ ወይም አስተያየት ካለዎት እርስዎ መቀጠል ይችላሉ

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ለትብብርዎ አመሰግናለሁ!!!

ለታካሚው የተዘጋጀ ቃለ መጠይቅ

ክፍል 1: መግቢያ

1. ፆታ፡ ወንድሴት☐ ☐
2. እድሜ: _____
3. የትምህርት ደረጃ፡ _____
4. የቃለ መጠይቁ ቀን: _____
5. ቦታ: _____

ክፍል 2: ጥናቱን የተመለከቱ ጥያቄዎች

6. አጠቃላይ መግቢያ
   - ❖ ለመጀመሪያ ጊዜ ኢንሱሊን በታዘዘልዎ ወቅት የጤና ባለሙያው ስለ መድሃኒቱ አጠቃቀም እንዴት እንዳስረዳዎት ያስታውሳሉ፡፡ እባክዎን የሚየስታውሱትን ሊያጋሩኝ ይችላሉ?
   - ❖ ኢንሱሊን እንዲጀምሩ የተጠየቁበት ምክንያቶች ምን ይመስልዎታል?

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7. የህመምተኛው አመለካከትና እምነት
   - ❖ የኢንሱሊን መድሃኒት ለመውሰድ ፍቃደኛ ኖት? ካልሆነ ፍቃደኛ ያልሆኑበት ምክንያቶች ምንድን ናቸው?
   - ❖ አብዛኛው ህመምተኛ ኢንሱሊን በሚጀምርበት ወቅት የተለያዩ ለውጦችንና አለመመቻቸት እንደሚያጋጥማቸው ፍርሃት በተሞላው አነጋገር ይገልፃሉ፡፡ የእርስዎ አስተያየት በዚህ ላይ ምን ይመስላል?
   - ❖ ኢንሱሊን ቢጀምሩ ኖሮ ምን አይነት ለውጦች/ችግሮች የሚያጋጥምዎት ይመስልዎታል?

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8. ኢንሱሊን በጊዜ እንዳይጀምሩ የሚያደርግ ከሀኪሙ ጋር ተያይዞ ያጋጠምዎት ችግር አለ?

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9. ከ ክሊኒኩ ወይም ከሆስፒታሉ ጋር ተያይዞስ ኢንሱሊን በጊዜው ወስነው እንዳይወስዱ የሚያደርግ ያጋጠምዎት ችግር አለ?

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10. ክትትል እና ድጋፍ

- ኢንሱሊን ቢጀምሩ ኖሮ አንዳንድ ከመድሃኒቱ ጋር ተያይዘው የሚመጡ ለውጦችን እንዴት አርገው ሊቋቋማቸው ያስባሉ?
- የአኗኗር ዘይቤን በተመለከተ ምን አይነት ለውጦችን ወይም ማሻሻያዎችን እንደሚኖሩ ይጠብቃሉ?
- ኢንሱሊንን ለመጀመር ምን አይነት ድጋፍ ወይም እርዳታ ይፈልጋሉ?

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በመጨረሻም በተጠቀሰው አርዕስት ላይ ተጨማሪ ሀሳብ ወይም አስተያየት ካለዎት እርስዎ መቀጠል ይችላሉ

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ለትብብርዎ አመሰግናለሁ!!!

ANNEX III: QUESTIONNAIRE FOR THE QUANTITATIVE PART

Addis Ababa University
College of health sciences
School of pharmacy
Department of pharmaceutics and social pharmacy

Introduction

This questionnaire form is prepared to assess the prevalence of delayed initiation of insulin in patients with type 2 diabetes at the Diabetes Clinic of Tikur Anbessa Specialized Hospital. I am postgraduate pharmacy students conducting a study on the aforementioned research topic and factors associated with it. The research could mainly serve for the clinic to identify for modifiable factors and intervene accordingly for a better patient outcome. For the purpose of obtaining the necessary in information I am delivering the following self-prepared questionnaire.

1. Age:
2. Sex- Male/Female
3. City of the patient=_____
4. Duration of the illness (T2DM):_____
5. Is there proper titration of medications: _____
6. If yes to question 5, is there a delay to insulin initiation? Yes/No

Insulin Type_____

7. Is there any complications/co-morbid conditions? Yes/No
8. If yes to question number 7, what kind?
   - □Cardiovascular diseases
   - □Retinopathy
   - □Diabetic foot ulcer
   - □Cerebrovascular Disease
   - □Neuropathy
   - □Nephropathy
   - □Hypertension
   - □Dyslipedmia

□Asthma

□Others: _____

9. FPG of the two consecutive months with high oral anti-hyperglycemic medications_____
10. Blood Pressure, if any, during the two consecutive months with high oral anti-hyperglycemic medications:_____
11. Are there concurrent Medications used? Yes/ No

□Beta blockers

□Calcium Channel Blockers

□Diuretics

□ACIs/ARBs

□Statins

□Digoxin

□Antiplatelet agents (Aspirin and/or clopidogrel)

□Others: _____

Thank You!

ANNEX IV: ETHICAL LETTERS

የውስጥ ደዌ ሕክምና ክፍል
ህክምና ትምህርት ቤት
አዲስ አበባ ዩኒቨርሲቲ

Department of Internal Medicine
School of Medicine
Addis Ababa University

Date: December 27, 2016
Ref. No. IMD/169/09

UNIVERSITY FACULTY OF MEDICINE * Department of Internal Medicine * ADDIS ABABA ETHIOPIA

To: Endocrinology Unit

From: Dr. Addisu Melkie
Head, Department of Internal Medicine

Subject: Approval of Research Proposal

A research entitled "***Assessment of Prevalence of Delayed initiation of insulin and associated factors in patients with Type 2 Diabetes Mellitus at the Diabetic Clinic of Tikur Anbessa Specialized Hospital"*** which will be performed by **Elham Reshid**, the above research proposal was reviewed and approved by Departmental Research and Ethics Committee. This research can be conducted in Tikur Anbessa Specialized Hospital, Department of Internal Medicine.

With regards

CC:

- To Elham Reshid

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Addis Ababa University

School of Pharmacy
Ethical Review Board

ቀን Date: December 08, 2016

ቁጥር Ref. No.: ERB/SOP/02/09/2016

To: Elham Reshid
School of Pharmacy

Re: Ethical Clearance

It is to be recalled that you submitted a study proposal entitled, "Assessment of Prevalence of Delayed Initiation of Insulin and its Factors in Patients with Type -2 Diabetes Mellitus at the Diabetic Clinic of Tikur Anbessa Specialized Hospital" for ethical approval by the School's Ethical Review Board (ERB). The Board thoroughly reviewed the proposal based on its operational guidelines and found it to fulfill all ethical requirements stipulated in the guidelines. This is, therefore, to inform you that the proposal is ethically approved for implementation.

With best regards,

Daniel Bisrat (Dr.)
Secretary, ERB

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