

ADDIS ABABA UNIVERSITY
COLLEGE OF HEALTH SCIENCES
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Research Title:

Knowledge, Practice, and Attitude of patients and physicians towards insulin therapy in Type 2 DM

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Acronyms

DM- Diabetes Mellitus

WHO- World Health Organization

HHS- Hyperglycemic Hyperosmolar State

DKA- Diabetic Ketoacidosis

ASCVD- Atherosclerotic Cardiovascular Diseases

CKD- Chronic Kidney Disease

TASH- Tikur Anbesa Specialized Hospital

eGFR- Estimated Glomerular Filtration

SGLT2i- Sodium-Glucose Transporter 2 Inhibitor

GLP-1 RA- Glucagon-Like Peptide-1 – Receptor Agonist

Abstract

Background: As type 2 DM is a growing health problem worldwide early treatment and intensification of therapy will decrease the vascular complications as evidenced by large trials. Insulin therapy is delayed in this group of patients and multiple physician and patient factors are mentioned in different settings.

Objective: This study aims to assess patients' and physicians' knowledge, practice, and attitude towards insulin therapy in Type 2 DM to answer the reason for not early insulin initiation by physicians and the patients' refusal to start insulin therapy.

Methods: This study is a cross-sectional, quantitative descriptive study conducted on 221 patients at TASH endocrine clinic and 122 physicians working at TASH, residents visiting for detachment, and Yekatit 12 hospital. Conducted on Jul 1- Sep 30, 2020, G.C

Result: 76% of physicians think taking insulin at the prescribed time is difficult while only 31.5% of patients think it's difficult. Hypoglycemia is one of the most fearful parts of having diabetes for 81.1% of patients on Insulin therapy. 87% of physicians and 76.6% of patients think insulin-treated diabetes controls life while. 56% of patients therapy know nothing about insulin therapy. 23% of patients said they will not accept insulin therapy the top reason being they will be afraid of insulin injection because they think it will be painful.

Conclusion: Physicians tend to overestimate the difficulty of insulin injection preparation and dose adjustment fears the risk of hypoglycemia when starting insulin therapy. More than half of our patients not on insulin therapy know nothing about insulin therapy which we have to improve. Even if patients not on insulin therapy overestimate insulin needle phobia and injection pain those who are already on insulin disagree with them.

Keywords: Type 2 DM, Insulin treatment, Treatment inertia

1. Introduction

1.1 Background

Diabetes mellitus is a group of metabolic disorders characterized by abnormal glucose, fat, and protein metabolism. The defining feature of diabetes is hyperglycemia which leads to acute complications like DKA, HHS, or chronic micro-and macrovascular complications like nephropathy, neuropathy, retinopathy, cardiovascular diseases. Diabetes occurs due to an absolute or relative deficiency of insulin secretion along with a varying degree of peripheral resistance to insulin action.[1–4]

Globally the prevalence of diabetes reached 463 million in 2019 and this is estimated to reach 578 million by the year 2030 and 700 million in 2045.[5] Around 4 million deaths were caused by diabetes in the year 2012 and this includes 1.5 Million deaths related directly to diabetes and additional 2.2 million deaths due to complications related to diabetes (cardiovascular disease, chronic kidney disease, and tuberculosis) in 2012. In Africa, the total number of adults with diabetes is 19.4 million from those 1.7 million are Ethiopians.[6, 7] Previous studies have shown that the prevalence of diabetes in Ethiopia is around 6.5% in urban areas and 1.9% in a rural setting.[8, 9] A recent STEPS survey done by the Ministry of Health has found a prevalence of 3.2%.[10]

According to the WHO 2019 classification of diabetes, it is classified as Type 1 which is mainly immune-mediated β -cell destruction, Type 2 which is characterized by impaired insulin secretion with peripheral insulin resistance, Hybrid type which has both features of type 1 and types 2, Other Specific types, Unclassified which is a temporary classification until we do the investigations and observe the clinical course and hyperglycemia first detected during pregnancy.[1]

Type 2 Diabetes is the most common type accounting for around 90 % of the cases[11, 12] The proportion of patients with Type 2 DM which is undiagnosed varies from 24-62% across regions in the world.[7] Of all patients with Type 2 DM, 40% of the patients are asymptomatic during diagnosis and from those asymptomatic patients, 32% of them will have a microvascular complication at the time of diagnosis.[8]

As patients with type 2 diabetes are mostly asymptomatic during diagnosis and around 32% of them already have a microvascular complication during diagnosis achieving good glycemic

control has shown significant benefit in different large clinical trials. The UKPDS trial showed significant benefit (12% reduction) in terms of diabetes-related endpoints (sudden death, death from hyperglycemia or hypoglycemia, fatal or non-fatal myocardial infarction, angina, heart failure, stroke, renal failure, amputation [of at least one digit], vitreous hemorrhage, retinopathy requiring photocoagulation, blindness in one eye, or cataract extraction); diabetes-related death (death from myocardial infarction, stroke, peripheral vascular disease, renal disease, hyperglycemia or hypoglycemia, and sudden death); all-cause mortality from an intensive glycemic control group and most of this benefit come from a reduction of microvascular complication by 25% and there was a borderline statically significant benefit in reducing Macrovascular complications. This was also proven in the long-term follow-up of these patients.[13, 14] In the Kumamoto study type 2 diabetic patients assigned to the intensive glycemic control group were shown to benefit from the treatment and lower incidence and progression of retinopathy and nephropathy were documented after 6 years of treatment.[15]

The ADVANCE trial in patients with intensive glycemic control (H_gA₁C -6.5%) has shown a 10% reduction in the combined outcome of macrovascular as well as microvascular events mainly due to a 21% relative reduction in nephropathy. In the ACCORD trial which relatively involved patients with long-standing Type 2 DM, there was a reduction of microvascular complications like retinopathy, nephropathy. But there was increased cardiovascular mortality in the intensive arm and the study was discontinued early.[16–18]

The VADT trial was performed to define the benefit of intensive glycemic control in patients with poorly controlled long-standing Type 2 DM with a mean duration of 11.5 years after diagnosis with 40% of the patients already with cardiovascular events. There was no difference in the occurrence of cardiovascular events between the intensive and conventional treatment groups.[19]

Target H_gA₁C levels in Type 2DM patients should be individualized according to the patient life expectancy, the already developed micro and macrovascular complications. Generally, the target H_gA₁C level is <7%. However, in those patients with long-standing diabetes with complications, elderly, children, comorbidity, and those with recurrent hypoglycemia and difficult to control diabetes despite appropriate therapy including insulin the less stringent target (<8%) is appropriate.[20]

The treatment of Type 2 DM starts with diabetes education, lifestyle measure, and prevention of microvascular and cardiovascular complications, and avoidance of drugs that exacerbate micro and macrovascular complications. The first-line pharmacologic treatment is Metformin unless contraindicated. The other treatments depend on whether there are established cardiovascular diseases or not, HF or CKD. If ASCVD or CKD predominates the preferred management will be GLP-1 RA or SGLT2i with proven CV benefit and should be started if the eGFR allows. If the priority is weight loss and Metformin is the first-line therapy and if still, the HgA1C is high, the addition of SGLT2i or GLP-1 RA or Addition of DPP-4 is possible. If cost is the major issue after we start the patient on metformin, we can add SU or TZD, and if still there is high HgA1C we can add basal insulin. For patients with HgA1C >10% or 2% above target HgA1C despite triple or dual therapy we have to consider to start the patients on injectable GLP-1 RA initially and if the HgA1C is still above the target we have to start the patients on basal insulin but if the patient has HgA1C >11% and has symptoms and evidence of catabolism like weight loss, polydipsia or polyuria we have to consider insulin as a first-line injectable. To avoid inertia we have to assess each patient every 03-06 months.[21–23]

Eventually, many patients with Type 2 DM will require insulin therapy; so, we have to educate all patients about the possibility of the need for insulin therapy and we have to counsel them not to consider it as a personal failure.

1.2 Literature review

Type 2 Diabetes is a group of metabolic disorders characterized by insulin resistance and progressive absolute insulin deficiency due to β -cell depletion over the years. Insulin could be used as initial therapy in patients with severe hyperglycemia at presentation and with catabolic features, patients with difficulty to differentiate the type of diabetes, or after oral hypoglycemic therapy failed to control hyperglycemia. [21][24]

Achieving tight glycemic control as early as possible after the diagnosis of type 2 DM has shown to be beneficial in preventing microvascular as well as macrovascular complications as shown in the UKPDS study.[13] Despite this evidences, there is significant clinical inertia on initiating and intensifying oral medication as well as initiating insulin therapy when indicated.[25]

As we go through works of literature there are multiple reasons quoted by the physicians as well as by patients for not initiating or accepting insulin therapy.[26] GAAP study is a multi-centered

survey conducted in 8 countries. Most physicians on this survey report that many insulin-treated patients do not have adequate glucose control (87.6%) and they would have treated aggressively if not for the fear of hypoglycemia. The majority of patients and /or physicians regard insulin treatment as restrictive, more patients see insulin treatment as positive than negative impact on their lives. [27] Another international survey DAWN study involving 13 countries showed patients and provider attitudes about insulin therapy differ significantly. Patients rate the clinical efficacy of insulin as low and blame themselves if they had to start insulin. Patients who are not managing their diabetes well consider insulin therapy as beneficial. Most nurses and general practitioners (50–55%) delay insulin therapy until necessary, but specialists and opinion leaders are less likely to do so.[28]

The DIPP FACTOR, a prospective observational study done in Korea shows patients' related factors for delay in insulin initiation included older age, shorter duration of diabetes, and lower HgA1C. Physicians related factors included age between 50-60, women sex, and the number of patients consulted per month <1000 especially patient's refusal (33.6%) and physician's concern of patient's noncompliance (26.5%) were the major physician reported reason for delaying insulin therapy. The inconvenience of insulin therapy (51.6%) and fear of injection (48.2%) were the major reason for the patient's refusal.[29]

Patients from China gave the following reason for resisting insulin therapy: inconvenience (64.3%); concerns over addiction (24.6%); pain (14.3%); side effects (14.1%); and high cost (13.6%).[30] In a study done at Turkish primary care, most patients (57.4%) considered that insulin was a drug of last resort; 34% thought that insulin lowered blood glucose level to an extreme degree and 14.9% disagreed. 27.6% of them thought self-injection was hard, another 27.6% required someone else to administer the injection, 33% say insulin injection was painful.[31]

According to a Caribbean study done in Trinidad, factors that delay insulin therapy included limited knowledge concerning insulin therapy, failure to conduct a regular and routine assessment of HgA1C values, perception of insulin being painful, fear of needle, hypoglycemia, weight gain, scarring at the injection site and embarrassment were specific barriers.[32]

A study from Kenya on psychological resistance to insulin in type 2 DM patients showed a prevalence of 82.6% and those who were already on insulin therapy have lesser psychological resistance compared to the non-insulin users.[33]

In Ethiopia in a study done at TASH majority of patients with type 2 DM have uncontrolled fasting glucose level and the factors which are significantly associated with poor glycemic control were longer duration of diabetes (AOR = 2.72 95%CI:1.16–6.32), and being on insulin therapy (AOR = 3.01 95% CI: 1.5–5.9).[34] There is no data for Ethiopia regarding patient's and physician's attitudes and knowledge in starting insulin in Type 2 diabetes.

2. Significance of the study

As discussed in the aforementioned introduction and literature review, type 2 diabetes is becoming a major health care burden in the world as well as in Ethiopia and it continues to increase in the coming years as estimated by IDF. Early treatment and prevention of complications are some of the areas where countries that are struggling economically like ours should focus on. Because of the financial as well as health care system strains that we have, the management of micro and macrovascular complications will be difficult.

As most of our patients with Type 2 Diabetes have poor glycemic control and insulin is an affordable injectable medication in our setup knowing the attitude, practice, and knowledge of patients and physicians and intervening based on the result will be a good solution for improving diabetes care of patients with uncontrolled hyperglycemia. This study involves residents, GPs and Internists, and patients from TASH and Yekatit 12 Hospital and visiting residents for detachment at TASH. As there is no data for our setup this will be a good starting point to have an idea about physician and patient's knowledge, practice, and attitude about insulin therapy.

3. Objectives

3.1 General objective

- To assess physicians and patient's knowledge, practice, and attitude towards insulin therapy in Type 2 DM patients

3.2 Specific Objectives

- To assess the knowledge of physicians treating T2DM patient about insulin therapy
- To describe barriers for initiating insulin therapy in patients with indications
- To Assess practice of insulin therapy in Type 2 DM patients among patients and physicians
- To assess the patient's knowledge about insulin therapy

4. Methodology

4.1. Study Area

The study was conducted on T2DM patients in TASH endocrine clinic and Residents, GP, Internists at TASH, Yekatit 12 hospital, Zewditu hospital, Mizan Tepi University, Debrebrhan university, Ras Desta Hospital, Jimma university medical center, Dilla university referral hospital, Adama medical college Arsi University, and St. Paul millennium medical college were who gave consent was involved.

4.2. Study design

This study is a cross-sectional, quantitative descriptive study

4.3. Study Period

The study was conducted from July-1 to September- 30, 2020

4.4. Source population

T2DM patients attending Endocrine clinic at TASH and Internal medicine residents at TASH and those visiting residents for detachment from other universities, Internists, and General practitioners working at Yekatit 12 hospital, Ras Desta hospital, Debrebrhan hospital, Dilla university hospital, Mizan tepi Hospital.

4.4.1. Sampling Methods

All General Internists, all residents, and General practitioners working in the Diabetic clinic who consented filled the online survey tool was included.

The sample size for the patients was calculated with the following formula: assuming 95% CI and P-0.82 taking the 82% psychological resistance reported in the Kenyan study.

$$n = \frac{Z^2 x (p) (1-p)}{d^2} = \frac{1.96^2 x 0.82(1-0.82)}{0.05^2} = 221$$

4.4.2. Sample size

A total of 122 physician and 221 patient was interviewed by convenient sampling from those interviewed patients 110 T2DM patients were not on Insulin therapy and 111 on insulin therapy were interviewed using a structured questionnaire.

4.5. Inclusion and exclusion criteria

4.5.1. Inclusion criteria

- All Internists, internal medicine residents, and general practitioners who gave consent for the study working at the Diabetes clinic in TASH, Yekatit 12, Zewditu Hospital and visiting residents for detachment from other university hospitals in TASH
- T2 DM patients on follow up at TASH diabetes clinic

4.5.2. Exclusion criteria

- All patients and physicians who will not provide informed consent
- Those patients with no record of HgA1C in the past 03-06 month

4.6. Study variables

4.6.1. Independent variables

- Age
- Gender
- Level of practice
- Year of experience
- Number of patients with Type 2 DM which have been seen each month on average

4.6.2. Dependent variables

- Knowledge about insulin therapy in Type 2 DM patients
- Attitude about insulin therapy in type 2 DM patients
- The practice of insulin therapy in type 2 DM patients

4.7. Data collection

Data collection was conducted using a structured questionnaire prepared for the patients (separate questionnaire prepared for patients on insulin therapy and those not started insulin yet) by the main investigator and nurses at the diabetic clinic. The physician's questionnaire was sent to them via e-mail and telegram individually using google forms separately by the main investigator. The questionnaires were pretested on 10 patients and 10 residents.

4.8. Data quality assurance

The quality of the data was assured by a daily on-site visit and checking for completeness of data by the main investigator and the online survey was sent by the investigator

4.9. Data management and analysis

After checking the data quality by the principal investigator, the data entry was done to MS. Excel 2019 for data cleaning and coding then exported to Statistical Package for Social Sciences (SPSS) Version 26 for analysis.

4.10. Ethical Clearance

Ethical clearance was obtained from the Department of Internal Medicine and Research and Publications Committee of the School of Medicine, College of Health Sciences, Addis Ababa University. Respondents were informed about the purpose of the study and the information required from them. There was no risk or harm to the participants associated with the study.

The study is designed to assess physician's and patient's knowledge, practice, and attitude towards insulin therapy in type 2 DM patients and the collected data was anonymous. The participants have the full right to withdraw from the study.

4.11. Dissemination of the result

As this study is being done for the fulfillment of residency training, the result will be presented for defense and the research output will also be submitted for scientific reviewers for possible publication in scientific journals.

5. Result

A total of 224 patients was interviewed using a structured questionnaire and 221 were selected and 3 were discarded for incomplete data. A total of 122 Physicians who consented to the online survey was included in the study.

5.1. Characteristics of the participants

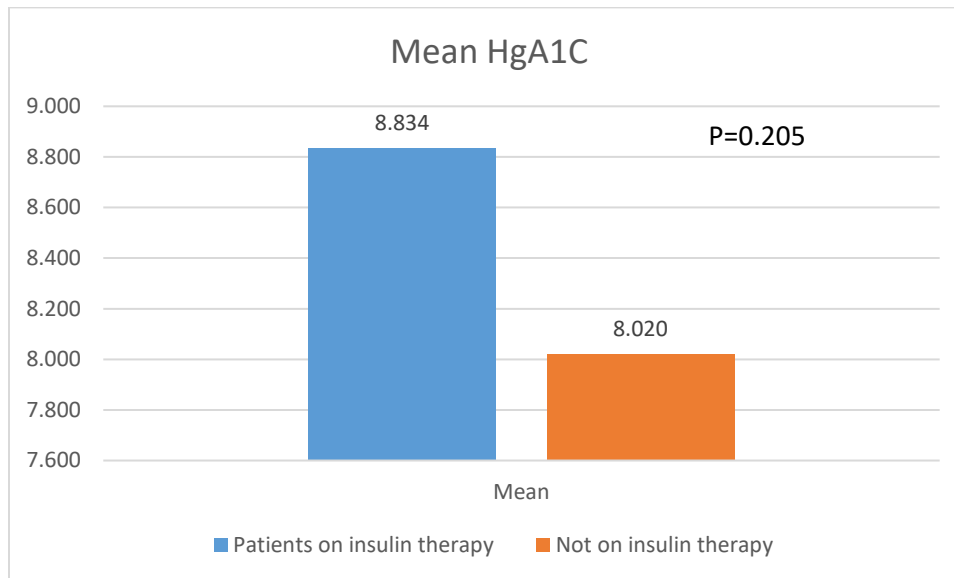
A total of 122 physicians 111 patients on insulin therapy and 110 patients not on insulin therapy were involved. **(Table:1)** Physician Mean age 28.9 ± 2.4 years and 71.3% of them are males. 77.9% of them were internal medicine residents and 12.3% were General practitioners; one endocrinologist and one endocrine fellow were also involved. Of all physicians, 56.6% had an experience of 3-5 years. The average number of patients seen per month was a median of 15.

Table 1 Characteristic of patients and physicians

	Patients on Insulin Therapy(n-111)	Patients not on insulin therapy (n-110)
Age (mean, SD)	54.5 ± 11.3	55.18 ± 11.9
Sex	Female 73(65.8%)	61(55.5%)
Residence	Urban -96.4% Rural-3.6%	Urban -97.3% Rural-2.7%
Level of Education	Illiterate-10(9%) Primary education-16(14.4%) Secondary Education-53(47.7%) Tertiary Education-28(25.2%) Advanced Degree-4(3.6%)	Illiterate-7(6.4%) Primary education-24(21.8%) Secondary Education-31(28.2%) Tertiary Education-35(31.8%) Advanced Degree-13(11.8%)
Duration of diabetes in Years	14.9 ± 9.1	7.45 ± 5.6
Last HgA1C	8.84% ± 2.08%	8.02% ± 2.07%
Percentage of patients who remember their last HgA1C	70.3%	70.9%
Physicians (n-122)		
Age (mean, SD)	28.9 ± 2.4	
Sex n (%)	Male-87(71.3%)	
Level of practice	Endocrinologist-1(0.8%) Endocrine fellow-1(0.8%) Internist-10(8.2%) Internal medicine resident-95(77.9%) General practitioner-15 (12.3%)	
Year of experience	1-12 months-12(9.8%) 1-2 years-31(25.4%) 3-5 years-69(56.6%) >5 Years-10(8.2%)	
Average no of T2DM Patients seen/month (median)	15	
Currently practicing at	1.TASH-89(73.3%) 2, Yekatit 12- 6(4.9%) 3, Dilla University referral hospital-9(7.4%) 4, Other- 18(14.8%)	

(Table:1) The mean age of patients was 54.5 ± 11.3 and 55.18 ± 11.9 years for those on insulin therapy and not on insulin respectively. The majority of patients were females 65.8% and 55.5% for those on insulin therapy and not on insulin respectively. The duration of diabetes is 14.9 ± 9.1 years for those on insulin therapy currently and 7.45 ± 5.6 years for those not on insulin therapy.

Figure 1 Mean HgA1c of patients on insulin therapy and Not on Insulin



(Fig:1) The HgA1c was mean of 8.8 for those on insulin and 8.02 for those, not on insulin therapy which is not statically significant (p=0.205(person correlation test))

5.2. Physician and patient's perception and reason for non-adherence to insulin therapy

Seventy-six percent of physicians think taking insulin at a prescribed time is difficult while only 31.5% of patients think it's very difficult or somewhat difficult. Physicians think measuring blood glucose routinely is difficult at 88.5%. Ninety-six percent of physicians wish to have an insulin treatment that would cover patients in case they forget a dose and 89.2% of patients Wish the insulin regimen that would fit daily life changes. **(Table:2)**

Experiencing low blood glucose events is one of the most fearful parts of having diabetes for 81.1% of patients on Insulin therapy. Eighty-seven percent of physicians think insulin-treated diabetes takes control of life, but 76.6% of patients agree with them. Sixty percent of physicians think it is hard to live a normal life while managing diabetes and 66.6% of patients agree with them.

Table 2; Patient and physician perceptions of insulin treatment

Categories	Patient	Physicians
<i>Patient difficulties[#]</i>		
Taking insulin at the prescribed time or with meals every day	31.5%	76.2%
Number of daily injections	32.4%	73.7%
Following the physician's instructions	14.4%	68%
Preparing injections	15.3%	54.1%
Adjusting insulin dose	21.6%	NA
Measuring blood glucose routinely	20.7%	88.5%
Changing the time of insulin to meet daily needs	NA	87.7%
<i>Opinion^{\$}</i>		
I would treat my patients' diabetes more aggressively if there was no concern over hypoglycemic events	NA	82%
I feel like I have to choose between efficacy and safety when treating diabetes patients with insulin	NA	88.5%
Wish there was an insulin treatment that would cover patients in case they forget a dose	NA	96.7%
Wish for good control with insulin that does not need to be injected every day	83.8%	NA
Wish the insulin regimen would fit daily life changes	89.2%	
Experiencing low blood glucose events is one of the most fearful parts of having diabetes	81.1%	NA
Insulin-treated diabetes controls life	76.6%	87.7%
Hard to live a normal life while managing diabetes	66.6%	59.9%

--Very difficult and somewhat difficult \$-strongly agree or somewhat agree

Being too busy, traveling, or changing normal routine and embarrassing to inject in public was the top 3 reasons for the omission of insulin doses mentioned by patients. The top 3 reasons

mentioned by physicians as a possible cause of non-adherence of insulin therapy is Traveling and changing normal routine, forgetting to take insulin during traveling, **(Table:3)**

Table 3; Reason for not taking insulin

Reasons	Patients		Physicians	
	%	Rank	%	Rank
Too busy	33.3%	1	13.9%	8
Forgot	19.0%	4	39.3%	3
Challenging to take insulin at the same time every day	---		39.3%	3
Fall asleep	19.0%	4	8.1%	10
Skipped Meal	9.5%	5	36%	4
Embarrassing to inject in public	23.8%	3	25.4%	6
Traveling or changing normal routine	28.5%	2	44.2%	1
Did not take insulin out/forgot to take it while traveling	---		40.1%	2
The regimen is too complicated	9.5%	5	7.3%	11
Injection are painful	---		14.7%	7
Stress or emotional problems	19.0%	4	30.3%	5
Avoid weight gain	---		9.0%	9
Other	---		5.7%	12

Almost all patients use insulin syringes to administer insulin and the mean duration of insulin therapy was 9.44 ± 7.87 years. Eighty-eight percent of patients inject two times daily and 95% of them said they are content with the current insulin strategy. Seventy-four percent of patients receive the treatment for free and 96.3% of them reported insulin is expensive whenever they have to buy it. **(Table 4)** Nineteen percent of patients admitted they missed insulin doses sometimes and 62.3% of physicians think their typical patient may have missed insulin injections.

Fifty-six percent of patients think their diabetes is mostly under control and only 2.7% of patient thinks their diabetes is under control. Eighty-seven percent of physicians think a significant number of diabetes patients are still not reaching target HbA1c adequate blood glucose levels with insulin treatment.

Table 4 Insulin usage practice in patient on insulin therapy

Insulin Usage experience	Response
Insulin administering device	Syringe-110(99.1%) Pen-1(0.9%)
Duration of insulin therapy in years	9.44 ± 7.87
Number injection per day	1 injection-13(11.7%) 2 injections-98(88.3%)
The convenience of the current insulin strategy	Yes-95(86.4%) NO-15(13.6%)
Self-administration of insulin	Yes-96(86.5%) No-15(13.5%)
Pain during injection	Never-55(49.5%) Sometimes-53(47.7%) Most times-3(2.7%)
Receive insulin for free	Yes-74.8%
Is it costly when you have to buy insulin	Yes-96.3%
Have you ever missed your insulin?	Yes-21(18.9%) No-90(81.1%)

5.3. Knowledge and Perception of patients not on insulin therapy

Fifty-six percent of patients in our clinic not started on insulin therapy know nothing about insulin therapy and 50.9% of patients want more communication from their doctors about insulin therapy. **(Table 5)**

Table 5: knowledge about Insulin therapy in Non-insulin treated T2DM patient

	Yes		No		Don't know	
	Count	Row N %	Count	Row N %	Count	Row N %
If your doctor ever recommended insulin therapy to better control your diabetes would you take it?	75	68.2%	26	23.6%	9	8.2
Have you ever felt the need for more communication from your doctor about insulin therapy?	56	50.9%	54	49.1%	—	—
How much do you know about insulin	Frequency	Valid Percent				
A great deal	13	11.8				
Some	10	9.1				
Little	25	22.7				
Nothing	62	56.4				

Twenty-three percent of patients said they will not accept insulin therapy if insulin is recommended by their treating physicians the top reasons, they mentioned are they will be afraid of insulin injection because they think it will be painful. 38.4% of patients fear passing out due to low blood sugar.

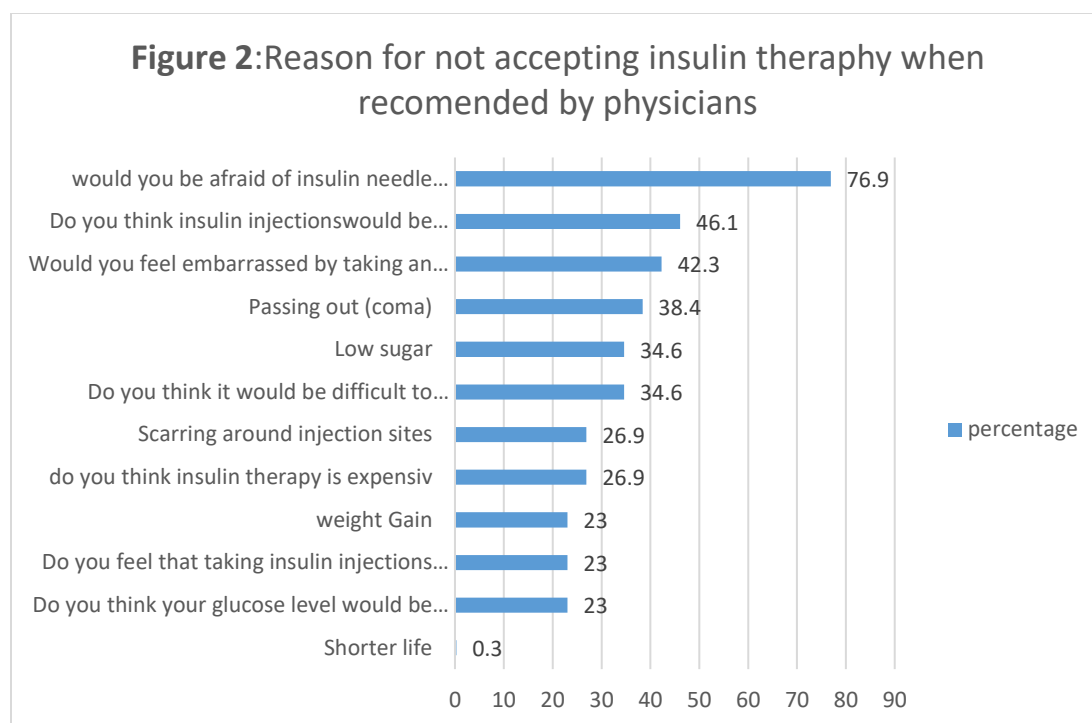


Figure 2 Reason for not accepting insulin therapy when recommended by physicians

5.4. Knowledge and practice of physicians

There was a statistically significant difference between Internists, Internal medicine residents on the frequency of HgA1C follow-up and agreement on a significant number of patients, not achieving target HgA1C. Sixty percent of Internists wait for >6 months to intensify treatment if patients are not achieving target HgA1C while 41.1% of internal medicine residents and 60% of General practitioners intensify therapy within 3 months.

Table 6 Knowledge attitude and practice of physician

	Internist(n=10)	Internal medicine resident(n=95)	GP(n=15)	P-value [#]
Target HgA1C				
HgA1C<6.5	0	17.9%	20%	
HgA1C<7	100%	80.0%	73.3%	
HgA1C<8.5	0	2.1%	6.7%	0.346
How long do you wait to start insulin if HgA1C is off-target?				
<3 month	40%	11.6%	6.7%	
3-6 month	50%	71.6%	66.7%	
6 month-1 year	10%	12.6%	26.7%	
1-2 year	0	4.2%	0	0.205
How long do you wait to intensify treatment if HgA1C is off-target?				
Immediately	50%	36.8%	40%	
after 3 months	10%	41.1%	60%	
3-6 month	0	18.9%	0	
>6 month	40%	3.2%	0	0.206
How frequently do you follow the HgA1c level?				
Every 3 month				
3- 6 month	30%	40%	40.0%	
Every 6 month	20%	43.2%	13.3%	
	50%	16.8%	46.7%	0.013
A significant number of patients are off-target glycemic control				
Agree	90%	90.5%	66.7%	
Disagree	10%	9.5%	33.3%	0.048
Do any of your typical patients fail to take their insulin as prescribed?				
Yes				
No	50%	61.1%	73.3%	

May be	10%	6.3%	0	0.692
	40%	32.6%	26.7%	

Fishers exact test

Fifty-five percent of physicians said they will mention insulin therapy at the time of diagnosis and 45.6% of them mention it at the time of intensifying oral treatment.

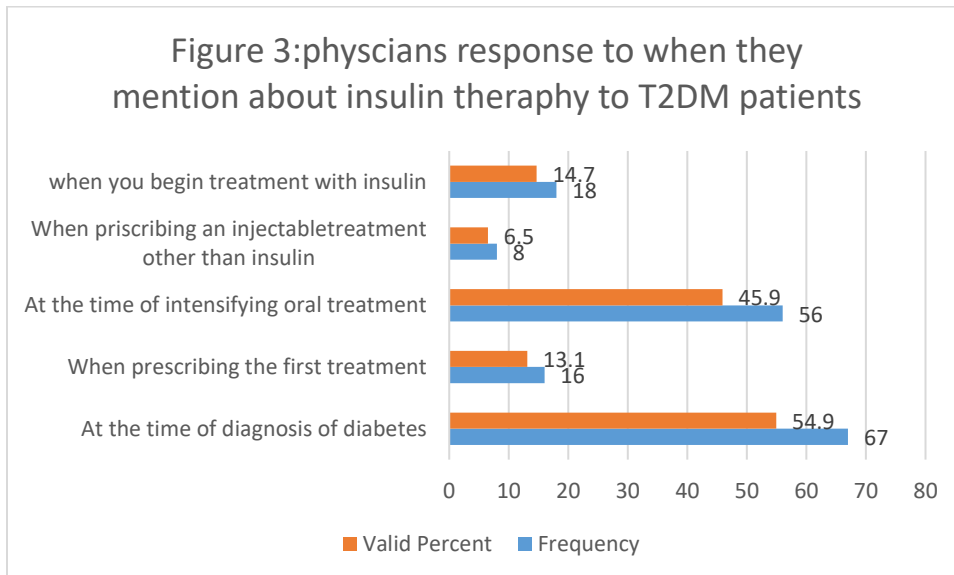


Figure 3: physicians' response to when they mention insulin therapy to T2DM patients

Only 81.2% of physicians start the patients on insulin therapy at the time of diagnosis if HgA1C >10% and 90.9% of them will start the patient on treatment if HgA1C is above target despite dual or triple therapy.

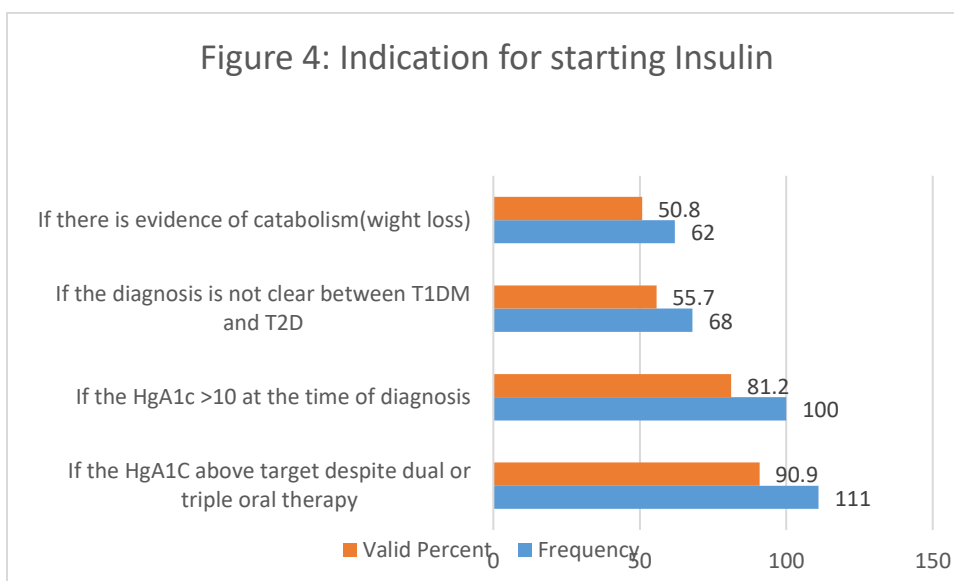


Figure 4 Indication for starting Insulin

6. Discussion

In this study, we tried to show differences in perception between patients and physicians about insulin therapy. There is no significant difference between those taking insulin and those not on insulin therapy on the HgA1C level which shows treatment is not being intensified timely in study patients. Although more than half of physicians think preparing injection is difficult for patients but only 15.3% of patients agree with them and this is comparable to The GAAP study in which only 10.3% of patients reported difficulty. Only 21.6% of patients said it's difficult to adjust the insulin dose; on the GAAP survey, 16.8% of them reported difficulty which will make it easier to recommend adjusting insulin dose according to their requirement.[27]

The majority (88.5%) of our physicians feel they have to choose between efficacy and safety when they treat diabetes with insulin and which is higher compared to Japanese physicians involved in the GAAP study which was 62%. This is probably due to the lesser availability of self-blood glucose monitoring in our setup.[35]

Most of our patients and physicians agree on a wish for possible insulin regimen that would cover if patients forget to take a dose or fits daily life which was 96.7% of physicians and 83.8% patients which are comparable to the GAAP study 92.5% and 91.2% for patient and physicians respectively.[27]

Compared to the patients on the GAAP study more patients in our setting said it is hard to live a normal life while managing diabetes 66.6% Vs 54.4 %.[27] this could be 96.3% of them said it's expensive for them to buy insulin. In the Kenyan study, 46.1% of patients feel insulin management will make life less flexible.[33]

Nineteen percent of patients admitted they missed insulin doses sometimes which is lesser than the GAAP study participants which were 33.2%, and 62.3% of physicians think their typical patient may have missed insulin injections which is still lesser than the physicians in the GAAP study 72.5%. The top reason mentioned by patients for the omission of insulin dose is being too busy both on the GAAP and our patients. Traveling was the second most common reason reported by both patients and physicians in our setting as well as in the GAAP study.[27]

When we see our patients not yet started on insulin therapy compared to the Trinidad study more than half of the 56.4% Vs 38% of patients admitted know nothing about insulin and 22.7% Vs 34.1% know a little about insulin therapy [32] which shows a great knowledge gap in our patients compared to our physicians reported only 54.7% of them to mention about insulin therapy at the time of diagnosis of T2DM.

More than half of our patients not on insulin therapy want more communication about insulin therapy from their physicians and 43.6% of them reported their physicians have recommended them insulin therapy to better control their diabetes which is greater than the patients in Trinidad which were 15 %. When our patients were asked if they would take insulin if recommended by their doctor, 68.2% of them said they will take it which is better than the Trinidad study which was 54.6%, and even if it's not directly comparable 82.7% of Kenyan patients has Psychological resistance to insulin therapy.[32][33]

The two top reasons for refusing insulin therapy by patients, not on insulin therapy is fear of insulin needles (79.6%) and possible pain during injection 46.1% of patients which is higher than Trinidad patients reported 54% and 56% respectively.[32] However, half of our insulin-treated patients reported they have never felt pain during injection.

There is no statistically significant difference between Internists, internal medicine residents, and GPs on the target HgA1C, delay to initiate insulin if HgA1C is off-target, intensification of therapy, and agreement on patients may fail to take insulin as prescribed. But there was a statically significant difference in the frequency of HgA1C follow-up in which 50% of internists and 46.7% of GPs want to follow HgA1C every 6 months while 43.2% of residents want to follow every 03-06 months which is in line with the ADA 2020 recommendation.[22] The other area which shows a significant discrepancy between physicians is the significant number of patients has off-target HgA1C where 33.3% of GPs tend not to agree with this opinion but 90% of our internists and 90.5% of our Residents agree on this idea which is in line with the Japanese patients on GAAP study.[35]

Most of our physicians mention insulin therapy at the time of diagnosis or during the intensification of oral therapy. Despite ADA 2020 guideline recommendation to start patients on insulin therapy for patients with evidence of catabolism only 50.8% of our physicians start these patients on insulin therapy, for those with HgA1C >10% at diagnosis only 55.7% of our physicians start these patients on insulin therapy, for patients with difficult to differentiate between type 1 and type 2 DM 81.2% of our physicians start these patients on insulin therapy and for patients with HgA1C above target despite dual or triple oral therapy 90.9% of our physicians start these patients on insulin therapy.[22]

7.Limitation of the study

The study participant patients are from single-center which may not be representative of the whole diabetic population in our country. The number of physicians involved in the study is small and we need a survey involving more internists and General practitioners in the future.

8.Conclusion

Most of our patients both in the insulin group and those not on insulin have poor glycemic control. Physicians tend to overestimate the difficulty of insulin injection preparation and dose adjustment fears the risk of hypoglycemia when starting insulin therapy. More than half of our patients not on insulin therapy know nothing about insulin therapy which we have to improve. Even if patients not on insulin therapy overestimate insulin needle phobia and injection pain those who are already on insulin disagree with them.

9.Recommendation

We need to educate our patients more about insulin therapy and possibly create a forum for patient-to-patient education on our diabetes follow up clinics

We need a continuous medical education forum on updated guidelines and treatment recommendations possibly online with GPs and Internists working out of teaching centers.

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ANNEXES

Consent form for physicians

Dear study participant,

I would like to thank you for participating in this survey, as part of the study on Knowledge and Attitude of patients and physicians towards insulin therapy in Type 2 DM

You are kindly requested to answer the study questionnaire as truthfully as possible.

TITLE OF THE STUDY: Knowledge and Attitude of patients and physicians towards insulin therapy in Type 2 DM.

PURPOSE OF THE SURVEY: This part of the study aims to assess the knowledge, attitude, and practice of participants on insulin therapy in type 2 diabetes

RISK OF THE STUDY: There is no risk associated with participating in the study.

POSSIBLE BENEFITS: By participating in the study, you will aid in generating an understanding of the current level of care offered to Type 2 DM patients. The study aims to **promote better practice in the care of patients with Type 2 DM.**

COMPENSATION: There will be no compensation given.

RIGHT TO WITHDRAW: Your participation in this study is voluntary. You are free to decline it, without any consequences. You also have the right to change your mind anytime without any consequences.

CONFIDENTIALITY: Your identity will remain confidential. The answers obtained will be documented and analyzed anonymously. Only researchers will have access to personal information which only includes your age, gender, specialty, and year of study. The researcher's aim for this study is purely academic and scientific purposes. If you have any questions about the study, contact Dr. Biniyam Woya, 0911-05-69-77. Before I involve you in my study, I kindly request you to sign the consent form below. You are free to ask any questions before signing the consent form.

Signature _____

Part I Demographic data Please encircle or write the data that describes you best		
1	Gender	[0]. Male [1]. Female
2	Age in Years	
3	Nationality	[0] Ethiopian [1] Other Specify.....
4	Level of practice	[0]. Endocrinologist [1]. Internist [2]. Internal Medicine Resident [3]. General practitioner
5	Year of Experience	[0]. 1-12 months [1]. 1-2 Years [2]. 3-5 years [3] >5years
6	How many patients with T2DM on average do you treat each month? (including inpatient and outpatient services)	
7	In which Hospital are you practicing?	[0] Tikur Anbesa Hospital [1] Yektit 12 Hospital
8	If you are a resident, in what kind of hospital are you going to work after completion of residency?	[0] Primary hospital [1] Secondary hospital [2] Tertiary hospital [3] Other specify.....
Part II Knowledge about Insulin in T2DM patients Please indicate/write your answers for the given questions in the given space		
1	What is the preferred initial pharmacologic agent in a patient with T2DM patients	[0].Metformin [1].Insulin [2].Sulfonylureas [3].GLP-1 receptor agonist [4].SGLT2
2	What's is the general glycemic target when treating T2DM patients in general	[0].HgA1C<6.5 [1].HgA1C<7 [2].HgA1C<8.5

3	What are the conditions we put patients with T2DM on Insulin Therapy	[0] If the HgA1C above target despite dual or triple oral therapy [1] If HgA1C >10 at the time of diagnosis [2] If the Diagnosis is not clear between T1DM and T2DM [3] If there is evidence of catabolism (Weight loss)
4	If the oral therapy doesn't achieve target levels how long do you take to start insulin therapy	[0].<3 month [1].3-6 month [2]. 6month-1 year [3]. 1-2 year
5	In the follow-up of a patient with type 2 diabetes, at what stage of treatment you mention the insulin treatment?	[0]. At the time of diagnosis of diabetes [1]. When prescribing the first treatment [2]. At the time of intensifying oral treatment [3]. When prescribing an injectable treatment other than insulin [4]. When you begin treatment with insulin
6	When do you consider intensification of therapy if the patient HgA1C is above the target	0.Immediately 1.after 3 month 2.3-6 month 3.>6 month
7	How frequently do you follow the HgA1c level	0. Every 3 month 1. 3- 6 month 2. Every 6 month
Part III Attitude about Insulin treatment in T2DM patients Please indicate/write your answers for the given questions in the given space		
8	A significant number of diabetes patients are still not reaching target HbA1c/adequate blood glucose levels with insulin treatment.	0. Agree 1. Disagree
9	Do any of your typical patients fail to take their insulin as prescribed?	0. Yes 1. No
10	If yes for the above question How many days in the past month do you expect a typical patient to have missed their basal insulin dose, or not taken their basal insulin exactly as prescribed?	Specify the no_____
11	Which one of the following reasons do you expect to be a reason for the omission of the dose of insulin prescribed for typical Patient	0. Too busy 1. Forgot 2. Challenging to take insulin at the same time every day 3. Fell asleep 4. Skipped meal 5. Embarrassing to inject in public 6. Traveling or changing normal routine 7. Did not take insulin out/forgot to take it while traveling 8. The regimen is too complicated 9. Injections are painful 10. Stress or emotional problems 11. Avoid weight gain

	Indicate the level of difficulty for your patients while taking insulin	
12	Taking insulin at the prescribed time or with meals every day	0. Very difficult 1. Somewhat difficult 2. Very easy 3. Somewhat easy 4. Don't know
13	Number of daily injections	0. Very difficult 1. Somewhat difficult 2. Very easy 3. Somewhat easy 4. Don't know
14	Following the physician's instructions	0. Very difficult 1. Somewhat difficult 2. Very easy 3. Somewhat easy 4. Don't know
15	Preparing injections	0. Very difficult 1. Somewhat difficult 2. Very easy 3. Somewhat easy 4. Don't know
16	Changing the time of insulin to meet daily needs	0. Very difficult 1. Somewhat difficult 2. Very easy 3. Somewhat easy 4. Don't know
17	Measuring blood glucose routinely	0. Very difficult 1. Somewhat difficult 2. Very easy 3. Somewhat easy 4. Don't know
	What's your opinion on the following issues	
18	'I would treat my patients' diabetes more aggressively if there was no concern over hypoglycemic events	0. strongly agree 1. somewhat agree 2. strongly disagree 3. somewhat disagree 4. Neither 5. Do not know
19	I feel like I have to choose between efficacy and safety when treating diabetes patients with insulin	0. strongly agree 1. somewhat agree 2. strongly disagree 3. somewhat disagree 4. Neither 5. Do not know

20	Wish there was an insulin treatment that would cover patients in case they forget a dose	0. strongly agree 1. somewhat agree 2. strongly disagree 3. somewhat disagree 4. Neither 5. Do not know
21	Wish for good control with insulin that does not need to be injected every day	0. strongly agree 1. somewhat agree 2. strongly disagree 3. somewhat disagree 4. Neither 5. Do not know
22	Wish the insulin regimen would fit daily life changes	0. strongly agree 1. somewhat agree 2. strongly disagree 3. somewhat disagree 4. Neither 5. Do not know
23	Do your patients feel diabetes controls their lives?	0. strongly agree 1. somewhat agree 2. strongly disagree 3. somewhat disagree 4. Neither 5. Do not know
24	Hard to live a normal life while managing diabetes	0. strongly agree 1. somewhat agree 2. strongly disagree 3. somewhat disagree 4. Neither Do not know

Consent form for patients

Dear study participant,

I would like to thank you for your participation in this survey, as part of the study on Knowledge and Attitude of patients and physicians towards insulin therapy in Type 2 DM

You are kindly requested to answer the study questionnaire as truthfully as possible.

TITLE OF THE STUDY: Knowledge and Attitude of patients and physicians towards insulin therapy in Type 2 DM.

PURPOSE OF THE SURVEY: This part of the study aims to assess the knowledge and attitude of Type 2 Diabetes patients on insulin therapy

RISK OF THE STUDY: There is no risk associated with participating in the study.

POSSIBLE BENEFITS: By participating in the study, you will aid in generating an understanding of the current level of care offered to you and other patients with a similar illness. The study aims to **promote a better understanding of a patient's concern regarding insulin therapy.**

COMPENSATION: There will be no compensation given.

RIGHT TO WITHDRAW: Your participation in this study is voluntary. You are free to decline it, without any consequences. You also have the right to change your mind anytime without any consequences.

CONFIDENTIALITY: Your identity will remain confidential. The answers obtained will be documented and analyzed anonymously. Only researchers will have access to personal information which only includes your age, gender, specialty, and year of study. The researcher's aim for this study is purely academic and scientific purposes. If you have any questions about the study, contact Dr. Biniyam Woya, 0911-05-69-77. Before I involve you in my study, I kindly request you to sign the consent form below. You are free to ask any questions before signing the consent form.

Signature _____

Questionnaire

S.No	Part I Demographic data of patients with T2DM Please encircle or write the data that describes you best	
1	Gender	0. Male 1. Female
2	Age in Years	
3	Residence	0. Urban 1. Rural
4	Level of education	0. Illiterate 1. Primary education 2. Secondary education 3. Tertiary education 4. Advanced degree
5	How long have you had diabetes	_____years _____months
6	In which hospital are you taking your treatment	0. Tikur anbessa specialized hospital 1. Yekatit 12 hospital
7	Are you currently on insulin therapy	0. Yes 1. No
8	Do you remember your last HgA1C	0. Yes 1. No
9	If yes What is it	_____ (to be checked from the patient record)
Part II For insulin users only		
1	What type of insulin administering device do you use?	0. Pen 1. Syringe 2. pump
2	How long have you injected insulin?	_____years_____months
3	The number of injections per day?	0. 1 1. 2 2. 3 3. 4 4. >4

4	If you had to inject insulin more frequently, would this trouble you?	0. Yes 1. No
5	Do you find it easy to take insulin the way you are taking it now?	0. Yes 1. No
6	Do you administer insulin to yourself?	0. Yes 1. No
7	Is insulin administration painful?	0. Never 1. Sometimes 2. Most times 3. Always
8	Is your insulin therapy always free?	0. Yes 1. No
9	If “No” when you have to purchase your insulin is it expensive?	0. Yes 1. No 2. Don’t know
11	Do you find insulin administration convenient?	0. Yes 1. No
12	Do you find it easy to take all the doses recommended by the doctor?	0. Yes 1. No
13	Do you ever miss your insulin dose or fail to take your insulin exactly as prescribed by your healthcare professional?	0. Yes 1. No
14	What are the 3 topmost common reasons for the omission of your insulin dose	0. Too busy 1. Forgot 2. Challenging to take insulin at the same time every day 3. Fell asleep 4. Skipped meal 5. Embarrassing to inject in public 6. Traveling or changing normal routine 7. Did not take insulin out/forgot to take it while traveling 8. The regimen is too complicated 9. Injections are painful 10. Stress or emotional problems 11. Stress or emotional problems 12. Avoid weight gain
Part III Attitude about Insulin treatment in T2DM patients who is on insulin therapy Please indicate/write your answers for the given questions in the given space		
	Indicate the level of difficulty while taking insulin	
15	Taking insulin at the prescribed time or with meals every day	0. Very difficult 1. Somewhat difficult

		2. Very easy 3. Somewhat easy 4. Don't know
16	Number of daily injections	0. Very difficult 1. Somewhat difficult 2. Very easy 3. Somewhat easy 4. Don't know
17	Following the physician's instructions	0. Very difficult 1. Somewhat difficult 2. Very easy 3. Somewhat easy 4. Don't know
18	Preparing injections	0. Very difficult 1. Somewhat difficult 2. Very easy 3. Somewhat easy 4. Don't know
19	Adjusting insulin dose	0. Very difficult 1. Somewhat difficult 2. Very easy 3. Somewhat easy 4. Don't know
20	Measuring blood glucose routinely	0. Very difficult 1. Somewhat difficult 2. Very easy 3. Somewhat easy 4. Don't know
21	To what extent do you feel that your diabetes is under control in terms of you managing your blood sugar levels, and low blood sugar events (hypoglycemia), diet, and exercise?'	0. Completely under control 1. Mostly under control 2. Somewhat under control 3. Not at all control
	What's your opinion on the following issues	
22	Wish for good control with insulin that does not need to be injected every day	0. strongly agree 1. somewhat agree 2. strongly disagree 3. somewhat disagree 4. Neither 5. Do not know

23	Wish the insulin regimen would fit daily life changes	0. strongly agree 1. somewhat agree 2. strongly disagree 3. somewhat disagree 4. Neither 5. Do not know
24	Experiencing low blood glucose events is one of the most fearful parts of having diabetes	0. strongly agree 1. somewhat agree 2. strongly disagree 3. somewhat disagree 4. Neither 5. Do not know
25	Insulin-treated diabetes controls life	0. strongly agree 1. somewhat agree 2. strongly disagree 3. somewhat disagree 4. Neither 5. Do not know
26	Hard to live a normal life while managing diabetes	0. strongly agree 1. somewhat agree 2. strongly disagree 3. somewhat disagree 4. Neither 5. Do not know

For Insulin none users

Knowledge and Attitude about Insulin treatment in T2DM patients who is not on insulin therapy		
Please indicate/write your answers for the given questions in the given space		
1	How much do you know about insulin therapy?	0. A great deal 1. Some 2. Little 3. Nothing
2	Has your clinic doctor ever recommended insulin therapy to better control your diabetes?	0. Yes 1. No
3	If your doctor ever recommended insulin therapy to better control your diabetes would you take it?	0. Yes 1. No 2. Don't know
4	Do you think insulin therapy is expensive?	0. Yes 1. No 2. Don't know
If you had to take insulin therapy:		
5	Would you be afraid of insulin needle injections?	0. Yes 1. No 2. Don't know
6	Do you think insulin injections would be painful?	0. Yes 1. No 2. Don't know

7	Do you think your glucose level would be better controlled on insulin?	0. Yes 1. No 2. Don't know
8	Do you feel that taking insulin injections would be time-consuming?	0. Yes 1. No 2. Don't know
9	Do you think it would be difficult to control your diet if on insulin therapy?	0. Yes 1. No 2. Don't know
10	Would you feel embarrassed by taking an insulin injection in public?	0. Yes 1. No 2. Don't know
11	Do you feel insulin therapy can result in any of the following?	0. Yes 1. No 2. Don't know
	Low sugar	0. Yes 1. No 2. Don't know
	Passing out (coma)	0. Yes 1. No 2. Don't know
	Weight Gain	0. Yes 1. No 2. Don't know
	Scarring around injection sites	0. Yes 1. No 2. Don't know
	Shorter life	0. Yes 1. No 2. Don't know
12	Do you think insulin treatment would interfere with everyday activities (social, leisure work, or school activities)?	0. Little 1. A lot 2. Not at all 3. Don't know
13	If insulin therapy was suggested for you which method of administration would you prefer?	0. Pen 1. Pump 2. Syringe 3. Don't know
14	Have you ever felt the need for more communication from your doctor about insulin therapy?	0. Yes 1. No

Declaration

I, the undersigned, declare that this postgraduate thesis is my original work, has not been presented for a degree in this or any other university, and that all sources of materials used for the thesis have been duly acknowledged.

Postgraduate Candidate: Biniyam Woya (MD)

Signature: _____

Date of submission: _____

This thesis has been submitted with my approval as an advisor.

Advisor: Ahmed Reja (MD, Internist, Consultant Endocrinologist)

Signature: _____

Date: _____