



SAINT PAUL'S HOSPITAL MILLENNIUM MEDICAL COLLEGE

**ASSESSMENT OF INSULIN INJECTION PRACTICE AND ITS ASSOCIATION WITH
INSULIN RELATED OUTCOMES AMONG PATIENTS WITH DM AT ENDOCRINE
CLINIC AT SPHMMC**

By: ZEMEDU LEGESSE JIMA (MD, IM RESIDENT)

RESEARCH THESIS TO BE SUBMITTED TO ST PAUL'S HOSPITAL MILLENNIUM
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ADDIS ABEBA, ETHIOPIA

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ADDIS ABABA, ETHIOPIA

Acronyms and Abbreviation

CGM: Continuous Glucose Monitoring

DM: Diabetes Mellitus

HgbA1C: Hemoglobin A1C

IM:Intramuscular

IT: Injection Technique

ITQ: Injection Technique Questionnaire

LatAM: Latin America

MAGE: Mean amplitude glycemic excursion

MD: Medical Doctor

NCD: Non Communicable Disease

OGLA: Oral Glucose Lowering Agents

OPD: Outpatient department

ROW: Rest of the world

SPHMMC: Saint Paul Hospital Millennium Medical Collage

SPSS: Statistical package for social science

TASH: Tikur Anbessa Specialized Hospital

T1DM: Type one diabetes mellitus

T2DM: Type two diabetes mellitus

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Abstract

Background : Diabetes mellitus (DM) is a chronic disease characterized by high blood glucose level which is associated with serious complications. Glycemic control is important to prevent/delay DM related macro or micro vascular complications. Appropriate insulin injection is indispensable to achieve adequate control of DM and prevent complications.

Objective: To assess insulin injection practice and its association with the insulin related-outcomes among DM patients who are on follow up at SPHMMC, at adult endocrine clinic.

Methods: An institution based, cross-sectional study was conducted using a structured questionnaire for interview on representative sample of 352 diabetic patients; who are on follow-up at St. Paul's Hospital Millennium Medical College endocrine clinic from January-March 2022 to assess insulin injection practice and related outcomes. Systemic random sampling was conducted to get the required sample size. The collected data was entered into a computer using Statistical Package for Social Sciences (SPSS) version 25.0 for windows. Means, standard deviations and percentages were calculated and cross-tabulation was used to compare different variables and subjected to Chi-square analysis to assess various relationships with a significance level of P-value < 0.05.

Results: Among 352 study population majorities are in age range of 20-60(64.2%) and 183 are male .The study has revealed skin fold making before injection, inspecting injection site, injection site rotation, resuspension of cloudy insulin, insulin syringe reuse and frequent hand washing before injection were practiced by 71.9%.58.3%,66%,94% ,93% and 69.9% respectively of the study population. According to this study appropriate insulin injection was practiced only by 16.2% of the study population. Optimal glycemic control was achieved in 54% of the study population.Age($p=0.001\%$),gender($p=0.048$ and monthly income($p=0.01\%$) have shown statistical significance with glycemic control. But place of residence ($p=0.52\%$) and good/poor appropriate insulin injection($p=0.608\%$) have not shown any statistical significance.

Conclusion and recommendation –Overall appropriate insulin injection practice is low. Therefore, every time a patient visits the hospital they should be educated on how to use insulin appropriately, with a focus on proper injection techniques. Periodic evaluations of knowledge on their use of insulin injections are necessary.

Keywords: Insulin, Diabetes mellitus, Injection ,Ethiopia

. Introduction

1.1 Background of the study

Diabetes mellitus is a serious, long-term condition that occurs when there is a raised level of glucose in the blood because the body can't produce any or enough insulin, or can't effectively use the insulin it produces(1). It is recognized as an important cause of premature death and disability & is one of four priority non-communicable diseases (NCDs) targeted by world leaders in the 2011 Political Declaration on the Prevention and Control of NCDs. The declaration recognizes that the incidence and impacts of DM and other NCDs can be largely prevented or reduced with an approach that incorporates evidence-based, affordable, cost-effective, population wide and multi-sectorial interventions(2). Diabetes mellitus has become a global epidemic. An estimated 463.0 million (20–79 years) worldwide have DM; 79.4% living in low- and middle-income countries. This is expected to rise to 578.4 million by 2030 and 700.2 million by 2045 DM(1). In Africa there are around 19 million people living with DM; according to the 2019 IDF report, which is estimated to project to 29 million and 47 million by 2030 & 2045 respectively(1).

The same report estimated Ethiopian DM prevalence to be around 3.2% and 1 in 31 adults; age 20-79yrs, having DM(1). Diabetes is a common health problem worldwide(3). It is a major cause of micro-vascular and macro-vascular complications such as diabetic retinopathy and blindness, chronic kidney disease (CKD), myocardial infarction (MI), stroke and lower limb amputation due to diabetic foot(2)(4). In 2019, the total burden of deaths from DM & its complications is estimated to be 4.2million and DM related health expenditure of around 760billion USD(1). The largest number of deaths resulting from high blood glucose occur in upper & middle income countries (1.5 million) and the lowest number in low-income countries (0.3 million)(2). It demands comprehensive therapy involving appropriate use of intensive insulin regimens, blood glucose monitoring, physical activity, body and devices inspection and a healthy diet(5). Proper insulin injection is indispensable to achieve adequate control of DM and prevent complications (6). Adequate knowledge and attitude about insulin self-administration could also improve the management of diabetes and eventually improve the quality of life(7). Insulin is an effective drug for the control of blood sugar level. It is the mainstay treatment for patients with type 1 diabetes (T1DM) and it is often used as an adjuvant to oral hypoglycemic agents in patients with type 2 diabetes (T2DM) who failed to achieve target blood glucose levels(8).

The primary goal of diabetes management is to achieve the blood sugar level within the target ranges. In an effort to meet this target, an appropriate delivery of insulin is essential(8). Diabetic patients are very likely to benefit from good adherence and proper implementation of specific recommendations(9).

Since diabetes management involves self-injection of insulin, improper injection of insulin may result in poor glycemic control and insulin related adverse effects such as hypoglycemia, and injection-related skin problems(5).

A correct injection technique is essential for insulin and other subcutaneously administered medications to ensure optimal effect in people with diabetes mellitus (DM). It implies the ability to (i) choose the best needles, (ii) rotate injection sites regularly, (iii) handle and store insulin appropriately, (iv) insert needles correctly into the skin, (v) let pen needles inside the skin long enough to get the whole dose be absorbed and (vi) manipulate the skin before and after the injection(10)..

Diabetes nurses and observant patients have long known that the technique of injection is critical to the successful use of insulin, but the medical community at large and most insulin-injecting patients remain woefully unaware of the how and whys of proper technique(11).

Therefore, patients must learn the correct insulin injection techniques to appropriately deliver the insulin into the subcutaneous tissues, to avoid intramuscular injections and to prevent complications(12). Studies aiming to explore insulin injection practice are timely and very critical, particularly for patients with inappropriate injection practice, which significantly affects their clinical outcome. As a result, patients would be advantageous as this study assess their injection practice and its effect on their clinical outcomes. Besides, research outputs from this study would be primarily beneficial to patients and prescribers for appropriate and efficient use of insulin. To the best of investigator's knowledge, little is known about insulin injection practice in Ethiopia, in which this study aimed to generate inferences for the study setting, SPHMMC.

1.2. Statement of the Problem

Diabetes mellitus is a common health problem worldwide. Insulin therapy is an essential component of medications used in DM treatment and the cornerstone of treatment in type 1 and type 2 diabetes. Proper insulin administration plays an important role in long term optimal blood sugar control(7) .

A good practice of insulin injection could also improve the management of diabetes and eventually improve the quality of life. Effect of insulin relies on correct dose and appropriateness of insulin injection technique. However, inappropriate technique is common among diabetes patients(13).

Repetitive injection at the same site will cause skin bruising and hypertrophy which will cause decreased insulin absorption. Direct injection without making skinfold may result in insulin injection into the muscle resulting in hypoglycemia(14). In addition, inappropriate usages of insulin and improper injection techniques have been reported by certain studies.

Professionals were observed to rarely explain the importance of using an appropriate needle length for the patients' subcutaneous tissue depth, proper rotation of injection sites, changing of needles between injections, storage of insulin and monitoring of their injection site for the presence of lipodystrophy. Therefore, it is important to assess insulin injection practice of patients with diabetes.

1.3. Significance of the Study

As DM related complications and associated morbidity and mortality from DM; which is recognized globally as one of the top causes of mortality and morbidity, are largely prevented or at least delayed by timely initiation and intensification of treatment. Knowing the barriers and the associated factors for poor glycemic control is very helpful not only for the patient but also for the healthcare system and the country as a whole. This study will help in showing barriers to good glycemic control by assessing injection practice and its association with insulin injection outcome patients on insulin therapy. So this study may help as a stepping stone for future further studies and more importantly it might be used as a basis & guide for the hospital to develop institution based interventions and can be used as initiative for other institutions & the country at large so as to combat this problem which ultimately improve quality of health care, reduce morbidity and mortality, reduce burden on the health care system and decrease health care costs related to poor glycemic control.

2. Literature review

2.1 DM prevalence and associated factors

According to the 2019 IDF report approximately 463 million adults (20-79 years) were living with DM; which is expected to rise to 700 million by 2045 & 374 million people are at increased risk of developing T2DM(1).

According to IDF report, Africa currently has the lowest prevalence among all the IDF Regions, likely due to lower levels of urbanization, under-nutrition and under-reporting. Based on this report estimated 19.4 million adults aged 20–79 years have DM, representing a regional prevalence of 3.9%. Of this, 45.9% live in low-income countries and 54.1% in middle-income countries. The highest prevalence (8.8%) of DM in the region is among adults aged between 65 and 69 years(1).

Ethiopia is among the countries with highest DM prevalence in the region. The same report estimated prevalence of 3.2% with 1.6 million people being affected(1).

Generally the risk factors for T2DM can be classified as modifiable and non-modifiable. The non-modifiable risk factors include age, ethnicity and genetics. The modifiable ones include overweight & obesity, diet, physical inactivity, smoking & IGT etc. with overweight and obesity being the major ones(1)(2).

2.1.1 Insulin injection practice

In 2020 GC, in Makkah, Saudi Arabia a cross sectional study was done to assess insulin injection technique among diabetic patients. Four hundred and thirty-seven DM patients have participated in the study. The most prevalent age group was between 20 and 60 years old (69.1%) and included both T1DM and T2DM patients. The study showed only 54.7%, 41%, 75%, and 63.2% of patients correctly had stored insulin inside fridge door, washed hands before injection, checked insulin

expiration date, and used alcohol swab to rub the site of injection, respectively. The study has concluded that insulin injection practice in Makkah region were not satisfactory(6).

Another crosssectional studydone at Chitwan Medical College Teaching Hospital in Bharatpur, Nepal has identified a significant gap between the insulin injection recommendation and current insulin injection practice. The assessment of insulin injection technique and insulin pen storage practice revealed that twenty (46.5%) patients were storing their insulin pen (insulin cartridge inside) at room temperature and an equal number of patients kept their insulin pen inside refrigerator while three (7%) patients stored their insulin pen in a clay pot. The study revealed insulin injection practice of the participants was in adequate (15).

Another injection technique questionnaire (ITQ) survey done in India has also shown poor injection technique (deep intramuscular) has resulted in higher HgbA1(16).

In Brazil also insulin Injection Technique Questionnaire (ITQ) survey was done to assess insulin injection technique in Brazilian patients and compare the results to data from Latin America (LatAm) and the rest of the world .The study showed, 48 percent of patients skip doses, 80 percent reuse pen needles, and 57 percent reuse syringes, with 27 percent of patients showing lipohypertrophy by exam .It showed that the insulin injection technique of Brazilian patients need further improvement(17).

In TASH, Ethiopia, a hospital-based cross-sectional study was conducted to assess insulin injection practice and it's association with insulin related outcome in T1DM patients. This study has shown poor injection practice will lead to non-optimal glycemic control, 83% of them had HgbA1C of above 7.5% (non-optimal) and 31% reported at least one episode of hypoglycemia .But higher proportion of the study subjects practiced appropriate insulin injection techniques when compared to previous study(5)

Another institution-based cross-sectional study that was conducted at Zewditu Memorial Hospital (ZMH), Ethiopia has reported malpractice of insulin self-administration .Although the majority 177(72.2%) of the study patients have administered insulin themselves, only 120(49.0%) of the patients injected insulin appropriately at 45 degree of angle. Frequent repetition of the injection site was practiced among 176(71.8%) patients and 139(56.7%) injected insulin before or immediately after food intake(7).

2.2. Conceptual framewor

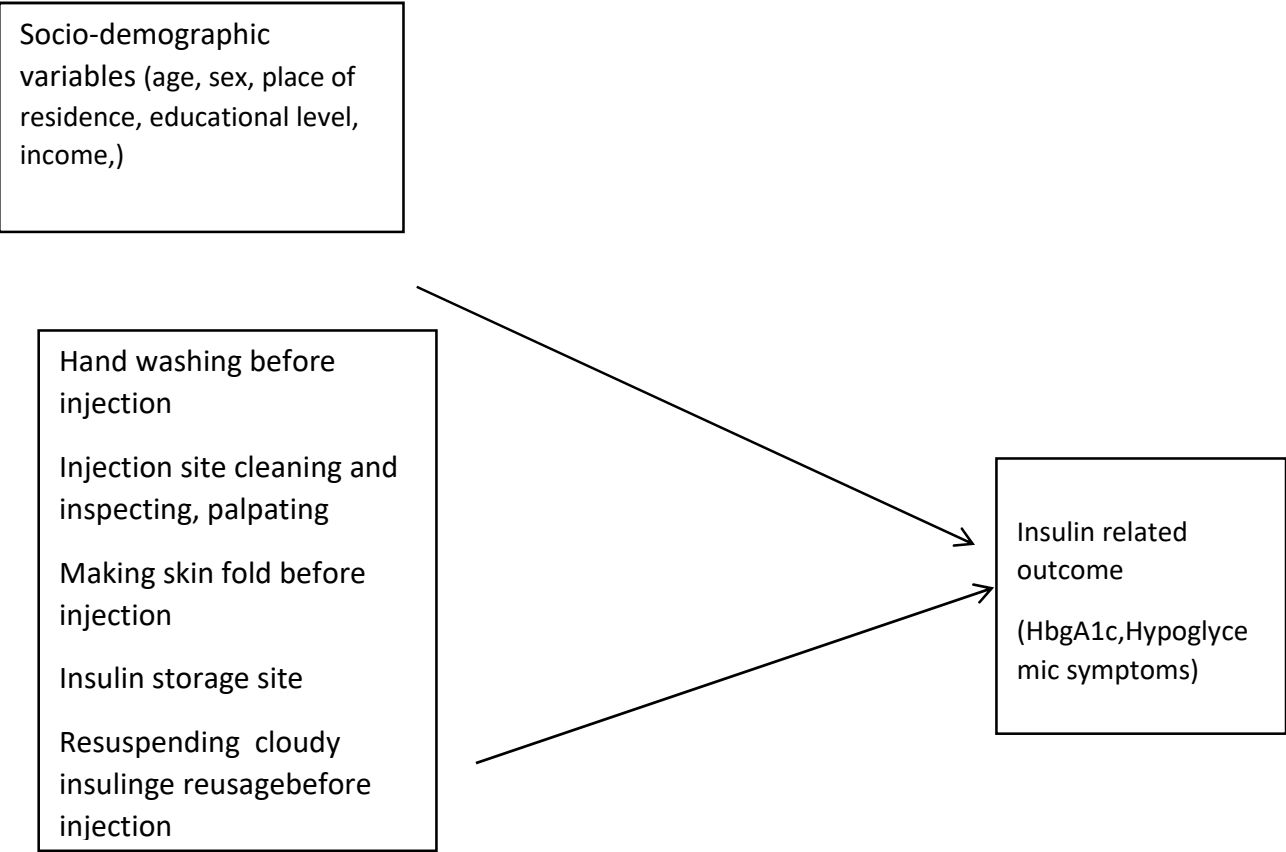


Figure 1: diagrammatic representation of conceptual framework (Self-prepared)

3. Research Objectives

3.1. General objective

To assess insulin injection practice and its association with insulin related outcomes among DM patients.

3.2. Specific Objectives

To assess insulin injection techniques among DM patients.

To assess association of insulin injection practice with insulin related outcomes among DM patients.

4. Methods

4.1. Study Area

The study was conducted in SPHMMC, in endocrinology follow-up clinic. St. Paul's hospital is one of the largest tertiary referral public hospital in the capital under the Federal Ministry of Health. The hospital is located at Gullele Sub city at Swaziland Street, Addis Ababa, Ethiopia. Established by Emperor Haile Selassie in 1961, the hospital primarily gives service to those unable to afford care elsewhere. It has over 1200 clinical and non-clinical staff. The hospital added a medical college in 2007 G.C. There are over 21 departments which include: internal medicine, pediatrics, gynecology/obstetrics, general surgery, emergency medicine, psychiatry, ophthalmology, radiology, dermatology. Under the department of internal medicine, there are a number of sub-specialties including gastroenterology, nephrology and cardiology (school website). Endocrinology specialty unit is one of the core areas where both outpatient and inpatient services as well as academic activities are carried out despite scarcity of human resource (18)

4.2 Study period

The study was conducted from January - March 2022.

4.3. Study Design

Cross-sectional study

4.4 Population

4.4.1. Source population

All diabetic patients on follow-up at SPHMMC adult endocrine clinic will be the source population.

4.4.2. Study population

Selected diabetic patients who are on insulin therapy at least for one year and on follow-up at SPHMMC during the study period.

4.5. Inclusion and exclusion criteria

4.5.1 Inclusion criteria

All diabetic patients who are on insulin for at least one year Age greater than 18 years and patients who are on follow-up at endocrine clinic were included in this study.

4.5.2. Exclusion Criteria

Patients below 18 years, those who are on only OGLA, patients who were diagnosed with gestational diabetes, patients who were using insulin treatment transiently (<1 year) and patients with mental/cognitive disorders were excluded from this study.

4.6. Sample size determination

Sample size is calculated by using the single population proportion formula

$$n = Z^2 p (1-p) / d^2$$

n= required sample size

Z= confidence level at 95% (standard value of 1.96)

d= margin of error = 5%

P= estimated insulin injection practice is not known in Ethiopia and 50% is taken as proportion of population to give maximum sample size.

$$n = (1.96)^2 \times 0.5 \times 0.5 / (0.05)^2$$

n=384

Since the study population is <10,000, there is a need to use population correction formula which is:

$$n = n_i \times N / (N + n_i)$$

where, ni= initial sample size=384, N= study population =1920 and N=total number of diabetic patients who have follow up at SPHMMC.

Because the source population is <10,000, the final sample size determined as follows

$$n_f = n / (1 + n/N)$$

$$n_f = 384 / (1 + 384/1920) = 320$$

Final sample size. by adding 10% contingency a total of 352 will be sampled.

4.7. Sampling Method

Total number of diabetic patients seen during the study period; from January to March 2022 was 1920 according to HMIS report. Average number of diabetic patients seen per day was 53; which is three times per week with maximum appointment of 3 months. With this consideration to give each diabetic patient an equal chance of inclusion, the total sample size was divided by 12 days which result in 29 diabetic patients to be studied every week; which means 10 patients were interviewed per day. To identify the potential study participants using a systematic random sampling technique, 29 was divided by 10 to obtain the constant for the sampling interval, which was 3. The first patient was selected randomly and then every 3rd patient was obtained until the daily limit was achieved and this technique was continued until the final sample size was obtained. For patient who was not eligible another patient (i.e either the 2nd or 4th patient was used).

4.8. Variables

4.8.1. Independent Variables

Age

Gender

Educational level

Residence

Marital status

Occupation

Income

Duration of DM

4.8.2. Dependent variables

1. Insulin injection related outcome (glycemic control)

2. Insulin injection techniques/practice

4.9. Operational definitions

Diabetes mellitus- defined fasting blood sugar >125 mg/dl, OR HgA1c >6.5 %,symptoms of hyperglycemia and random blood sugar >200 ,OR two hour oral glucose tolerance test >200 mg/dl(19)

Hypoglycemia- was defined as the occurrence of one or more symptoms of hypoglycemia (such as palpitations, tiredness, sweating, strong hunger, dizziness and tremor) and a confirmed blood glucose meter reading of ≤ 70 mg/ dL(3.3 mM/L)(20).

Optimal glycemic control- is HgbA1c <7.5

Non optimal glycemic control- is HgbA1c ≥ 7.5

injection technique –is defined as one that reliably delivers medication into the subcutaneous space without leakage and with minimal discomfort(21).

Appropriate(good) insulin injection practice : If 70% and above is practiced(14)(5).

-Recommended injection sites (abdomen, thigh ,buttock, upper arm)

-Injection site rotation at least weekly

-Making skin fold before injection

- Proper angle needle entry preferred is 90 degree)
- Avoid needle reuse
- Removing air bubble before injection
- Avoid insulin leakage (counting too ten after plunger)
- Injection site and hand hygiene
- injection site inspection and palpation
- injecting insulin 1-3 finger apart from previous site
- proper storage site

Inappropriate(poor) insulin injection practice- if <70% is practiced.

4.10 .Data Collection Procedure and Data Quality Management

Data was collected from January to March 2022 G.C. Data collection checklist prepared in English language, then translated into Amharic language, with components of, age, sex of the patient,, educational level and chronic illness as well as specific questions about insulin injection practice and charts was also be reviewed.

Its prepared based on review of records prior to the study period and similar literature used for this study was used. An hour-long training was given to eight data collectors (Internal Medicine residents of SPHMMC) on the components of the checklist and how to fill the data into a computer. Records of the study population were assessed for completeness before data entry and the entered data was checked by the data supervisor on a daily basis for any incompleteness and/or inconsistency.

4.11 Data quality control

To ensure the quality of data, prior to data collection, training of the data collectors was carried out for one day by the principal investigator on the objective, relevance of the study and confidentiality of information.

Pretest was done by taking 5% total sample size, two weeks before actual data collection to check its variability and the questionnaire was assessed for its clarity, length and completeness and the necessary correction will be done accordingly.

4.12. Data analysis

Data was analyzed using the Statistical Package of Social Sciences (SPSS) version 25.0 for Microsoft Windows. Means, standard deviations and percentages was calculated and cross-tabulation was used to compare different variables and subjected to Chi-square analysis to assess various relationships. The significance level was set at $P < 0.05$.

4.13. Ethical Consideration

Ethical clearance was obtained from the Institutional Review Board of St. Paul's Hospital Millennium Medical College, and then permission was granted from the school administration through the academic provost of the school to carry out the study. Each patient's information was collected using a structured checklist. The collected informations was only used for this particular study and was be kept confidential.

4.14. Dissemination of Results

The output of this study will be communicated to the Department of Internal Medicine and Public Health, St. Paul's Hospital Millennium Medical College in partial fulfillment of the requirement for a specialty certificate in Internal Medicine. It will also be submitted to the hospital's Endocrinology unit. Attempts will be made to publish the information in peer-reviewed journals and make presentations in scientific conferences.

5. Result

5.1 Demographic and socioeconomic characteristics

A total of 352 diabetic patients were enrolled in the study making a response rate 100%. Of 352 patients who were included in the final analysis nearly equal number of males and females represented gender group giving 1:1.08 ratio. Almost two-third of the age of the patients 226(64.2%) ranged from 20 to 60 years. Majority of the patients 295(83.8%) came from urban area. Subjects with a secondary level of education comprised the highest proportion in the study (152, 43.2%). Majority of the patients 235(66.8%) were married and more than one third136 (38.6%) of the total of 352 patients earned monthly income between 1000 to 3000 birr. Details on demographic characteristics are found in Table 1.

Table 1: Sociodemographic characteristic of study participants (n=352)

Variable	Category	Frequency	Percent (%)
Age in years	<20	53	15.1
	20-60	226	64.2
	>60	73	20.7
Sex	Female	169	48
	Male	183	52
Marital status	Single	98	27.8
	Married	235	66.8
	Divorced	11	3.1
	Widowed	8	2.3
Educational status	Primary	54	15.3
	Secondary	152	43.2
	Higher	102	29.0
	No formal education	23	6.5
	Can read and write	21	6.0
Religion	Orthodox	129	36.6
	Muslim	114	32.4
	Catholic	49	13.9
	Protestant	60	17.0
Residence	Urban	295	83.8
	Rural	57	16.2
Monthly income in birr	<1000	91	25.9
	1000-3000	136	38.6
	>3000	125	35.5

5.2 Type of Diabetes and insulin treatment

Out of the total 352 Diabetes patients those with type 2 diabetes are more than twice 237(67.3%) that of those with type 1 diabetes. One- third of the subjects 117(33.2%)have been using insulin for 5 years or more while a slighter higher than one third of the subjects used insulin for 2 years or lesser 134(38.1%). Nearly half (167, 47.4%) of the prescriptions contains NPH while more than one - third 132(37.5%) of the prescriptions contains both intermediate-acting and regular insulin in combination. Similarly, in Majority of the prescriptions 285(81%) insulin was prescribed to be injected two times per day. A quite high proportion of the patients take insulin by themselves. Fig 2.

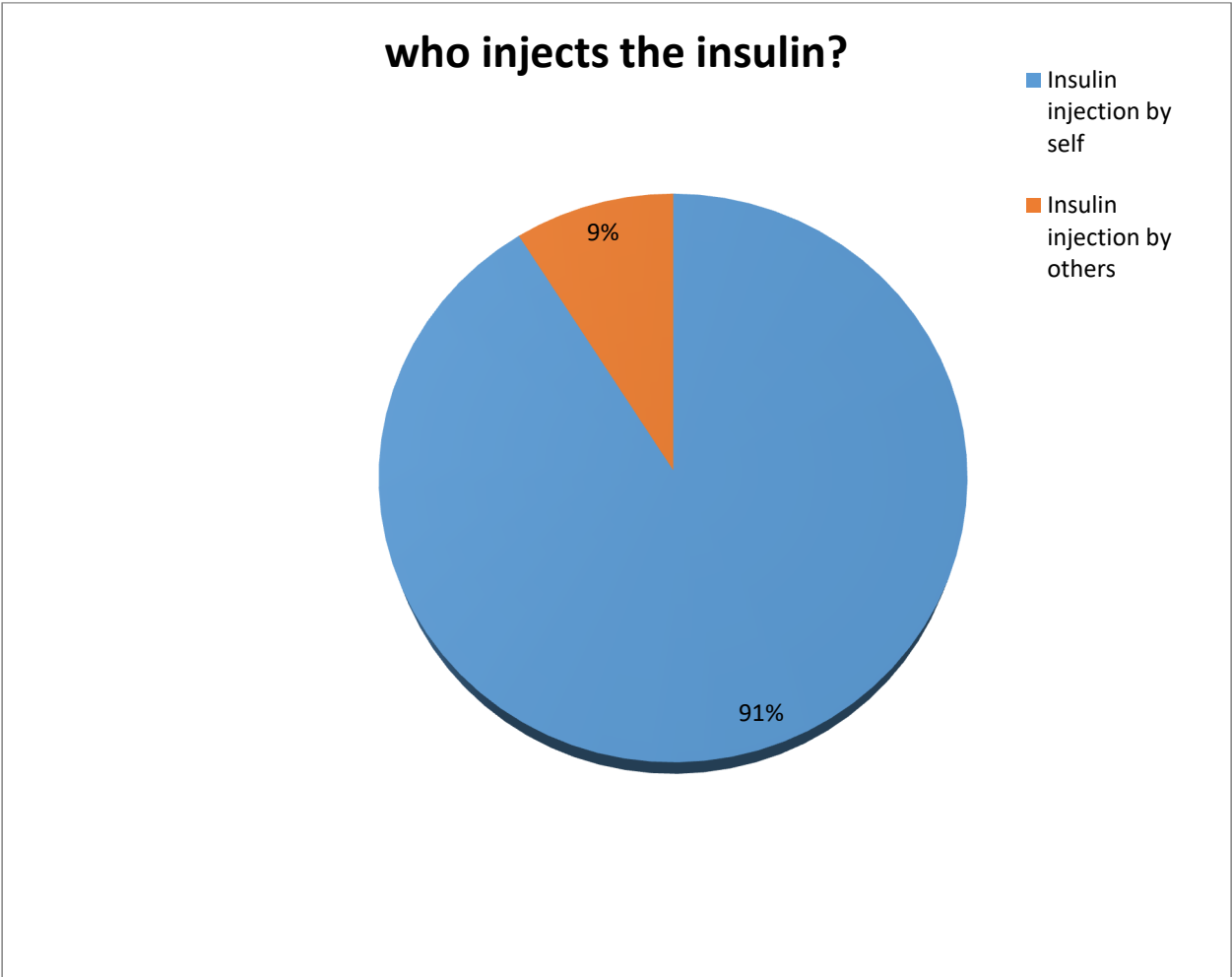


Figure 2: Pie chart on Insulin administration

5.3 Insulin injecting practices

Participants were asked on insulin injection techniques they practice. More than Two-third 246(69.9%) of the total patients wash their hands before injection, and more than half (199, 56.6%) of the total participants had never clean their injection sites or do it sometimes only. Less than half (149, 42.3%) of the patients always inspect their insulin vials for any appearance change: similar proportion (154, 43.8%) of the participants reported that they always eliminate bubbles from the insulin syringe. Two- third (207, 58.8%) of the patients always inspect injection sites visually and palpate the skin for the presence of any abnormality. A large proportion (253, 71.9%) of the participants reported that they always lift the skin fold of the injection sites while administering

insulin subcutaneously. 5.7% of the participants never re-suspend the cloudy insulin during injection time.

Half (177, 50.3%) of the participants reported that they measure and record blood sugar in most days of a week. Almost all (327, 92.9%) participants were not changing the needle of insulin syringe at every injection time of which nearly half of the participants (160,45.5%) reused the insulin syringes more than 5 times. The most 176 (50.0%) reported reason for this was insulin syringe unavailability followed by financial incapability 145(41.2%).

Near to two in three (233, 66.2%) of the participants move or rotate the injection site every week as recommended. One in three (114, 32.4%) of the participants reported that they inject with 1-3 fingers apart from the previous injections. For majority of the patients 202(57.4%) the injecting angle was inclined. More than half 200(56.8%) of the participants keep the syringe at injection site for one to five seconds. Details about the techniques of insulin injection are found in Table 3.

Nearly 2 in three 226(63.6%) of the patients store the insulin in refrigerator. Fig3. Concerning to injection site, the most frequently used injection site was Thigh (174, 49.4%) followed by abdomen (93, 26.4%) and arm (60, 17%) (Fig. 4). According to this study overall insulin injection practice was in appropriate/poor practice in more than 80% of the study population, (Table 4).

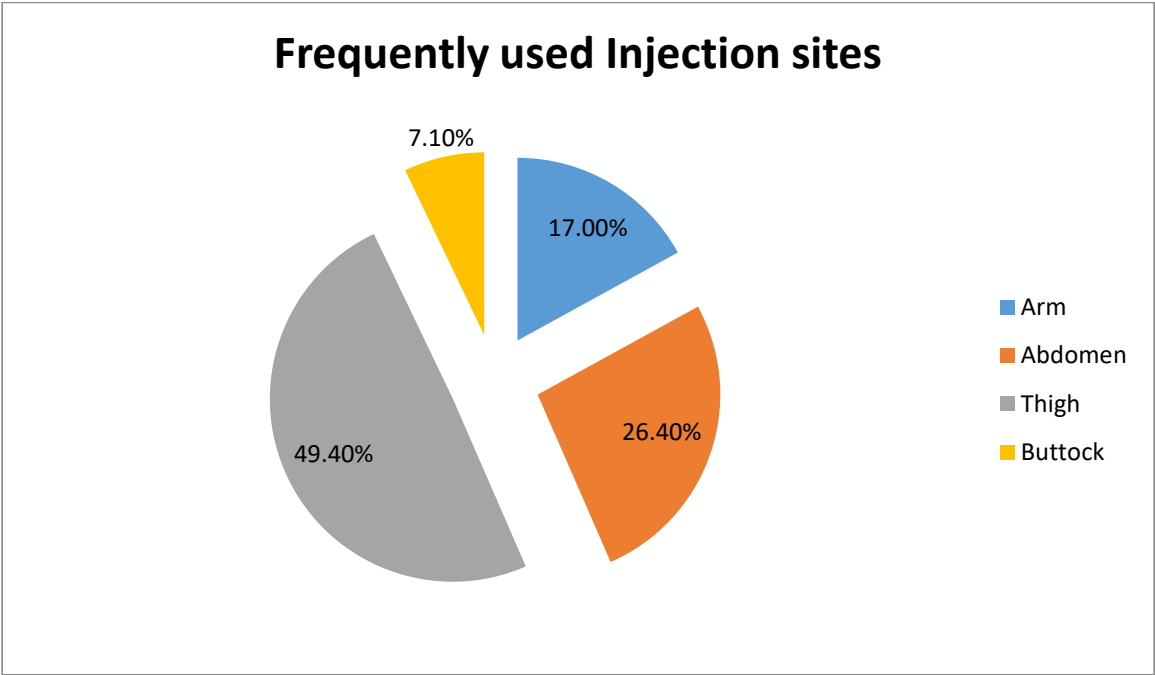


Figure 3: Pie chart on frequently used injection sites

Table 2: Association between Good/poor appropriate insulin injection practice and glycemic control (n=352)

Practice category		How is your glycemic control, Hgb A1C		total	Significance
		optimal	non optimal		
	poor	161	134	295	P=0.608
		84.7%	82.7%	83.8%	
	Good	29	28	57	
		15.3%	17.3%	16.2	
Total		190	162	352	
		100.0%	100.0%	100.0 %	

Table 3: Frequency and percentages of insulin injection practice among the study population (n=352)

Variable	Category	Frequency	Percent (%)
Injection Site rotation every week	Yes	233	66.2
	No	119	33.8
Space measurement (1–3 cm) to avoid injecting in the same site	Yes	114	32.4
	No	184	52.3
	I don’t know	54	15.3
Syringe insertion angle	Perpendicular	143	40.6
	Inclined	202	57.4
	Flat	7	2.0
Length of time stay of syringe before removal	1-5 secs	200	56.8
	5-10 secs	48	13.6
	10-60 secs	20	5.7
	I don’t keep it	27	7.7
	I don’t know	57	16.2

Table 4: Frequency and percentage of good/poor appropriate insulin injection practice(n=352)

Variable	Category	Frequency	Percent (%)
Appropriate injection practice	poor	295	83.8%
	good	57	16.2%



Figure 4: Graph showing frequently used insulin storage site(n=352)

5.4 Insulin-related outcomes

5.4.1 Hypoglycemia

Hypoglycemia was assessed by asking patients whether they manifested one or more of the following symptoms; poor concentration, irritability, palpitation, tiredness, sweating, strong hunger, dizziness, and tremor during the past few months Then it was confirmed by self-monitoring blood glucose reading of less than or equal to 70 mg/dL. Based on that, all of the interviewed participants reported at least one episode of hypoglycemia symptom during the past few months and 256(72.7%) participants measure their Random Blood Sugar level, from whom that measured during symptomatic period 91(25.9%) patients actually had blood sugar level less than 70.

5.4.2 Glycemic control

In the study, two in three (244, 69.3%) of the patients had HgbA1C of greater than 7.5% and this was declared as non-optimal glycemic control. A chi-squared analysis revealed a statistically significant relationship between non-optimal glycemic control and the independent variables; absence of hand washing prior to injection(P<0.01%), poor injection site hygiene (P<0.01%), elimination of air bubbles from syringe (P=0.041%), inspection and palpation of injection sites (P=0.014%), shaking of cloudy insulin (P=0.035%), inspection of insulin vial (P=0.012%), physical exercise (P=0.012%), storage of insulin (P<0.01%); However, the parameter frequent injection site was not significantly associated with glycemic control (Table 5). The study also revealed there is no statistically significant association between good or poor appropriate insulin

injection practice (p=0.608%).The study has also revealed significant association between demographic parameters and glycemic control (Table6).

Table 5: Glycemic control in comparison with insulin usage of participants(n=352)

Parameter	Categories	Practice status		Significance
		Optimal HgA1C	Non-Optimal HgA1C	P value
Routine hands hygiene	Yes	98 (39.8%)	148(60.2%)	*<0.001
	No	10 (9.4%)	96(90.6%)	
Routine injection site hygiene	Yes	68 (44.4%)	85 (55.6%)	*<0.001
	No	40 (20%)	159 (79.9%)	
Routine inspection of insulin vial	Yes	35(23.5%)	114 (76.5%)	*0.012
	No	73 (36.0%)	130 (64.0%)	
Routine elimination of air bubbles in the Syringe	Yes	56(36.4%)	98(63.6%)	*0.041
	No	52(26.3%)	146 (73.7%)	
	Yes	74 (35.7%)	133 (64.3%)	

Routine injection site visual inspection and palpation	No	34 (23.4%)	111 (76.6%)	*0.014
	Thigh	49(28.2%)	125(71.8%)	
Injection site frequently used	Arm	13(21.7%)	47 (78.3%)	0.05
	Abdomen	34(36.6%)	59(63.4%)	
	Buttock	12(48%)	13(52%)	
Rolling/tilting of cloudy insulin	Yes	102 (32.5%)	212(67.5%)	*0.035
	No	6(15.8%)	32 (84.3%)	
Storage of insulin	Refrigerator	57(25.4%)	167 (74.6%)	*<0.001
	Room temperatur	48(45.7%)	57 (54.3%)	
	Sand and others	3(13%)	20(87%)	
Routine physical exercise	Yes	73(36%)	130(64%)	

Table 6: Association between sociodemographic character and glycemic control(n=352)

Parameter	Categories	Practice status		Significance
		Optimal HgA1C	Non-Optimal HgA1C	P value
Age	<20	40(21.1%)	13(8%)	*0.001
	20-60	125 (65.8%)	101(62.3%)	
	>60	25(13.2%)	48(29.6%)	
Gender	Male	108(56.8%)	75 (46.3%)	*0.048
	Female	82 (43.2%)	87 (48%)	
Residence	urban	157(82.6%)	138 (85.2%)	*0.52
	rural	33 (17.4%)	24 (14.8%)	
Income	1000	55(28.9%)	36(22.2%)	0.01
	1000-3000	81(42.6%)	55 (34%)	
	>3000	54(28.4%)	71(43.8)	
Marital status	single	62(32.6%)	36(64.3%)	0.049
	married	122(64.2%)	113(33.2%)	
	divorced	3(1.5%)	8(4.9%)	
	Widowed	3 (1.5%)	5 (3%)	

5.5 Discussion

Due the aim of this study was to assess insulin injection practice and its association with insulin related outcomes among diabetic patients on follow-up at SPHMMC. This study reveals that only 57(16.2%) of participants practice appropriate insulin injection practice. A higher percentage of the participants in our study (69.9%) reported washing their hands frequently.

This result is almost identical to research conducted in Nepal (72.1%). (21). The administration of insulin into clean locations with clean hands has been advised (8). However, the majority of our participants (56.6) failed to disinfect the injection site prior to giving themselves insulin.. Patients who didn't keep their injection sites clean were found to have significantly higher HgbA1C% (>7.5%) compared to those who did not routinely clean ($p<0.001$). This might be due to the fact that poor injection site hygiene may cause injection site infection and skin hypertrophy which may cause decreased insulin absorption. Evidence-based guidelines recommends Patients should always wash their hands with soap and water before injection. Similarly, injection sites should be always cleaned using either soap with water or antiseptics such as alcohol(13,22) .

Two-thirds of the trial participants failed to examine and remove air bubbles from the insulin vial. This result was less than that of the A. Tsadik et al. study (66.5%) (5). Air bubbles in the syringe, if not eliminated appropriately, might affect the dosing of insulin and leads to poor glycemic control (8,14). Evidence based guidelines recommend patients should inspect insulin vials for any appearance change and eliminate air bubbles in the syringe at every injection (8,14).

The practice of injection site inspection was reported by more than half of our study participants (58.8),unlike report by A.Tsadik *et al* (90.3) which was done at TAH(5). This study has revealed statistically significant association between non optimal glycemic control and injection site inspection ($p=0.014$). This might be due to the fact that patients could early detect abnormal changes of the injection sites and rotate to the normal sites. patients should always inspect their own sites to detect lipohypertrophy (1,8).

Similar to study in Nepal(74.4%)(15), the practice of skin folding was reported by more than two-third of our study population. But study done in Meka ,Saudi Arabia revealed only 50.3% practiced skin fold making (6).This variation could be due to difference in body habitus between the two study populations. A skin lift may be warranted to prevent an intramuscular injection in a slim limb or abdomen, even when a shorter needle is used(14)

Our study revealed near 90% of the study population re suspend cloudy insulin before injection ,unlike study done in Nepal where only 40% were practicing(22). Adequate re-suspension of cloudy insulin is promoted to maintain the right dose of insulin so that to keep optimal glycemic control(14).

Contrary to the advice, a sizably large percentage of participants keep opened insulin in the fridge.This result was comparable to research conducted in Meka, Saudi Arabia, and by A.Tsadik

et al. (5) (6). Generally, administration of insulin which is stored at room temperature may reduce irritation, burning or painful injections, and facilitates the resuspension of cloudy insulin(14,23).

Considerably high proportion of our study participants (92.9%) of were reusing insulin syringe. This practice is comparable to those seen in studies by A.Tsadik et al. (5) and in Nepal(15), in which 71.2% and nearly all participants, respectively, reused insulin syringes. Unlike our study finding, study done in Meka, Saudi (6) and Brazil(17) show insulin syringe re usage of 37.3% and 57% ,respectively. In ability to afford for new syringe per injection was the reason for re usage in our study .A single insulin syringe needle should be used for only an injection(8,14,23).

Each injection site should be divided into four equal quadrants (or two equal halves if using the thighs or buttocks), with each quadrant being used once per week and always moving clockwise .To avoid repetitive tissue injury , injections within any quadrant or half should be separated by at least 1-2 cm (6,22,23). About two-thirds and fewer than half of the participants in our study, respectively, reported experiencing this, which is similar to a study conducted in Nepal (14). To avoid insulin-related side effects on the skin such lipodystrophy, lesions, and infections, injection sites must be rotated (22,23). About half of the study participants reported keeping insulin syringe in place for up to 5seconds before removal and inclined angle of injection.

This study has also revealed significant association between sociodemographic parameters and glycemic control. Age ($p=0.001\%$), income ($p=0.01\%$), gender ($p=0.04\%$) and marital status ($p=0.049\%$) have shown significant association. But there are no other studies that have shown such association. The findings in our case could be due to age and gender related comorbidities like cardiac disease, hypertension and dyslipidemia which may lead to poor glycemic control. The same is true for an income as financially constrained patient cannot afford for insulin. With regard to marital status divorced and widowed patients may be exposed to other life stressors and mental illness. These may indirectly affect their glycemic control. Place of residence has no significant association with glycemic control (table 4 above).

But there was no statistically significant association between good/poor appropriate insulin injection practice and glycemic control T. Although there was no such previous comparison, this finding could be due to the fact that majority of our study population are T2DM patients and they are probably on both insulin and OGLA so that their glycemic control cannot be merely explained by insulin.

Approximately one-fourth of the participants reported experiencing episodes of hypoglycemia in the three months before to the interview. But it was significantly greater than a report provided by Baruah et al (24). Due to the analysis's reliance on self-reported hypoglycemia symptoms and self-monitoring blood glucose measurements, this percentage may have been overstated. This might be due to the side effect of insulin, deep injection in to the muscle or concomitantly used OGLA.

Though non-optimal glycemic control was explained by many of the study variables, it does not mean that inappropriate insulin injection practices are the only determinants. The poor glycemic control might be explained by other practices other than variables included in this study. Therefore,

this finding requires further investigation by incorporating factors which might affect glycemic control.

Limitation of the Study

The study was conducted in a single center and so it may not be generalized to the overall populations of diabetics. The study didn't assess other factors that may affect the glycemic control. AS majority of our study populations are T2DM, probably they are taking OGLA in addition to insulin injection. In Addition, a self-constructed questionnaire was employed which requires further validation process.

6. CONCLUSION

The present current revealed how participants were utilizing insulin and also assessed the effect of injection practices on diabetic outcomes. The study has shown high percentage of the study population practice inappropriate insulin injection practice. With regard to glycemic control, it is optimal in about 54% of the study population. Overall, this study showed that insulin injection practices are considerably not appropriate and there is no statistically significant association between good/bad appropriate insulin injection and glycemic control.

7. RECOMMENDATION

Therefore, a routine education on appropriate insulin usage and in particular on the proper injection techniques should be given at every hospital visit. There should be periodic assessment of knowledge of their insulin injection practice. Since this study has limitations further studies that can establish cause and effect between dependent and independent variable should be done; including studies in community, private clinics and other hospitals.

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9. Annexes

9.1 ANNEX I: Information Sheet

You are kindly invited to participate in this study, which involves diabetic patients who are on SPHMMC endocrine clinic.

A. Purpose: the purpose of this study is to assess insulin injection practice and associated factors among DM patients who are on follow up at SPHMMC, at adult endocrine clinic.

B. Duration: The duration of this study is from January 1 2022 to March 30, 2022 G.C

C. Procedures to be carried on: the procedure of data collection is using standardized questioner on biographic data, and insulin injection practice of diabetic patients by trained interviewer.

D. Risk and discomfort: there will be no any risk associated during data collection.

E. Expected benefits: You will not get special and direct benefit from this study. However, the finding of this survey will be useful for patients in providing appropriate care and preventing DM related morbidity and mortality, alert stake holders, institutional and national policy makers to assure the practice of evidence based treatment and utilization to improve quality of health service.

G. Confidentiality: All your personal information will be kept confidential.

H. Compensation: No compensation will be provided by participating in this study.

I. Termination of the study: Participation in the study is voluntary, and refusal to participate involves no penalty or loss of benefits to which you are otherwise entitled. The study participants have a right to keep hold information, decline to cooperate in the study and to refuse provision of data.

I would also like to inform you that this study will be approved by Department of Internal medicine and St. paul's Hospital Millennium medical College research and ethical Review Committee. If you have question about the study the address of the principal investigator is:

Dr Zemedu legesse Jima

Tel: 0910764418 e- mail address: zemedulegesse5@gmail.com

9.2. ANNEX II: Individual consent form

SPHMMC Department of Internal medicine individual consent form for the study on: Assessment of insulin injection practice and its association with insulin related outcomes among patients with DM at endocrine clinic, SPHMMC, Addis Ababa, Ethiopia, 2022.

My name is _____. I am working with the research team of SPHMMC. We would like to assure you your name will not be mentioned in the questionnaire and the information that you will give us will be kept confidential and used only for research purpose. You have full right to refuse to take part or to interrupt the interview at any time. But the information that you will give us is quite useful to achieve the objective of the study and improve our service.

Are you willing to participate in the study? 1- Yes 2 - No

If the answer is yes, thanks! Conduct the interview.

If the answer is no, Thanks!

Don't force or reinforce an individual to participate in the survey

Interviewer's: name ----- signature -----

Date of interview -----

Checked on -----

Complete 1 Incomplete 2 other (specify) -----

9.3. ANNEX III. Data Collection Checklist

9.3.1. ENGLISH VERSION QUESTIONNAIRE

I. Socio-demographic characteristics of the participant

1. Age

A) less than 20 years B) 20-60 years C) above 60 years

2. Gender

A) Female B) Male

3) Marital status

A) Single B) married C) Divorced D) Widowed

4) Residence A. Urban B. Rural

5).Religion

A .Orthodox B. Muslim C. Catholic D. Protestant E.Other

6). Educational level

A) Primary B) Secondary C) Higher education D) No formal
education E.can read and write

7).Monthly income

A . <1000 B.1000-3000 C)>3000

II. Insulin injection practice

1) Types of diabetes

A) Type 1 B) Type 2 C) Other

2) When did you start using insulin?

A) Less than 2 years

B) 2-5 years

C) more than 5 years

3) What is the frequency of insulin administration?

A) Once daily

B) Twice daily

C) three times daily

D) Four times daily

4) Who gives you insulin injection?

A) Some One

B) My self

5) Insulin type

A) Regular B) NPH C) mixed D) Other type

6) Do you routinely wash your hands before injection?

A. YES B. No C. some times

7) Do you clean injection site every time you take insulin?

A. YES B.NO C. some times

8) Do you routinely inspect insulin vial for any change in color?

A. YES B NO

9) Do you eliminate air bubble from the syringe?

A) Yes B) No C) Some times

10) Do you routinely inspect and palpate injection sites every time you Inject insulin?

A) Yes B) No C) Some times

11) Do you notice pain, bleeding or swelling at the site of injection?

A.YES B.NO C. some times

12) Do you always shake the cloudy insulin vial before injection?

A) Yes B) No C. some times

13) Do you always make skin fold before injection?

A) Yes B) NO C. Some times

14) What is the angle that you use to inject insulin?

A) Perpendicular (at 90 degree)

B) Inclined (at 45 degree)

C) Flat

15) Do you reuse insulin syringe?

A) Yes B) No

16) If Qn 10 above is 'YES', why do you reuse?

A) That is how I was told B) Financial reason

C) Syringes are not available D) Other

17). How many times do you reuse the needle?

A) 1-5 Times

B) More than five times

C) I don't reuse it

18) What injection site you commonly use?

A) Arm B) Thigh C) Abdomen D)Buttock E) Other

19) Where do you store your insulin

A) Refrigerator B. Sand C. Room temperature D) Clay pot E)
Other

20) How long do you keep the syringe at injection site before removal?

A) I don't know

B) 1-5 Sec

C) 5-10 Sec

D) 10-60

E) I don't keep it

21) Do you rotate the injection site after the injection, at least weekly?

A) Yes B) No

22 Do you inject 1-3 fingers apart from previous site ?

A.YES B.NO C.I don't know

23.Do you measure your blood glucose most of the days per week

A.YES B.No

24. Do you perform physical exercise as ordered by your health care provider? A.YES B.NO C. i was not told to do so

III. Insulin related out comes

1. Have you ever experienced the following symptoms

A. loss of concentration,

B. irritability,

C. palpitation,

D .tiredness,

E.sweating,

F. strong hunger,

G. dizziness, and

F. tremor during previous months

H. any other....

2. If question number 1 (above) is yes for any of the listed symptoms ,do you usually measure your blood glucose during that time?

A.YES B.NO

3) If question number 2 of the above is yes, what is the usually recorded RBS?

A. <70 B.>=70

4) How is your glycemic control ?

A. Optimal B. Non optimal

9.3.2Amharic version

I. የሕመም አካላት-የሕመም ምልክቶች

1. የሕመም

☐ 20 በብር በሰዓት ☐ 20-60 በብር በሰዓት ☐ 60 በብር በሰዓት

2. የሕመም

☐ በሰዓት ☐ በሰዓት

3) የሕመም ምልክት

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4) የሕመም ምልክት. የሕመም ምልክት

5) የሕመም

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6) የሕመም ምልክት

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7) የሕመም ምልክት

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II. የሕመም ምልክት ምልክት ምልክት

1) የሕመም ምልክት ምልክት

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2) የሕመም ምልክት ምልክት ምልክት ምልክት?

☐ 2 የሕመም ምልክት

☐ 2-5 የሕመም ምልክት

☐ 5 የሕመም ምልክት

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9.4.ANNEX IV: Declaration

I the undersigned resident that this thesis is my original work, in partial fulfillment of the requirement for certificate of specialty in internal medicine. I also declare that it has never been presented in this or any higher institution and all the resources and materials used in the research work have duly acknowledged.

Name of the Resident: _____

Signature:_____

Date: _____

Approval of Advisors

This research work has been submitted for examination with my approval

Name of Public Health Advisor:_____

Signature:_____

Date:_____

Name of Clinical Advisor: _____

Signature:_____

Date: _____

