PREVALENCE AND FACTORS ASSOCIATED WITH ABSCESS AND SCAR FORMATION AT THE SITE OF INSULIN INJECTION AMONG PATIENTS ATTENDING DIABETIC CLINICS IN SELECTED PUBLIC AND PRIVATE HOSPITALS IN DAR ES SALAAM

Dennis Patson Mbwambo, B.Pharm

Master of Pharmacovigilance and Pharmacoepidemiology Dissertation
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Department of Clinical Pharmacy and Pharmacology

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By

Dennis Patson Mbwambo

A Dissertation Submitted in (Partial) Fulfilment of the requirement for the Degree of Master of Pharmacovigilance and Pharmacoepidemiology of

Muhimbili University of Health and Allied Science
October, 2024

CERTIFICATION

The undersigned certifies that they have read and hereby recommends for acceptance by Muhimbili University of Health and Allied Sciences a dissertation entitled; **"Prevalence and factors associated with abscess and scar formation at the site of insulin injection among patients attending diabetic clinics in selected public and private Hospitals in Dar es Salaam"** in (partial) fulfillment of the requirements for the Degree of Master of Pharmacoepidemiology and Pharmacovigilance of Muhimbili University of Health and Allied Sciences.

_____

Dr. Alphonce Ignace Marealle

(Supervisor)

Date: _____

_____

Mr. Wigilya Mikomangwa

(Co-Supervisor)

Date: _____

_____

Ms. Bertha Mallya

(Co-Supervisor)

Date: _____

DECLARATION AND COPYRIGHT

I, **Dennis Patson Mbwambo**, declare that this **dissertation** is my original work and that it has not been presented and will not be presented to any other university for a similar or any other degree award.

Signature…… **Date**……..……

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DEDICATION

I have always been motivated by the quote from **William A. Ward,**
"Study while others are sleeping; work while others are loafing; prepare while others are playing, and dream while others are wishing."

I therefore dedicate this study to my family, parents, brothers and sisters, instructors, and Mwananyamala Hospital management to repay the sacrifice they have made for my career advancement.

ABSTRACT

Background: More than 530 million people live with diabetes worldwide, and in Tanzania, the prevalence of diabetes among adults is 12.3%. Insulin remains the cornerstone of therapy in all type 1 diabetic patients and a substantial number of patients with type 2 diabetes mellitus. Despite the increase in the number of insulin users, there is a shortage of data in Tanzania regarding its safety, particularly for skin-related adverse complications, including abscess formation and scarring at injection sites.

Aim: This study aimed to assess the prevalence of abscess formation and scarring at insulin injection sites and to identify the determinants among diabetic patients on insulin therapy.

Methodology: A hospital-based cross-sectional study was conducted, involving 428 randomly selected patients on insulin therapy from two selected public hospitals (Mwananyamala and Temeke regional referral hospitals) and two private hospitals (Shree Hindu Mandal and Hubert Kairuki Memorial Hospital) in Tanzania. Sociodemographic and clinical data were collected using a questionnaire. Data were analyzed using Stata version 15.0 software, and modified poison regression was employed to determine factors associated with abscess and scar formation among patients on insulin therapy. The variables with a p-value of <0.05 in the final model were considered the main factors associated with the abscess and scarring.

Results: The study found the prevalence of abscesses and scars were 22.2% and 46.7% respectively. Factors associated with abscess included; improper injection technique (aPR= 1.11; 95%CI:1.02-1.21, p = 0.009), occupation (particularly self-employment) (aPR = 2.34; 95%CI:1.04-5.27, p = 0.4), and improper injection site rotation (aPR = 2.7; 95%CI:1.13-6.45, p = 0.025). The use of an insulin pen was observed to be protective from abscess formation at (aPR = 0.13; 59%CI:0.04-0.48, p = 0.002).

Scars were observed to be influenced by improper site rotation (aPR = 1.63; 95%CI:1.03-2.32 P = 0.037), uncontrolled blood glucose level (aPR = 1.69; 95%CI:1.01-2.84, p = 0.049), the use of insulin and syringes obtained from other places apart from at facilities patients attended clinics (aPR = 2.51; 95%CI:1.22-1.98, p = 0.035) and occupation where the self-employed had

more chances of developing scars (aPR = 2.0; 95%CI:1.21-3.33, p = 0.007) followed by those with the formal employment (aPR = 1.9; 95%CI:1.04-3.41, p = 0.036) when compared to the non-employed.

Conclusion and recommendations: This study observed a high prevalence of abscesses and scars at injection sites among diabetic patients on insulin therapy. The factors associated with abscesses include improper injection technique, occupation(self-employment), and improper injection site rotation. The use of an insulin pen was protective against abscesses. Factors associated with the scars included improper site rotation, uncontrolled blood glucose, occupation, and sourcing insulin and syringes from the community drug outlets.

Abscesses and scars adverse events can be mitigated if; healthcare staff provide education on proper injection techniques, site rotation, and regular blood glucose monitoring. The Ministry of Health, hospital management, and other stakeholders should ensure consistent supply and advocate using insulin pens. Community drug outlet healthcare staff should be trained on DM and its management to enable them to provide proper counseling to insulin users. There is a need for further studies on why occupation in particular self-employment is associated with abscesses and scars.

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LIST OF ABBREVIATIONS

ADR	Adverse drug reaction
DM	Diabetes Mellitus
TMDA	Tanzania Medicines and Medical Devices Authority
MRRH	Mwananyamala Regional Referral Hospital
TRRH	Temeke Regional Referral Hospital
MUHAS	Muhimbili University of Health and Allied Sciences

DEFINITION OF KEY TERMS

An abscess is a swollen area within a body tissue (e.g., skin) containing an accumulation of pus.

Adverse Drug Reactions are defined as events which are noxious and unintended and occur in doses normally used in humans for prophylaxis, diagnosis, or therapy of disease, or for the modification of physiological functions.

An adverse event is any untoward medical occurrence in a patient administered with a medicinal product that does not necessarily have a causal relationship with this treatment.

Lipoatrophy is a localized loss of fat tissue usually as a result of subcutaneous injection of insulin.

Lipohypertrophy is a lump under the skin caused by the accumulation of extra fat at the site of subjected to many subcutaneous injections of insulin.

Scar is a mark left on the skin after the abscess has not healed completely and fibrous connective tissue has developed.

CHAPTER ONE

1.0 INTRODUCTION

1.1 Background

Incidence and prevalence of all types of diabetes mellitus (DM) are increasing at an alarming rate (1). It is estimated that around 537 million individuals globally equal to 10.5% of the world's populace were affected by DM affecting different nations, ethnicities ages, and genders (2). It was further projected that the burden of DM will increase to 785 million by 2045 (2). Unlike previous years when insulin was for type 1 DM, insulin has recently remained the cornerstone of therapy in both types of diabetes mellitus (1). Out of 463 million diabetic patients globally, 150 to 200 million depend on insulin therapy (3). Around 3.1 million adults aged ≥ 20 years equal to 10.8% of all United States adults diagnosed with diabetes are on insulin therapy (4). In Africa, prevalence is estimated to be 7.1% compared to 3.1% in 1980 (CDC,2019). The prevalence of DM among adults aged ≥18 years in Tanzania was 12.3% and the country was ranked among the top five African countries with a high prevalence of diabetes (4). The prevalence of DM among the general population in Dar-es-salaam increased from < 2% to 9.1% from 1980 to 2012 (5).

Insulin therapy plays a vital role in the regulation of blood sugar in diabetic patients preventing them from micro-and macro-complications such as nervous system damage and organ dysfunction (6). In addition to its role in DM, insulin mediates the physiological functioning of several key organs in the body including the brain, heart, kidney, bone, skin, and hair follicle (7). Access to insulin remains an issue in both high-income and low-income countries although the underlying reasons differ (3). Insulin and related supplies are often unavailable and unaffordable among low-middle-income countries' healthcare facilities including Tanzania (8). Data collected from private primary care pharmacies in low-middle and high-income countries show that the total mean availability of insulin 100IU/ml was only 36.21% and Tanzania had the highest purchasing power parity-adjusted prices ($4334.17) for 30-day treatment with innovator brand followed by Bangladesh ($80.21) (9).

Proper injection technique for insulin has shown some advantages including good glycemic control, patient comfort, good adherence and patient satisfaction (10). An abscess is a localized collection of purulent material surrounded by inflammation and granulation in response to an infectious source (11). With time the abscess can become a hard-dark fibrous mass known as sequelae or scar. The scar formed at the insulin injection site compromises insulin absorption hence poor glycemic control (12). The scars are also cosmetically unacceptable to patients therefore poor patient treatment adherence (13).

Pharmacovigilance is the science and activities relating to detecting, assessing, understanding and preventing adverse effects or any other drug-related problem (14). Adverse drug events i.e. abscesses and scars at the insulin injection site can have a great impact on a patient's health-related quality of life (15). The presence of the scar or abscess at the injection site can impair insulin absorption and therefore failure in blood glucose regulation. Further, the scar at the injection site is cosmetically unacceptable. Safety monitoring for DM patients on regular use of insulin will aid early detection, characterization and quantification of the skin-related ADRs and therefore proper strategies for mitigation of the problem can be addressed (16).

The study conducted decades ago in the United Kingdom, found the prevalence of scar formation at the site of insulin injection to be 48% and cases of abscess were rare (17). The common predictors for abscess and scar formation at the insulin injection site were suggested to be needle length, poor hygiene at the injection site, and improper injection technique (3,18). There is a shortage of data on the magnitude of abscess or scar formation at the insulin injection site among DM patients using insulin in Tanzania. Therefore, this study will assess the prevalence and predictors of abscess and scar formation at the insulin injection site among DM patients attending clinics at public and private hospitals in Dar-es-salaam.

1.2 Problem Statement

The rate and pattern of use of insulin have increased significantly as insulin has become the cornerstone of therapy in both types of diabetes mellitus (1). Performing pharmacoepidemiology studies following this change in rate and user pattern among diabetic patients is inevitable, as it will facilitate the detection of adverse drug reactions previously uncaptured or underestimated due to limited patient exposure and user patterns (19). Apart from the amyloidosis which has been very well studied, other kin-related complications associated with insulin use include abscesses and scar formation. like other skin complications, abscesses and scars affect insulin absorption kinetics causing glycemic excursions above and below target levels for blood glucose (17,20). In addition to the clinical implication, the scars formed at injection sites are cosmetically unaccepted (21).

Despite the increasing prevalence of diabetes mellitus and insulin use (5), there is a lack of published data regarding skin-related complications of insulin injection among patients on regular use of insulin in Tanzania. The prevalence and predictors of abscess and scar formation at insulin injection sites among patients attending diabetic clinics in public and private hospitals in Dar es Salaam have not been reported. Therefore, this study aims to address this gap in knowledge by determining the prevalence of abscess and scar formation at insulin injection sites and identifying the factors associated with their occurrence.

1.3 Conceptual framework

Abscess and scaring (the outcome variables) have been associated with different factors including poor hygiene, improper care of vials, and needles, needle size, and faulty injection technique (22). The variables were categorized into patient-related and non-patient-related independent variables as described pictorially below in **Fig. 1**

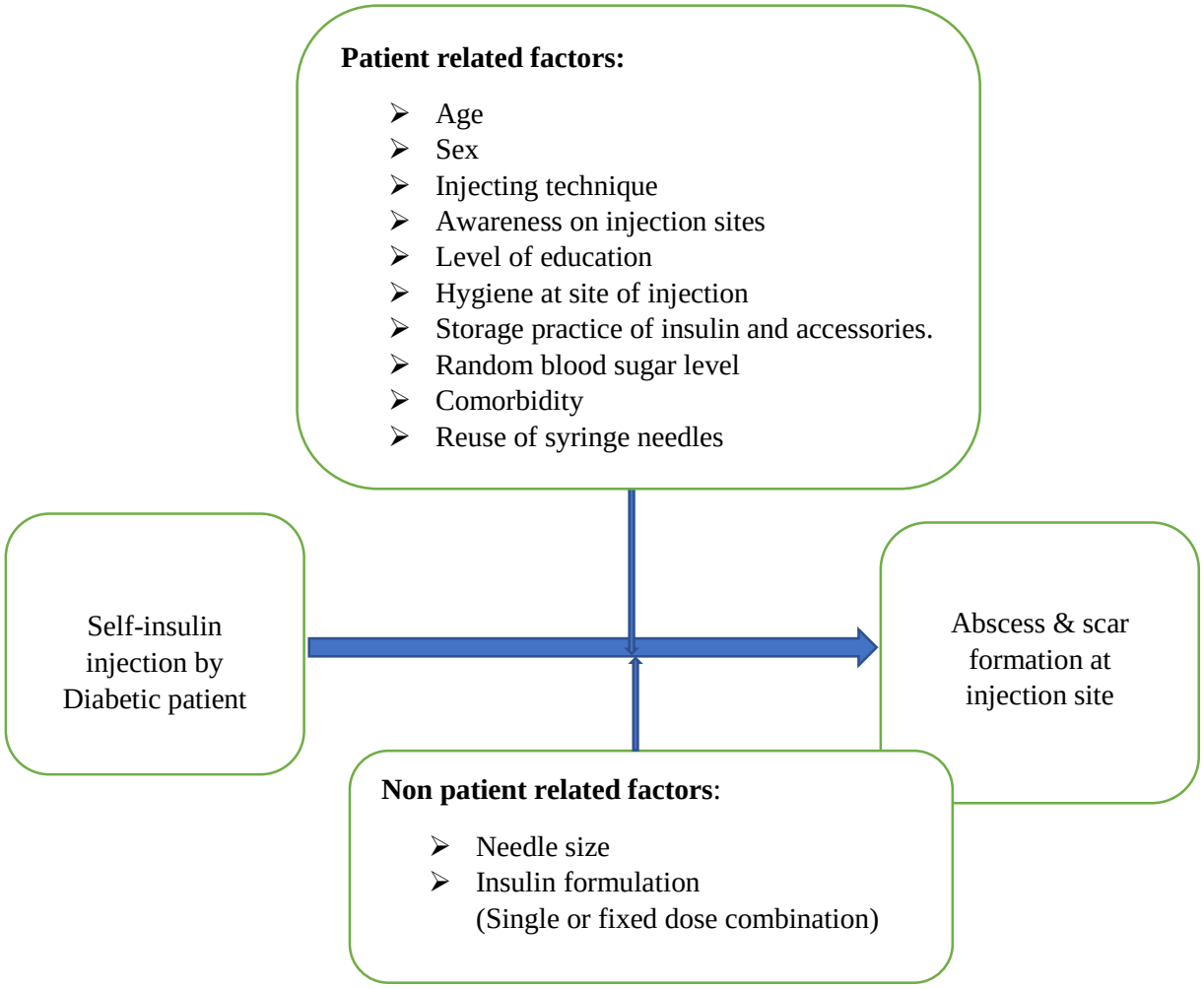


Figure 1: The conceptual framework detailing the different factors that may contribute to the formation of abscesses and scars at the injection site.

1.4 Rationale of the study

In pharmacovigilance, it is assumed that whenever there is an increase in the consumption of a particular product or if there is a change in the pattern of use of the medicinal product, there is the possibility for an increase in ADRs that were previously underreported, also new previously un-reported ADRs can emerge. This study is done in support of the evidence on the increased rate and pattern of use of insulin globally including Tanzania and Dare-salaam in particular. The study would serve as a baseline for understanding the magnitude of abscess and scarring ADRs. The results would save the source of data for signal evaluation for the safety profile of insulin or related accessories to the Tanzania Medicine and Medical Devices Authority (TMDA) and the international drug databases e.g. Uppsala Monitoring Centre (UMC). Additionally, the study results could impose a need to improve the current practice of insulin administration to avoid unnecessary skin-related adverse drug reactions. Furthermore, the study findings might highlight the urgency of addressing the issue and guide the development of appropriate interventions, including educational programs, and innovations to prevent or mitigate the complications.

1.5 Research questions

1.5.1 Broad research question

What are the prevalence and factors associated with abscess and scar formation at insulin injection sites among diabetic patients on insulin therapy who attend clinics at selected private and public hospitals in Dar es Salaam?

1.5.2 Specific research questions

1. What is the prevalence of abscess formation at the site of insulin injection among diabetic patients on insulin therapy?
2. What is the prevalence of scar formation at the site of insulin injection among diabetic patients on insulin therapy?
3. What are the factors associated with abscess formation at the site of insulin injection among patients on insulin therapy?

4. What are the factors associated with scar formation at the site of insulin injection among patients on insulin therapy?

1.6 Objectives

1.6.1 Broad objective

To determine the prevalence and factors influencing abscess and scar formation at the site of insulin injections among diabetic patients attending clinics in selected public and private hospitals in Dar es Salaam.

1.6.2 Specific objectives

1. To determine the prevalence of abscess formation at the site of injection among diabetic patients on insulin therapy.
2. To determine the prevalence of scar formation at the site of injection among diabetic patients on insulin therapy.
3. To determine factors associated with abscess formation among diabetic patients on insulin.
4. To determine factors associated with scar formation among diabetic patients on insulin.

1.7 Literature review

1.7.1 Prevalence of abscess and scar formation at insulin injection sites

Skin complications among diabetic patients on regular use of insulin are not uncommon (23,24). It was reported that more than 50% of the diabetic patients who were on insulin therapy, were affected by at least one of the sin-related complications (24). The leading type of skin complication experienced by the majority of the patients on insulin therapy was amyloidosis (23–26). Apart from amyloidosis which captured the attention of a significant number of researchers, abscesses and scar formation at insulin injection sites were also found to be the adverse event of health concern (17,20,27). In the US, the prevalence of scars was common up to 48% while abscesses were reported to be rare (17). However, this was two decades ago and we did not find updated information that could provide a clear picture regarding the current status of the matter.

Tanzania is among the top five African countries with a high burden of diabetic patients on insulin (28), however little is known about the skin-related complications among DM patients on regular use of insulin in particular abscess and scar formations. The prevalence and factors associated with abscess and scar formation among diabetic patients attending clinics in public and private hospitals in Dare Salaam have not been reported. This represents a noteworthy research gap.

1.7.2 Factors associated with abscess and scar formation at the insulin injection site

Poor hygiene at the insulin injection site was associated with cutaneous manifestation in DM patients on the use of insulin (29). It was reported that diabetic status is associated with more favorable conditions for the growth of skin microflora (22). Studies suggest diabetic patients exhibit significant viable and anaerobic bacteria (22). The common microbes observed were *Staphylococcus aureus* and other rare microbes *Mycobacterium fortuitum* (20). Additionally, immunocompromised patients may develop abscesses at the injection site due to non-common acid-fast bacilli called *Mycobacterium chelonae* (30).

The abscess at the insulin injection site occurs when the skin's normal flora gets access to the skin throng injection (20). A study done in Bangladesh involving 847 subjects reported that 33.8% of diabetic patients never cleaned the injection site before injecting. Even for those who ever practiced hygiene only 43.2% were reported to clean the injection site always (12). Poor hygiene-associated cutaneous manifestations at the site of insulin injection including abscess and scarring can be prevented if the injection site is properly and thoroughly cleaned. The site can be cleaned with cotton balls soaked with water or alcohol swabs before each injection. When alcohol is used the skin should be allowed to dry up completely to avoid a stinging sensation (31).

Faulty injecting technique has been associated with not only pain but also result in poor glucose control and cosmetically unaccepted scars (28). In addition to that improper insulin injecting practice was associated with lipoatrophy (21). For the best result, it is advised to make a skin fold and insert the needle into the skin at a 90% angle, especially in lean patients due to less thick skin (28). Alternatively, an angle of 45% can be used without making any skin fold (28). Both of this technique prevent the risk of intramuscular administration and also avoid intradermal insulin delivery (20). Furthermore, patients are advised to divide the injection site into quadrants (abdomen) or halves (thighs, buttocks, and arms), and each quadrant or half should be used per week. Within a particular quadrant, injections should be spaced at least 1-2cm apart to avoid trauma on the skin. Despite its importance in glycemic control and preventing unnecessary trauma to patients, knowledge of insulin injecting practice was reported to be low not only in patients but even among healthcare providers (32). This knowledge gap seems to be observed in both developed and developing countries. On the other hand, patients seem to be well-informed about insulin and its use. This was observed in the study done in Bangladesh where 92.1% of insulin users were well-educated on insulin injection and self-monitoring of blood glucose (12).

The needle length of the syringe is another factor reported to be associated with the formation of abscesses and scarring at the insulin injection site. Larger needle size can lead to intramuscular or intradermal delivery (22). It has been reported that the 4 mm needle length is

appropriate for insulin administration since the average skin thickness was 2.29 ± 0.37 mm in the abdomen and 2.00 ± 0.34 mm in the upper arms and the mean sub-cutaneous fat thickness was 10.15 ± 6.54 mm in the abdomen and 5.50 ± 2.68 mm in the upper arms (18). These findings were reported by different researchers (33,34). Previously it was thought that the size of the needle for insulin depends on people's weight meaning that obese people could need longer needles. However, evidence from other studies shows that body weight overall is not a factor in needle size effectiveness (33). It was therefore concluded that, regardless of the body mass index (BMI), a 4-millimeter needle is effective in nearly all diabetic patients.

Syringes with short needles deliver insulin appropriately to the site of absorption. This will also reduce unnecessary trauma caused by a failure to adhere to complicated injection techniques such as tilting the needle at a 45% angle and making the skin fold (18). An insulin pen is an advanced device that is more user-friendly in administration of insulin when compared to traditional vials and syringes (3).

Diabetic patients are taught to discard insulin syringes after a single use. The reason is that reusing syringe needles will cause skin infections that can lead to abscesses and even scarring (35). However, insulin syringe reuse seems to be a common practice among diabetic patients with a prevalence of 75% as surveyed in Porto Alegre, Brazil (36). It was observed that patients re-used syringes on average of two to twenty-one times. However, interestingly unlike lipohypertrophy and hematoma which were reported from 7% and 18% respectively, only one subject had injection site infection (36). Furthermore, it was reported that, despite the significant number of normal flora present on the skin of DM patients, the contamination of the used syringe needles by those patients was negligible (37). However, the data came from a small study involving not more than 100 subjects.

Storage conditions for temperatures and humidity for the insulin are specified by the manufactures and need to be adhered to throughout the product's shelf life (38). Depending on the type of insulin, there may be differences in how well the insulin can be stored and how long it will last once open (13). In most cases, the recommended storage temperature for insulin pens, unused cartridges, and vials is between 2^{o}C and 8^{o}C (39). At this temperature, insulin can

maintain its efficacy until its expiration date. When stored at a temperature below 30^{o}C, shelf life is reduced to four weeks (13). On traveling insulin should preferably be stored in an insulated bag or cooled thermo flasks with ice if the ambient temperature exceeds 30^{o}C (31). Improper storage of insulin cannot directly cause an abscess. However, inappropriate storage could result in the breakdown of insulin, affecting its ability to control blood sugar effectively (39). Patients with poorly controlled blood glucose have a 1.4 times likelihood of developing abscess (40).

It was claimed that there was a decrease in skin-related adverse events following the improvement in insulin formulations since it was invented in 1921 compared to the current modified formulation (3). This was based on observations of the decrease in the number of adverse events among insulin users. However, cases regarding skin complications including abscesses and scar formation were still available (22,27), signifying the problem exists.

CHAPTER TWO

3.0 METHODOLOGY

3.1 Study design

This was a hospital-based cross-sectional study. This study design was chosen due to its cost-effectiveness and its usability. In addition, the cross-section study design is not time-consuming and, therefore, would enable obtaining the estimated sample size within the allocated time.

3.2 Study setting

The study involved two public hospitals (Mwananyamala and Temeke) and two private hospitals (Shireel Hindu Mandal and Hubert Kairuki Memorial Hospital). In addition to having a large number of diabetic patients on insulin, the four healthcare facilities have a significant number of qualified professionals and are distributed in at least three of the five municipalities of Dar-es-salaam (Kinondoni, Temeke, and Ilala)

According to the Tanzania census of 2022, Dar-es-salaam is the most populated city in the country with around 7.8 million people contributing 12% of the nation's population. The city has several healthcare facilities with improved healthcare systems. All four selected hospitals are in the secondary-level category and each facility has healthcare professionals specializing in diabetes. Each facility handles a significant number of DM patients per month including 1007,670, 560, and 502 for Hindumandal, Mwananyamala, Temeke, and Kairuki hospitals respectively. Therefore, this facilitated the attainment of the proposed sample size.

3.3 Study population

The study involved diabetic patients on insulin therapy who attended clinics at the selected healthcare facilities.

3.4 Inclusion criteria

- Any diabetic patient who had used insulin for at least four weeks between January to December 2023
- Diabetic patients who attend clinic at any one of the four selected facilities,

3.5 Exclusion criteria

- Patients who had already developed abscesses at the injection site before being initiated with the insulin therapy were excluded,
- Patients who had already developed scars at the injection site before being initiated with the insulin therapy were excluded,
- The diabetic patients who were not regular customers at the selected facilities were excluded.

3.6 Sample size determination

The sample size of patients included in the study was calculated by using the cross-sectional study formula (41).

$$N = \frac{Z^2 P (100-P)}{d^2}$$

Where N = sample size,

Z - statistic level of confidence (aimed level of confidence for this study is 95%), Therefore z = 1.96,

d - Precision (corresponding to effect size); which is approximately 5%

P - A proportion of diabetic patients ever experienced at least one skin-related ADR during insulin therapy. The proportion used was 50%, and the minimum sample size was 385. After adjusting for the 10% non-despondence, 428 participants were needed.

3.7 Sampling technique

Using simple random sampling, the two study sites (Mwananyamala and Temeke) were selected from a list of the top ten public facilities with a high patient load of diabetic clients. Names of ten public facilities were written on pieces of paper, then kept in the container shaken and two pieces were picked. The top ten public facilities with high patient load in Dar Esalaam were; Mwananyamala RRH, Temeke RRH, Amana RRH, Kilwa road police, Sinza Health Center, Kigamboni Health Center, 511KJ Gongolamboto Health Center, Kigamboni council district hospital, Mnazimmoja district hospital, and Kigogo health center.

A similar procedure was used in obtaining the two private hospitals from a list of the top ten private health facilities which included; Regency Hospital, Rabinisia Hospital, Shire Hindu Mandal Hospital, CCBRT hospital, Kitengule Hospital, Kairuki Hospital, TMJ Hospital, Masana Hospital, Kitonka Hospital and St.Laurent Hospital.

Determination of the number of study participants to be contributed by each facility to the total sample of 428 was done through proportionate sampling. The proportionate sampling was done by multiplying the total number of diabetic patients on insulin from each facility with the sampling fraction. The sampling fraction was obtained by dividing the study sample size (428) by a cumulative number of all diabetic patients on insulin from attending clinics in all four selected health facilities.

Finally, simple random sampling was used to obtain study subjects at each participating facility. The sampling interval was established by taking the total number of diabetic patients on insulin at a particular facility divided by the number of study participants to be contributed by the facility in the study. In each facility the sampling interval was one, hence each participating subject was picked after skipping one client.

3.8 Study variables

- Dependent variables included abscesses and scar formation
- The independent variables included age, gender, awareness of injection technique, injection practice, level of education, hygiene at the injection site, storage practice for insulin and accessories, random blood sugar level, comorbidity, reuse of needles, needle

size, and insulin formulation. The variables were adapted from the previous studies (25,26,34,42).

3.9 Data source, tool & collection procedure

3.9.1 Data source

The source of data for this study was from the medical records of the DM patients who use insulin. DM patients provided information on whether they developed the outcome of interest (abscess or scarring) during their regular use of insulin.

Other information was supplemented by pharmacy records including invoices and delivery notes which were used to identify the needle lengths of insulin syringes supplied at a specified period.

3.9.2 Data collection tool

A well-structured questionnaire was used in the collection of information from the study subjects. A questionnaire was checked for completeness and correctness. The document was divided into 8 sections with 27 questions aimed at capturing all information on the study objectives. Each section carries questions that solicit information on a particular predicted dependent variable.

The tool was pre-tested at Amana Regional Referral Hospital with 30 test subjects. The pre-test helped to modify the tool and to familiarize the research assistants with the tool. Amana Regional Referral Hospital was chosen because it was not one of the selected study sites. Also, the facility setting and healthcare providers are related to the selected study sites.

3.9.3 Data collection procedure

Data were collected daily during the regular patient clinic visits. Before enrollment, eligible patients were sensitized about the study. Those who showed interest were given the consent form to read and understand. Both English and Swahili versions were used at the subject's convenience. Those incapables of reading were supported by their guardian or the researcher. Following an understanding of the study, patients who were willing to join the study were asked to sign or thumb at the consent form.

The face-to-face interviews were held in a private room to ensure the client's comfort and confidentiality. Furthermore, each participant was assigned a unique identification number with a two-letter facility prefix. E.g., TM001, where TM stands for Temeke RRH.

The interviewer probed the study participant by reading the questions printed in the questionnaire. Patients' responses were marked with a tick at the corresponding response box. A physical examination was performed to observe the abscess and scar at the insulin injection site. The interview could take an average of 6-12 minutes per client.

3.10 Data management plan and analysis

Data entry and cleaning were done using Microsoft Excel. Stata version 15.0, developed by Stata Corp in California in the United States of America was used to analyze the coded data. A simple descriptive analysis was presented using tables and figures.

The modified Poisson regression analysis was used to establish the association between the independent and dependent variables. The modified poison regression was chosen because the prevalence of abscesses and scars were not uncommon and, therefore, could provide the best estimate compared to logistic regression (43). Only variables associated with the outcome of interest at the p-value less than 0.2 at univariate analysis were included in the multivariable model.

A backward elimination technique was applied to find a suitable final model. Only the variables that showed significance at the final modal were considered the main predictors.

3.11 Ethical consideration

Ethical clearance was sought from Muhimbili University of Health and Allied Sciences Institutional Review Board (MUHAS-IRB) before the commencement of data collection. Further permission to collect data at the health facilities was obtained from the medical officer in charge of the corresponding health facilities. The informed consent form was obtained from each participant before data collection **(Appendix I)**.

There was no anticipated harm to study participants imposed by their participation in the study. Study participants joined the study voluntarily and were allowed to withdraw from the interview at any time if decided to do so.

To maintain confidentiality, the interview was done in a well-secured room. On top of that, research subjects were assigned numbers instead of using their names. Study subjects were assured that all documents including data collection tools would be kept in a well-secured environment throughout the study period and five years after the study.

CHAPTER THREE

4.0 RESULTS

4.1 Sociodemographic characteristics of the study participants.

A total of 428 diabetic patients on insulin therapy were included in the study. The average age of the study participants was 38.4 years (SD = 19.4). There were more adults aged ≥ 45 years, accounting for 44.6% (191/428). The lowest age group was 25-44 at 22.4% (96 participants). There were more females than males with 54.4% (233 participants) and 45.6% (195/428) respectively. For the case of occupation, the majority were unemployed accounting for 59.6% (255/428). Among the employed, 14.9% were public servants while 6.3% comprised of those employed in the private sector. At least 70.3% (301/428) were covered by health insurance. The majority of participants were not smokers or alcohol users, except for a small number of participants who were reported to smoke or use alcohol at 1.9% (8 participants) and 6.3% (27/428), respectively (**Table 1)**.

Table 1: Sociodemographic characteristics of respondents (N = 428)

Variables	Category	Frequency	Percent
Age (years)	≤24	141	33.0
	25-44	96	22.4
	≥45	191	**44.6**
Sex	Male	195	45.6
	Female	233	**54.4**
Level of education	Non-primary education	185	**43.2**
	Secondary education	182	42.5
	University	61	14.3
Patient occupation	Unemployed	255	**59.6**
	Self-employed	109	25.5
	Employed	64	14.9
Health insurance	Have health insurance	301	**70.3**
	No health insurance	127	29.7
Cigarette smoking	Yes	8	1.9
	No	420	**98.1**
Alcohol consumption	Yes	27	6.3
	No	401	**93.7**

A significant portion of the participants, 22.2% (95/428), experienced an abscess at the injection site which varied throughout 2023. The highest incidences were between October and December (27.4%) and January to March (26.6%). However, the cases were not severe and therefore resolved within a few days. Scar formation at the injection site was noted in 46.7% (200/428) of the study population, with the highest occurrences reported between October and December (25.4%) and January to March (10.6%).

The most common syringe used for insulin injection had a needle length of ≤ 6mm accounting for 55.6%. Additionally, a significant number of participants, 93% (398/428), reported reusing syringe needles, with varying frequencies from one shot per needle to more than three shots per needle.

At least 65% of study subjects know all the body parts recommended for optimum insulin absorption. Interestingly, at least 90.2% (386/428) demonstrated the ability to inject insulin correctly. However, 63.2% (273/428) did not know how to perform injection site rotation. Moreover, 79.4% (340/428) had poorly controlled average blood glucose (**Table 2)**.

Table 2: Clinical characteristics of respondents

Variables	Category	Frequency	Percent
Skin allergy	Yes	47	11.0
	No	381	89
Ever developed abscess	Yes	95	22.2
	No	333	77.8
When abscesses happened (n=95)	Between Jan-Mar 2023	33	34.7
	Between April-Jun 2023	12	12.6
	Between July-Sept 2023	16	16.8
	Between Oct-Dec 2023	34	35.9
Seriousness of the abscess (n=95)	Mild resolved within a few days	52	54.7
	Needed Medication	36	37.9
	Severe Needed Hospitalization	7	7.4
Ever developed scar at the injection site	Yes	200	46.7

	No	228	53.3
When scars happened (n=200)	Between Jan-Mar 2023	45	22.5
	Between April-Jun 2023	23	11.5
	Between July-Sept 2023	24	12
	Between Oct-Dec 2023	108	54
The source of insulin and syringes	At the health facility	378	88.3
	Other Places	50	11.7
Type/insulin formulation	Single separate formulations	95	22.2
	Mixed/fused Formulation	207	48.4
	Insulin Pen	126	29.4
Insulin needle length in 'mm" (n=378)	≤ 6mm	238	55.6
	Insulin pen needle	125	29.2
	Unknown	65	15.2
Ever reused syringe needle	Yes	398	93
	No	30	7
How often reused the needle (n=398)	Sometimes	134	31.3
	Often	137	32
	Always	127	29.7
Frequency of needle re-use (n=398)	Up to three shorts	217	57.7
	More than three shorts	181	42.3
Aware of injection sites	Know all the sites	278	65
	Know a few of the sites	150	35
Insulin injecting technique	Correct	386	90.2
	Not correct	42	9.8
Injection site rotation	Rotates correctly	155	36.2
	Does not rotate correctly	273	63.8
Clean injection site site	Sometimes	290	67.8
	Always	138	32.2
Cleaning procedure (n=253)	Correct	165	65.2
	Not correct	88	34.8
Average blood glucose	Well-controlled	88	20.6
	Not controlled	340	79.4
Insulin storage	2 to 8^{o}C	339	79.4
	>8^{o}C	89	20.6
Presence of any comorbidities	Yes	102	23.8
	No	326	76.2

4.2 Association between sociodemographic, clinical characteristics and the abscess formation.

During the analysis of the baseline and clinical characteristics associated with abscess formation at insulin injection sites among the study participants using the Chi-square test, it was observed that age, type of insulin, needle length, injection technique, and average blood glucose level were significantly associated with the abscess at the p-values of 0.005, 0.001, 0.001, 0.003, and 0.003 respectively (**Tables 3 and 4).**

Table 3: Sociodemographic characteristics associated with the abscess formation (N=428).

Variable	Total (N=428)	Abscess Yes (%) n=95	p-value
Age			
≤24	141	42 (29.8)	
25-44	96	24 (25.0)	
≥45	191	29 (15.2)	**0.005**
Sex			
Male	195	45 (23.1)	
Female	233	50 (21.5)	0.688
Education Level			
At least primary education	185	43 (23.2)	
Secondary	182	40 (23.0)	
University	61	12 (19.7)	0.825
Occupation			
Unemployed	255	51 (20.0)	
Self employed	109	30 (27.5)	
Employed	64	14 (21.8)	0.084
Health insurance			
Insured	301	61 (20.3)	
Not insured	127	34 (26.8)	0.139
Cigarette smoking			
Yes	8	1 (12.5)	
No	420	94 (22.4)	0.505
Alcohol use			
Yes	27	3 (11.1)	
No	401	92 (22.2)	0.152

Table 4: Clinical characteristics associated with abscess formation.

Variable	Total (N=428)	Abscess Yes (%) n=95	p-value
Skin allergy			
Yes	47	11 (23.4)	
No	381	84 (22.1)	0.833
Source of insulin & syringes			
At health facility	378	79 (20.9)	
Other sources	50	16 (32.0)	0.076
Insulin formulation			
Single separate formulation	95	18 (18.9)	
Mixed/fused	207	66 (31.9)	
Insulin Pen	126	11 (8.7)	**0.001**
Needle length			
≤ 6mm	238	69 (28.9)	
Insulin pen needle	125	11 (8.8)	
Unknown	65	15 (23.1)	< **0.001**
History of needle re-use			
Yes	398	91 (22.9)	
No	30	4 (13.3)	0.226
Re-use frequency			
2 to 3 shots/needle	217	49 (22.6)	
>3 shots/needle	181	42 (23.2)	0.883
Injection sites aware			
Yes	278	67 (24.1)	
No	150	28 (18.7)	0.197
Injecting technique			
Correct	386	93 (24.1)	
Not correct	42	2 (4.8)	**0.003**
Injection site rotation			
Yes	155	28 (18.1)	
No	273	67 (24.5)	0.121
Ever clean injection site			
Sometimes	290	67 (23.1)	
Always	138	28 (20.3)	0.513
Cleaning procedure			
Correct	165	30 (18.2)	
Incorrect	88	25 (28.4)	0.06

Blood glucose level			
Controlled	88	12 (13.6)	
Not controlled	340	83 (24.4)	**0.03**
Presence of comorbidity			
Yes	102	17 (16.7)	
No	326	78 (23.9)	0.124
Insulin storage			
2 to 8^{o}C	339	70 (20.7)	
>8^{o}C	88	25 (28.4)	0.119

4.3 Determinants for abscess formation at the insulin injection site

In the determination of factors associated with abscess formation at the insulin injecting site, the univariable analysis was performed followed by the multivariable analysis. All variables with p-values less than 0.20 at univariable model analysis were included in the multivariable model analysis. During the univariable analysis, several independent variables were associated with abscess formation with p-values of less than 2.0. The final model obtained following the multivariable analysis revealed that four independent variables; occupation, injection site rotation, type of insulin, and injecting techniques were statistically associated with abscess formation at the insulin injection site.

Subjects with good techniques for injecting insulin (386 out of 428,90.2%) had a reduced risk of developing abscesses compared to those with improper insulin injection techniques. Those with improper injection techniques were at high risk of developing an abscess (aPR=1.11; 95%CI:1.02-1.21 p = 0.009) when compared to those with good injecting techniques. There was a significant association between the type of insulin formulation and abscess formation. The insulin pen was protective against abscess formation at the injection site (aPR = 0.13; 95%CI:0.04-0.48, p = 0.002). The risk was high for the mixed insulin formulation vials (Apr = 1.45; 95%CI:0.59-3.53, p = 0.42) when compared to the single formulation vial however, this was not statistically significant. Furthermore, the injection site rotation was statistically associated with abscesses. It was observed that improper injection site rotation was associated with abscess formation (aPR=2.7; 95%CI:1.13-6.45 p = 0.025) when compared to practicing the

proper injection site rotation. Moreover, the study observed a significant association between abscess and occupation. When compared to the nonemployed, those who were self-employed had a higher risk of developing an abscess (aPR=2.34; 95%CI:1.04-5.27 p=0.4).

Table 5: Factors associated with abscess formation at insulin injection site

Variable	N	Abscess formation (%)	Unadjusted		Adjusted	
			cPR,95% CI	p-value	aPR,95% CI	p-value
Age group						
≤24	141	42 (29.79)	Ref			
25-44	96	24 (25.00)	0.83(0.96-1.09)	0.41	0.99 (0.65-1.53)	0.99
≥45	191	29 (15.18)	0.51(1.03-1.14)	0.002	0.60 (0.99-1.15)	0.06
Sex						
male	195	45 (23.08)	Ref			
female	233	50 (21.46)	0.93(0.97-1.06)	0.689	1.02(0.97-1.08)	0.87
Occupation						
Non	255	51 (20.00)	Ref			
Self-employed	109	30 (27.5)	1.38(0.93-2.04)	0.290	2.34 (1.04-5.27)	**0.04**
Employed	64	14 (21.88)	1.09(0.64-1.84)	0.572	1.14 (0.39-3.32)	0.815
Source of insulin & syringes						
Health facility	378	79 (20.90)	0.94(0.86-1.02)		0.91 (0.79-1.03)	0.13
Other sources	50	16 (32.00)	Ref	0.119		
Site rotation						
Yes	155	28 (18.06)	Ref			
No	273	67 (24.54)	1.36(0.91-2.01)	0.108	2.7 (1.13-6.45)	**0.025**
Insulin formulation						
Single vial	95	18 (18.95)	Ref			
Mixed/fused	207	66 (31.88)	1.68(1.06-2.67)	0.034	1.45 (0.59-3.53)	0.42
Insulin Pen	126	11 (8.73)	0.19(0.23-0.93	0.012	0.13 (0.04-0.48)	**0.002**
Needle length						
≤ 6mm	238	69 (28.99)	3.30 (1.01-1.05)	0.32	0.94 (0.83-1.08)	0.43
Unknown	65	15 (23.08%)	2.60 (0.85-0.98)	<0.01	1.12 (0.97-1.29)	0.11
Pen needle	125	11 (8.80)	Ref			
Injecting technique						
Correct	386	178 (46.11)	Ref			
Not correct	42	22 (52.38)	1.11 (1.07-1.16)	<0.01	1.11 (1.02-1.21)	**0.009**

4.4 Sociodemographic and clinical characteristics associated with the scar.

Using the Chi-square test it was observed that there was statistical association between the scar formation and some of the patients' clinical characteristics including the place where the insulin was obtained, the type of insulin, the needle length, the average blood glucose level and the insulin storage practice. Each of these independent variables has p-value of less or equal to 0.05. (**Tables 5 and 6)**.

Table 6: Sociodemographic associated with the scar formation.

Variable	Total	Developed scar (%)	p-value
Age group			
≤24	141	68 (48.2)	
25-44	96	50 (52.1)	
≥45	191	82 (42.9)	0.31
Sex			
Male	195	93 (47.7)	
Female	233	107 (45.9)	0.715
Education Level			
At least primary	185	89 (48.1)	
Secondary	182	85 (46.7)	
University	61	26 (42.6)	0.758
Occupation			
Un employed	255	108 (42.4)	
Self-employed	109	59 (54.1)	
Employed	64	33 (50.1)	0.084
Health insurance			
Insured	301	136 (45.2)	
Not insured	127	64 (50.4)	0.324
Cigarette smoking			
Yes	8	3 (37.5)	
No	420	197 (46.9)	0.597
Alcohol use			
Yes	27	13 (48.2)	
No	401	187 (46.6)	0.879

Table 7: Clinical characteristics associated with the scar formation (N=428).

Variable	Total	Develop scar (%)	p-value
Skin allergy			
Yes	47	24 (51.06)	
No	381	176 (46.19)	0.53
Source of insulin & syringes			
At health facility	378	166 (43.92)	
Other sources	50	34 (68.00)	**0.001**
Insulin formulation			
Single formulation	95	44 (46.32)	
Mixed/fused	207	114 (55.07)	
Insulin Pen	126	42 (33.33)	**0.001**
Needle length			
≤ 6mm	238	119 (50.00)	
Unknown	65	40 (61.54)	
Insulin pen	125	41 (32.80)	**0.001**
History of needle re-use			
Yes	398	187 (46.98)	
No	30	13 (43.33)	0.699
Re-use frequency			
2 to 3 shots/needle	217	101 (46.54)	
>3 shots/needle	181	86 (47.51)	0.847
Awareness of injection sites			
Yes	278	132 (47.48)	
No	150	68 (45.33)	0.671
Injecting technique			
Correct	386	178 (46.11)	
Not correct	42	22 (52.38)	0.439
Injection site rotation			
Yes	155	66 (42.58)	
No	273	134 (49.08)	0.195
Ever cleaned the injection site			
Sometimes	290	142 (48.97)	
Always	138	58 (42.03)	0.179
Cleaning procedure			
Correct	165	74 (44.85)	
Not correct	88	39 (44.32)	0.936

Blood glucose level			
Controlled	88	31 (35.23)	
Uncontrolled	340	169 (49.71)	**0.015**
Presence of comorbidity			
Yes	102	40 (39.22)	
No	326	160 (49.08)	0.081
Insulin storage			
2 to 8^{o}C	339	150 (44.25)	
>8^{o}C	88	49 (55.68)	0.055

4.7 Determinants for scar formation at the insulin injection site

In determining factors associated with abscess formation at the insulin injecting site, the independent variables that were statistically significant with p-values less than 0.20 at the univariable model were taken into the multivariable analysis. The independent variables statistically significant in the multivariable model at the p-value of less or equal to 0.05 were considered the main determinants for scar formation at the insulin injection site.

Scars were observed to be influenced by improper site rotation (aPR = 1.63; 95%CI:1.03-2.32 P = 0.037), uncontrolled blood glucose level (aPR = 1.69; 95%CI:1.01-2.84, p = 0.049), the use of insulin and syringes obtained from other places apart from at facilities patients attended clinics (aPR= 2.51; 95%CI:1.22-1.98, p= 0.035) and occupation where the self-employed had more chances of developing scars (aPR= 2.0; 95%CI:1.21-3.33, p= 0.007) followed by those with the formal employment (aPR= 1.9; 95%CI:1.04-3.41, p= 0.036) when compared to the non-employed.

Table 8: Factors associated with scar formation at insulin injection site

Variable	Total	Developed scar (%)	Crude estimates		Adjusted estimates	
			cPR,95% CI	p-value	aPR,95% CI	P-Value
Age						
≤24	141	68 (48.23)	Ref			
25-44	96	50 (52.08)	1.07 (0.89-1.06)	0.561	0.96 (0.88-1.05)	0.44
≥45	191	82 (42.93)	0.89 (0.96-1.11)	0.340	1.02 (0.95-1.10)	0.40
Sex						
Male	195	93 (47.69)	Ref			
female	233	107 (45.92)	0.96 (0.95-1.07)	0.715	0.99 (0.93-1.05)	0.79
Occupation						
Un employed	255	108 (42.35)	Ref			
Self-employed	109	59 (54.13)	1.65 (1.02-2.52)	0.360	2 (1.21-3.33)	**0.007**
Employed	64	33 (50.09)	1.45 (0.84-2.51)	0.831	1.9 (1.04-3.41)	**0.036**
Source of insulin & syringes						
At health facility	378	166 (43.92)	Ref			
Other sources	50	34 (68.00)	2.71 (1.45-5.09)	0.001	2.51 (1.22-1.98)	**0.035**
Injection site rotation						
Yes	155	66 (42.58)	Ref			
No	273	134 (49.08)	1.30 (0.87-1.93)	0.191	1.63 (1.03-2.32)	**0.037**
Presence of comorbidity						
Yes	102	40 (39.22)	1.07 (0.99-1.14)	0.073	1.03 (0.96-1.11)	0.35
No	326	160 (49.08)	Ref			
Insulin storage						
2 to 8^{o}C	339	150 (44.25)	Ref			
>8^{o}C	88	49 (55.68)	1.26 (0.86-1.01)	0.061	0.95 (0.88-1.03)	0.21
Blood glucose level						
Controlled	88	31 (35.23)	Ref			
Uncontrolled	340	169 (49.71)	1.82 (1.12-2.96)	0.015	1.69 (1.01-2.84)	**0.049**

CHAPTER FOUR

5.0 DISCUSSION

The findings on the prevalence of abscess which was reported to be high in this study 22.2% is congruent with what was reported by (20,44–46). However, according to Singha and Richardson with data from India and the US, the prevalence of abscesses was reported as a rare event (17,20). The observed variation in magnitude could be due to different sample sizes, study sites, and socio-demographic characteristics of the study subjects. Likewise, the large magnitude of scar formations at injection sites of 46.7% observed from this study was similar to what was observed in the US (17) which reported a prevalence of 48%. The similarities in the magnitudes of both adverse events at insulin injection sites indicate that the two problems do exist. They should not be underestimated due to their impact clinically and cosmetically.

A significant association was observed between the insulin injecting technique and the occurrence of abscesses at the insulin injection site. It was found that patients who injected their insulin incorrectly were more likely to develop abscesses at insulin injection sites compared to those who adhered to the recommended procedure of injecting insulin. This finding corresponds to the insulin injection technique survey reported in Bangladesh (12). Both studies displayed similarities in patients' practice of injecting insulin. In both studies, the majority of clients had good adherence to the injecting technique. However, those few subjects reported improper injecting techniques had a high chance of developing the abscess. This necessitates regular training for insulin users to ensure each one adheres to the recommended injection techniques.

Furthermore, the study revealed that use of an insulin pen reduces the chances of developing abscess by 87%. These findings are consistent with what was observed in Saudi Arabia (42,47). An explanation for this could be that an insulin pen reduces the chance of skin trauma (48).

Injection site rotation was associated with abscess formation and also scaring. This study observed that failure to adhere to injection site rotation increases the chance of developing an abscess and these findings match what was found in Ethiopia (27). In both studies, clients were presented with fair practice of injection site rotation. This may imply the similarities in practice

among insulin users across the sub-Saharan. This significant association could be due to the repeating number of shorts at the skin segment leading to trauma and eventually abscess formation.

There was an observation that occupation is associated with abscesses and scaring at the insulin injection site. Compared to the unoccupied, people with occupational had an increased risk of developing abscesses or scars. Among the occupied, the risk was even higher for those who were self-employed when compared to those with formal employment. Although we did not find a clear scientific explanation, findings reported that some occupational works are associated with skin diseases (49). However, this study was too general and did not exactly concentrate on abscesses and scars, therefore we need further studies to explore this. Alternatively, the unemployed group included children under 18 years old. It was noted that children under 18 years were kept under special programs with close monitoring and regular health education support.

It was found that there was an association between where the subject obtained insulin and the accessories with the scar at the insulin injection site. Participants who obtained their insulin and syringes from sources other than at the health facility where they attended clinics had a significantly higher likelihood of developing scars. This association can have different explanations including insufficient instruction provided by the healthcare provider in other places, improper storage conditions for the insulin and the accessories, etc. This implies that there is a need to insist that patients receive insulin and accessories in places where they attend clinics. Studies reported the need to obtain medical supplies from reliable and consistent sources (50).

Failure to keep the blood glucose level at the recommended range is associated with abscess formation. Having uncontrolled blood glucose levels increases the risk of developing scars among insulin users. This concurs with what was reported by other scientists (de Macedo et al., 2016; Jennifer Huizen — Updated on March 28, 2023). We couldn’t establish what came first between the abscess and the uncontrolled blood sugar. However, it can be predicted that having

an abscess led to poor absorption of insulin at the injection site and therefore failure of insulin to perform according to its intended purpose.

Therefore, the findings from this research highlight the two skin-related adverse events abscess and scar at the site of insulin injection, and the associated factors among the diabetic patients on insulin. Demographic factors appear less influential in abscess or scar. an insulin pen was protective against abscesses while a type of occupation, improper injection site rotation, and injection technique influenced the occurrence of abscesses. The scar formation was influenced by occupation, the source of insulin and its accessories, incorrect injection site rotation, and uncontrolled blood sugar.

The analysis's statistically significant output underscores the importance of continuous patient education, proper injection techniques, injection site rotation, needle and insulin type selection, and regular blood glucose monitoring. Addressing these areas through targeted interventions and enhanced healthcare support can significantly improve diabetes management outcomes and reduce the incidence of adverse events at injection sites.

CHAPTER FIVE

6.0 LIMITATIONS CONCLUSION AND RECOMMENDATIONS

6.1 Limitation

This study has several limitations that must be acknowledged. The reliance on self-reported data for variables such as when he or she experienced the adverse event, and when he or he reused the syringe needle introduces the potential for recall bias. Also, self-reported data on hygiene at injection sites introduces the potential for social desirability bias hence potentially compromising the accuracy of the findings. Additionally, the cross-sectional design limits the ability to establish causal relationships between observed variables and health outcomes. Furthermore, the lack of detailed information on the duration and severity of diabetes among participants and other potential confounding variables may have impacted the robustness of the analysis.

6.2 Conclusion

In conclusion, this study highlights the magnitude of abscess and scar formation at the insulin injection site and the associated determinants among DM patients on insulin. It was observed that the prevalence of abscess was 22.2% and that of scar was 46.7%. Factors influencing abscesses include occupation, improper injection site rotation, and incorrect injection technique. On the other hand, an insulin pen was protective against abscess formation. The scar formation was influenced by occupation, improper injection site rotation, un-regulated blood glucose, and sourcing of insulin and its accessories from other places apart from the health facility where patients attend the clinic.

6.3 Recommendations

Based on the findings of this study, several recommendations can be made to improve diabetic care and reduce insulin injection-related adverse events:

1. Health care professionals: Enhance patient education on proper injection technique, site rotation and regular blood glucose monitoring.
2. Ministry of health and stake holders should ensure consistency supply of insulin pen and its accessories and advocate the use of pen over other conventional syringes and vials.
3. Community pharmacy health care staff should be trained on the Diabetes and its management. The training package should include patient counselling on proper insulin injection technique, site rotation etc. The trained community pharmacy health care staff will disseminate the knowledge to the DM patients. This is because those staff accessible by the community therefore easily contacted by the DM patients. Proper counselling that will be offered by the trained community pharmacy staff will prevent unnecessary abscesses and scars among DM patients.
4. Regular monitoring and follow-up: Healthcare providers should implement regular monitoring and follow-up with patients to assess their injection practices and address any issues promptly. Routine checks of injection sites for signs of complications and immediate interventions can help reduce the incidence of abscesses and scars.
5. We recommend further studies to address the pending question raised from this study on how the occupation works is associated with the abscesses and also scars.

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APPENDICES

Appendix I: Informed consent form - English version

IDENTITY NO | | | | |

Consent to participate in the study entitled:

PREVALENCE AND PREDICTORS OF ABSCESS AND SCAR FORMATION AT THE SITE OF INSULIN INJECTION AMONG PATIENTS ATTENDING DIABETIC CLINICS IN SELECTED PUBLIC AND PRIVATE HOSPITALS IN DAR ES SALAAM.

Introduction

Dear participant, my name is Dennis Patson, a second-year master's student in Pharmacoepidemiology and Pharmacovigilance at Muhimbili University of Health and Allied Sciences (MUHAS). I would kindly like to inform you that I am conducting this study titled above, so as to identify and quantify abscess and scar formation adverse event at the site of insulin injection. Additionally, we will determine the factors associated to this type of adverse event. I would kindly request you to participate in this study as a study subject.

Confidentiality:

Your name will not appear in any of the study documents or reports as the result no one will be able to identify you. The information solicited from you will always be kept under safe custody, and will only be accessed by the study investigators.

Expected risks:

No risk is associated with this study.

Your rights:

Participation in this study is voluntary; you are free to agree or to disagree to participate in this study. You are free to leave at any time and the information obtained already will not be used for this study.

Benefits:

The prevalence data will serve as a baseline for understanding the magnitude of the problem and its potential impact on diabetes management. The result may add a signal for the safety profile of insulin and related accessories to the local (TMDA) and global (UPSALA) data bases. Additionally, the study results may impose a need to improve the current practice of insulin administration to avoid unnecessary skin-related adverse drug reactions. Furthermore, the study findings may highlight the urgency of addressing the issue and guide the development of appropriate interventions, educational programs, and innovations to prevent or mitigate the complications.

Whom to contact:

Use any of the following contacts in case of any questions related to participation in this study;
The office of Director of Research, Consultancy and Innovation, Muhimbili University of Health and Allied Sciences, PO Box 65001, Dar es Salaam.
Tel; 022-2152489

Dennis Patson (Principal investigator)
Muhimbili university of Health and Allied Sciences
Cell phone: +255 658333469

Dr. Alphonce Marealle (Research Supervisor)
Muhimbili university
Cell phone; +255 0713629365

I would appreciate if you would kindly participate in the study.
I agreed to participate in this study; I have understood all the information in this form and my questions have been answered.
Signature of the study participant……
Date ...../…/……
Signature of the researcher……
Date...../…/……

Appendix II: Consent form (Kiswahili version)

FOMU YA MAELEZO KUHUSU UTAFITI:

NAMBA YA UTAMBULISHO: ☐☐☐☐

Fomu ya maelezo ya utafiti yenye kichwa cha habari:

KUTAFITI UWEPO NA UKUBWA WA TATIZO LA KUTOKWA NA MAJIPU AU MAKOVU KATIKA SEHEMU ILIYOCHOMWA SINDANO AINA YA INSULIN KWA WAGONJWA WA SUKARI WANAOFANYA KLINIKI KATIKA HOSPITALI BINAFSI NA ZA SERIKALI SPITALI ZILIZOTEULIWA DAR ES SALAAM..

Utangulizi

Ndugu mshiriki, jina langu ni Dennis Patson Mbwambo, mwanafunzi wa shahada ya uzamili ya ufamasia nikibobea katika usalama wa dawa kwa mtumiaji katika chuo cha afya na sayansi shirikishi Muhimbili. Ningependa kukutaarifu kuwa ninafanya utafiti huu kwa nia ya kuangalia uwepo na ukubwa wa tatizo la kutokwa na majipu kisha makovu katika sehemu iliyochomwa sindano aina ya insulin. Kadhalika tutaona ni vitu gani vinachangia uwepo wa madhara hayo. Hivyo Naomba ushiriki wako.

Usiri:

Hatutaonesha jina lako katika nyaraka zozote na hakuna atakayeweza kukutambua. Namba zitatumika kwa utambulisho ili kuongeza usiri.

Matarajio ya hatari:

Utafiti huu hauna madhara yoyote.

Haki yako:

Ushiriki wako ni wa hiari, Una uhuru na haki yakukubali au kutokukubali kushiriki katika utafiti na una uhuru wa kusitisha ushiriki muda wowote na taarifa ulizotoa kutokutumika tena.

Faida:

Matokeo ya tokanayo na utafiti huu yatasaidia kubain uwepo na ukubwa wa tatizo na athari zake katika matibabu ya sukari. Kadhalika matokeo yatatupatia picha halisi juu ya usalama wa dawa

aina ya insuli pamaoja na vifaa vinavyotumika kuchomea insulin na taarifa hii itawekwa katika benki ya taarifa na kimataifa ya utunzaji wa taarifa za usalama wa dawa. Matokeo ya utafiti huu yanaweza kuwa chachu ya maboresho ya utaratibu uliopa katika matumizi ya insulin. Kadhalika matokeo ya utafiti yanaweza kusaidia nchi juu ya nini kifanyike kama ni elimu, kuboresha aina ya vifaa vyakuchomea dawa nk, kwa ajili ya manufaa ya jamii nzima.

Mawasiliano:

Ukiwa na swali kuhusu kushiriki utafiti huu usisite kuwasiliana na yeyote kati ya wafuatao;

Mkurugenzi wa tafiti, chuo cha Afya na Sayansi shirikishi Muhimbili, PO Box 65001 Dar es Salaam

S.L.P 65001, Dar es Salaam.

Nambari ya simu: 022-2152489

Dennis Patson (Mtafiti)

Muhimbili university of Health and Allied Sciences

Namba ya simu: +255 658333469

Dr. Alphonce Marealle (Msimamizi wa mtafiti)

Muhimbili university

Namba ya simu; +255 0713629365

Nitashukuru sana kama utaamua kushiriki kwa hiari katika utafiti huu.

Nakubali kushiriki utafiti huu baada ya kuelewa maelezo yote katika fomu hii . Maswali yangu yote yamejibiwa.

Sahihi ya mshiriki……..Tarehe…..../…./…….

Saini ya mtafiti…… Tarehe ...../…/……

Appendix III: Questionnaire for participants (English version)

Questionnaire for collecting data regarding occurrence of abscess and scar at insulin injection site for diabetic patient on insulin therapy.

Name of health facility/Study site ……...

Patient code……..……...Date: .....

Section I: Patient socio-demographic information

For every question write the number for the correct response in the box provided.

1. Patient age (yrs); ……

2. Sex;
   1) Male
   2) Female

3. Level of education;
   1) Non
   2) Informal education,
   3) Primary education,
   4) Secondary education,
   5) University,

4. Employment status;
   1) Not employed at all
   2) Self-employed
   3) Employed by private institutions
   4) Government employee
   5) Others (specify)……...

5. Health insurance coverage;
   1) Covered by insurance
   2) Not covered

6. Do you smoke?.
   1) Yes,
   2) No,

7. Do you use alcohol?
   1) Yes,
   2) No,

8. Do you have any family member with skin related allergy?
   1) Yes,
   2) No,

Section II. Assessment of abscess and scarring Adverse Event following insulin injection

9. Have you ever developed an abscess at the insulin injection site within the past 12 months of insulin use?

1) Yes,
2) No,

10. If yes, when did it occur in the year 2023?

1) Between Jan-Mar
2) Between April-Jun
3) Between July-Sept
4) Between Oct-Dec

11. How serious was the adverse event (abscess)?

1) Mild that resolved within few days
2) Needed medication
3) Severe needed hospitalization

12. Have you ever developed a scar at the insulin injection site within the past 12 months of insulin use?

1) Yes,
2) No,

13. If yes when did it occur in the year 2023?

1) Between Jan-Mar
2) Between April-Jun
3) Between July-Sept
4) Between Oct-Dec

Section III. Identification of type insulin and syringe needle size consumed

14. By the time you experienced the Adverse event, where did you get insulin and the syringes?

1) At this health facility
2) Other places

Note. If the insulin and syringes were provided at the same facility then check dispensing records and invoices from the main store and or dispensing unit to determine the types of insulin and syringe size issued to the patient and then use that information to answer qn.15 & 16.

15. Type of insulin consumed;

1) Single formulation
2) Mixed (Rapid + Slow) formulation
3) Insulin pen

16. Needle size used;

1) (0-4) mm length
2) (5-6) mm length
3) Other sizes (specify) ……

Section IV. Assessment of re-use of needle

17. Have you ever reused syringe needle?

1) Yes,
2) No,

If yes, continue with question 18 and 19.

18. How often do you reuse the needle.?

1) Sometimes,
2) Frequently,
3) Always,

19. How many times do you reuse a single needle?

1) Two times
2) Three times
3) More than three times

Section V. Assessment of injecting practice/technique

Can you demonstrate how you inject yourself with insulin?

Note: Observe and score whether correct or incorrect injecting practice at question 20 & 21.

For lean patients consider correct only if patients Lift a skin fold & insert the needle at a 90^{o} angle. Alternatively, if the skin fold is not lifted then should inject at a 45^{o} angle. Fat patients may inject at 90^{o} without skin lift. Any practice other than that is considered incorrect

20. Does the patient inject insulin correctly?

1) Yes correctly ☐
2) No, not correct

21. Does the patient know the correct site for injecting insulin for adequate absorption?

1) Yes. He/She knows ☐
2) No, He/She doesint know

Note; Note recommended site include anterior abdomen, anterior and outer mid-thighs, upper arms, upper and outer quadrants of the buttock.

22. Does a patient perform injection site rotation?

1) Yes ☐
2) No

Note: it is usually advised to divide the injection site into quadrants(abdomen) or halves (thighs, buttocks & arms) and a single quadrant or half should be used per week.

Section VI. Assessment of hygiene practice at injection site.

23. Do you clean the injection site before administration of insulin?

1) Never ☐
2) Sometimes
3) Always

If yes, is the cleaning process done correctly? Listen to the patient's explanation on how he/she does the cleaning then fill in the correct response in question 24.

Note. Clean water or alcohol can be used with a cotton swab. Cleaning should be circular motion from the middle outwards.

24. Does the patient clean correctly?

1) Yes,
2) No,

Section VII. Adherence to blood glucose control

25. What is the overall patient's glucose status within the three recent months?

1) Well controlled
2) Varies
3) Un known
4) Normally above the recommended level.
5) Normally below the recommended level.

Note. You can check at least three consecutive patient visits and assume well controlled if observed normal in 70% of the visits after initiation of insulin. Norma range (3.9-7.2) mmol/L or (70-130) mg/dL before meals.

26. Do you have any co-morbidities (chronic illness)? like HIV, TB, HTN etc.

1) Yes
2) No

If yes specify …….

Section VIII. Adherence to storage practice.

27. Where do you store the insulin?

1) In the refrigerator (2-8) ^{o}C
2) Others (specify)……

……. End of interview **……**

Appendix IV: Questionnaire (Swahili version)

Dodoso la kupata taarifa za madhara ya kutokwa na majipu na makovu katika sehemu ilipochomwa sindano aina ya insulin kwa wagonjwa wa sukuari

Jina la kituo cha utafiti/Hospitli ya ……..

Nambari ya uambulisho wa mgonjwa ……...Tarehe: .....

Sehemu ya I: Taarifa za mshiriki wa utafiti

Kwa kila swali andika namba ya jibu katika kiboksi kilishopo pembeni kilia

Sehemu II. Taarifa za mgonjwa kupata majipu na makovu baada ya kuchoma insulin

1. **Umewahi kutokwa na majipu katika sehemu husika baada ya kuchoma sindano aina ya insulini ndani ya kipindi cha miezi 12 ya utumiaji wa insulin?.**
    1) Ndiyo
    2) Hapana
2. **Kama ndiyo, tatizo hili lilitokea lini (mwezi) gani ktk mwaka 2023 ?.**
    1) Kati ya mwezi 1-3
    2) Kati ya mwezi 4-6
    3) Kati ya mwezi 7-9
    4) Kati ya mwezi wa 10-12
3. **Ukubwa wa tatizo (Majipu) ulikuwa ni wa namna gani?.**
    1) Madogo yalipona ndani ya siku chache
    2) Yalihitaji tiba
    3) Makali ya kuhitaji kulazwa hospitalin
4. **Umewahi kutokewa na makovu katika eneo ulipochoma insulin ndani ya kipindi cha** miezi 12 ya kutumia insulin?
    1) Ndiyo
    2) Hapana

5. **Kama ndiyo, tatizo hili lilitokea lini ktk mwaka 2023?.**
    1) Kati ya mwezi 1-3
    2) Katiya mwezi 4-6
    3) Kati ya mwezi 7-9
    4) Kati ya mwezi wa 10-12

Sehemu ya III. Aina ya insulin na ukubwa wa nido ya sindano ilotumika.

6. **Kwa kipindi ulichopata madhara ulipata wapi dawa ya insulin na mabomba ya sindano?.**
    3) Katika hospitali hii
    1) Sehemu nyingine

Zingatia.Endapo insulin na mabomba yalitolewa ktk hospitali husika, chukua taarifa za aina ya insulin (Single or Mixed formulation) na urefu wa nido ya sindano. Utapata taarifa hizi dispensing famasi (dispensing records) au invoices toka bohari ya dawa ya hospitali husika. Tumia taarifa hizi kujaza swali nambar 15 &16.

7. **Aina ya insulin iliyotumika ni;**
    4) Single formulation
    1) Mixed formulation
    2) Insulin pen
8. **Urefu wa nido ya sindano ilotumika;**
    4) Urefu wa (0-4)mm
    1) Urefu wa (5-6)mm
    2) Urefu mwingine. (Taja) ……

Sehemu ya IV. Taarifa za utumiaji wa nido ya sindano Zaidi ya maramoja.

9. **Umesha wahi kutumia nido ya insulin kujichoma Zaidi ya maramoja?.**
    1) Ndiyo
    2) Hapana

Kama jibu ni ndiyo, endelea na swali no.18 na 19.

10. Ni mara ngapi umeitumia nido kwa kuirudia?.

1) Marachache
2) Mara nyingi
3) Mara zote

11. Nido moja umekuwa ukiirudia kujichoma mara ngapi?

1) Mara 2,
2) Mara 3,
3) Zaidi ya mara 3.

Sehemu ya V. Kupata taarifa za namna mgonjwa ananyo jichoma insulin

Waweza onesha /elezea kwa mifano namna unavyo jichoma sindano ya insulin?. **Zingatia**: Tazama na sikiliza kwa makini maelezo yake kisha jibu swali na.20 - 22.

Kama ni mwembamba utaratibu wa kujichoma ni sahihi endapo atainua mkunjo wa Ngozi na kujichoma nido ya sindano ikiwa ktk nyuzi tisini (90^o). Kadhalika anaweza asiinue Ngozi lakin ajichome nido ikiwa ktk nyuzi arobaini na tano (45^o).

Endapo ni mnene atapaswa ajichome bila kuinua ngozi na nido ya sindano iwe ktk nyuzi tisini (90^o). Yeyote atakaye onesha utaratibu wa kujichoma kinyume na maelezo tajwa hapo juu atazingatiwa kuwa hajichomi insulin kwa usahihi.

12. Mgonjwa hujichoma sindano kwa usahihi?.

1) Ndiyo sahihi
2) Hapana siyo sahihi

13. Mgonjwa anafahamu sehemu sahihi ya kujichoma insulin?.

1) Ndiyo anafahamu
2) Hapana hafahamu

Zingatia; Maeneo sahihi ni; Sehemu ya mbele ya tumbo, Sehemu ya mbele na ya pembeni ya paja, Sehemu ya juu ya mikono, Sehemu ya juu na pembeni ya makalio.

14. Mgonjwa huwa anapishanisha maeneo ya kujichoma insulin (injection site rotation)?

1) Ndiyo
2) Hapana

Zingatia: Inashauriwa kugawa sehemu ya kuchoma insulin ktk pande nne za tubo, au kugawa (paja, Kalio, na mkono) katika nusu mbili. Kisha kila kipande kitumike kwa kipindi cha wiki moja kisha hamia ktk kipande kingine.

Sehemu ya VI. Maandalizi ya usafi ktk sehemu ya mwili inapochomwa insulin.

15. Huwa unasafisha sehemu ya mwili kabla hujajichoma insulini?.

1) Hapana
2) Ndiyo marachache
3) Ndiyo mara zote

Kama unasafish aje, Je. Anasafisha kwa usahihi?. Msikilize anavyo jieleza, kisha jaza jibu sahihi hapo chini. Ktk swali nambari 24.

Inashauriwa kusafisha kwa pamba yenye **maji safi** au **spiriti**. Usafishaji ni wa mzunguko kutokea kati kuelekea nnje ya duara.

16. Je? Ana safisha kwa usahihi?.

1) Ndiyo
2) Hapana

Sehemu ya VII. Matokeo ya udhibit wa kiwango cha sukari mwilini

17. Kiwango cha sukari mwilini kwa ujumla ktk kipindi cha miezi mitatu mfululizo ya hivi karibuni kikoje?.

1) Imedhibitiwa vizuri
2) Hubadilika mara kwa mara
3) Haijulikani
4) Maranyingi ipo juu ya kiwango
5) Maranyingi ipo chini ya kiwango

Zingatia: Sukari imedhibitiwa endapo asilimia 70% ya vipimo vilivyochukuliwa ndani ya miezi mitatu ya karibuni mgonjwa akiwa anatumia insulin ilikuwa ktk kiwango kinachokubalika. Ambacho ni (3.9-5.6) mmol/L au (70-100) mg/dL

18. Una ugonjwa wowote sugu?. Mfano; HIV, TB, Pumu nk.

1) Ndiyo
2) Hapana ☐

Endapo jibu ni ndiyo, taja aina ya ugonjwa sugu …….

Sehemu ya VIII. Utaratibu wa utunzaji insulin.

19. Huwa unahifadhi wapi insulini?

1) Kwenye jokofu (2-8)^{o}C ☐
2) Sehemu nyingine (eleza)……

……. ***Mwisho wa dodoso……***

Appendix V: Approval for ethical clearance



UNITED REPUBLIC OF TANZANIA

MINISTRY OF EDUCATION, SCIENCE AND TECHNOLOGY

MUHIMBILI UNIVERSITY OF HEALTH AND ALLIED SCIENCES

OFFICE OF THE DIRECTOR – RESEARCH, PUBLICATIONS AND INNOVATION



Ref. No DA 282/298/01.C/2057 Date: 26/02/2024

MUHAS-REC-02-2024-2057
DENNIS PATSON
MUHAS

RE: APPROVAL FOR ETHICAL CLEARANCE FOR A STUDY TITLED: PREVALENCE AND FACTORS ASSOCIATED WITH ABSCESS AND SCAR FORMATION AT THE SITE OF INSULIN INJECTION AMONG PATIENTS ATTENDING DIABETIC CLINICS IN SELECTED PUBLIC AND PRIVATE HOSPITALS IN DAR ES SALAAM.

Reference is made to the above heading.

I am pleased to inform you that the Chairman has on behalf of the University Senate, approved ethical clearance of the above-mentioned study, on recommendations of the Senate Research and Publications Committee meeting accordance with MUHAS research policy and Tanzania regulations governing human and animal subjects research.

APPROVAL DATE: 26/02/2024
EXPIRATION DATE OF APPROVAL: 26/02/2025

STUDY DESCRIPTION:
Purpose:

The purpose of this hospital-based cross-sectional study is to assess prevalence and factors associated with formation of abscess and scar at site of insulin injection among patients attending diabetic clinics in selected public and private hospitals in Dar es salaam.

The approved protocol and procedures for this study is attached and stamped with this letter, and can be found in the link provided: https://irb.muhas.ac.tz/storage/Certificates/Certificate%20-%2014554.pdf and in the MUHAS archives.

The PI is required to:

1. Submit bi-annual progress reports and final report upon completion of the study.
2. Report to the IRB any unanticipated problem involving risks to subjects or others including adverse events where applicable.
3. Apply for renewal of approval of ethical clearance one (1) month prior its expiration if the study is not completed at the end of this ethical approval. You may not continue with any research activity beyond the expiration date without the approval of the IRB. Failure to receive approval for continuation before the expiration date will result in automatic termination of the approval for this study on the expiration date.
4. Obtain IRB amendment (s) approval for any changes to any aspect of this study before they can be implemented.
5. Data security is ultimately the responsibility of the investigator.
6. Apply for and obtain data transfer agreement (DTA) from NIMR if data will be transferred to a foreign country.
7. Apply for and obtain material transfer agreement (MTA) from NIMR, if research materials (samples) will be shipped to a foreign country,
8. Any researcher, who contravenes or fail to comply with these conditions, shall be guilty of an offence and shall be liable on conviction to a fine as per NIMR Act No. 23 of 1979, PART III section 10 (2)
9. The PI is required to ensure that the findings of the study are disseminated to relevant stake holders.
10. PI is required to be versed with necessary laws and regulatory policies that govern research in Tanzania. Some guidance is available on our website https://drp.muhas.ac.tz/.

Dr. Nahya Salim Masoud,

Chairperson, MUHAS Research and Ethics Committee

Muhimbili University of Health and Allied Sciences
DIRECTOR
Research, Publications & Innovations
Box 65001

Appendix VI: Permission letter

SHREE HINDU MANDAL
DAR ES SALAAM
HOSPITALS | SCHOOLS | WELFARE

RESEARCH AND TRAINING

P.O.Box 581, Landline:+25522211140-4 Ext 6258 Email: research@shm.or.tz

RESEARCH

Date: 18th March 2024

Ref: RNT/KR/24/006

Name: Dennis Patson
Address: MUHAS
P.O Box 65001, DSM

Dear applicant,

RE: ACCEPTANCE OF DATA COLLECTION.

In reference to the above subject. Please be duly informed that your request for data collection for your research at Shree Hindu Mandal Hospital (SHMH) titled "*Prevalence and factors associated with abscess and scar formation at the site of insulin injection among patients attending diabetic clinics in selected public and private hospitals in Dar es salaam.*" has been approved. Below are the details.

Subsidiary:	SHMH	Department(s):	Internal Medicine
Reporting to:	Dr. Sadiq Sibtain Dawood	Designation:	HOD
Start Date:	19/03/2024	End Date:	30/04/2024

Your research project period with our hospital will deal with important and sensitive information, records and other matters of the hospital. You will, therefore, be required to sign our Research projects Terms of Reference and Research agreement attached.

You are also reminded that total of 50,000/=Tsh administration cost shall be paid via the following back account prior to the data collection.

Bank: NMB Bank plc, Ohio branch, Dar es salaam
Account Name: Shree Hindu Mandal Research & Training
Account Number: 24110008250
Swift Code: NMIBTZTZ.

Kindly sign and send back the attached TOR as acceptance to the terms and conditions mentioned.

Yours,

SHREE HINDU MANDAL
DAR-ES-SALAAM
RESEARCH & TRAINING

Prof. Kaushik Ramaiya
Research & Training Convenor
Shree Hindu Mandal Research and Training