# PREDICTIVE FACTORS FOR PROSTHETIC FITTING AFTER DIABETIC FOOT AMPUTATION AT A TERTIARY HOSPITAL: A RETROSPECTIVE REVIEW.

**Edmund Mujuni, MD.**

**MMed (General Surgery) Dissertation**
**Muhimbili University of Health and Allied Sciences**
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**Muhimbili University of Health and Allied Sciences**

**School of Clinical Medicine**

**Department of General Surgery**

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**A Dissertation Submitted in (Partial) Fulfillment of the Requirements of the Degree of Master of Medicine (General Surgery) at**

**Muhimbili University of Health and Allied Sciences**

**October, 2024.**

## CERTIFICATION

The undersigned certifies he has read and hereby recommend for acceptance by Muhimbili University of Health and Allied Sciences a dissertation entitled: **"Predictive factors for prosthetic fitting after diabetic foot amputation at a tertiary hospital: a retrospective review"** in (partial) fulfillment of the requirements for the Master of Medicine in Surgery of the Muhimbili University of Health and Allied Sciences (MUHAS).

_____

**Prof. Larry O. Akoko.**

(Supervisor)

Date: _____

_____

**Dr. Kitembo Salum Kibwana**

(Co-Supervisor)

Date: _____

## DECLARATION AND COPYRIGHT

I, Dr. Edmund Mujuni, declares 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 dedicate this dissertation to my late father: Dr. Paschal Fidelis Mujuni.

## ABSTRACT

**Background**: Amputations are frequently performed as a life-saving procedure in underdeveloped nations due to trauma, infection, uncontrolled diabetes mellitus, and malignancy. Diabetes is a major contributing factor to lower limb amputation. Prosthetic rehabilitation plays a crucial role in restoring functional mobility for diabetic foot amputees, allowing them to regain independence and actively engage in their communities. Lack of access to prosthetic rehabilitation in low- and middle-income countries causes significant physical, financial, **social** and emotional effects from limb loss, which affect their overall quality of life.

**Aim**: To determine factors that predict prosthetic fitting of diabetic foot amputees at Muhimbili National Hospital Complex.

**Methodology**: This was a retrospective cross-sectional study among diabetic lower limb amputees at Muhimbili. Patients were included if they had transtibial or transfemoral amputation, healed stump, are available to participate and provide consent to be interviewed. Variables collected included demography, clinical features, and type of amputation were collected using a predefined data abstraction sheet on RedCap platform, Analysis was conducted using SPSS software version 27 to establish prosthesis fitting rate and factors associated with it among diabetic amputees. A significant association was considered when P-value was <P < 0.05.

**Results:** A total of 146 diabetic foot amputees met the study criteria and were included with a **Median age of 61 years with IQR 28.9**, majority of which were ≥55 years at 81(55.50%) of study participants. Most of the patients were male at 88(60.03%). Only 17(11.6%) of the patients had a foot prosthesis fitted with age <55, female sex, education of prosthesis, attending physiotherapy, and referral to prosthesis being significant predictors.

**Conclusion**: Prosthetic rehabilitation rates are low among diabetic limb amputees at Muhimbili. There are low referral rates for prosthetic fitting among limb amputees at this facility and this needs to be addressed. Only 50% of referred patients


***Key terms***: Rehabilitation, Prosthetic fitting, Amputation of limb, Limb loss surgery.

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## LIST OF ABBREVIATIONS

AKA– Above Knee Amputation.

BKA– Below Knee Amputation.

DFU– Diabetic Foot Ulcer.

DM– Diabetes Mellitus.

MNH– Muhimbili National Hospital.

MOI– Muhimbili Orthopedic Institute.

WHO– World Health Organization.

TATCOT– Tanzania Training Centre for Orthopedic Technologists

TFA– Trans - femoral Amputation.

TTA– Trans - tibial Amputation.

TMA– Trans - metatarsal Amputation.

2MWT– Two Minute Walk Test.

## OPERATIONAL DEFINITIONS

- **Amputation** is the surgical removal of all or part of a limb or extremity to treat severe infection, gangrene or loss of blood flow in a diabetic foot or diabetic foot ulcer (1).
- **Above -knee amputation (AKA) -** An amputation performed through the femur at any level with a maximum distance of 10 cm from the knee joint or 15 cm from the greater trochanter (1).
- **Below-knee amputation (BKA) -** Is an amputation performed through the tibial that involves removing the foot, ankle joint, distal tibia, fibula at 12.5 cm to 17.5 cm below the knee joint **(1).**
- **Prosthetic Rehabilitation -** is prosthetic fitting of an amputated limb to enable limb function at the highest level with the most efficient gait possible and mobility without assistance at minimum distance at 29m and maximum at 45m (2).
- **Diabetic Foot Ulcer** is an open sore or wound that occurs in patients with diabetes, and is located on any part of the lower limb most commonly on the bottom of the foot (13).

# CHAPTER ONE

## 1.0 INTRODUCTION.

### 1.1 Background.

Around 200–500 million amputations are thought to be performed annually on a global scale. Differences in clinical decision-making, level of standardized medical care protocols involving conservative treatment and vascular surgery, as well as ethnic disparities, all contribute to variations in patient management outcomes (3)(4). Amputations are frequently performed in underdeveloped nations as a result of trauma, infection, uncontrolled diabetes mellitus, and malignancy (5), as opposed to affluent countries where they are frequently performed due to vascular disease brought on by peripheral vascular disease or diabetes (6)(7).

Although there are few reliable statistics on amputations and they vary widely around the globe, the majority of experts concur that the number of amputations rises yearly, and this is due to a higher prevalence of diabetes and other peripheral vascular diseases among the elderly population (1). In Europe, the prevalence of extremity amputation varies from 17 to 30 per 100,000 population. It results from peripheral arterial disease in 70 to 84% of cases and mostly in patients who are 70 years and above (8)(9).

In Africa, hospital-based studies conducted, particularly in Nigeria, have shown that the prevalence of limb ulcerations among individuals with diabetes falls within a range of 11.7% to 19.1% resulting in lower limb amputation (10). In low and middle income countries amputation occurs in an attempt to save a patient's life in failed treatment to salvage the affected limb(3). Despite amputation being a last-ditch attempt at management, it can be successful if functional mobility is maintained by prosthesis rehabilitation (11). The most recent research indicates that diabetes mellitus is one of the most important contributing variables, increasing the risk of lower limb amputation by 20 to 30 times (12).

Tanzania has an estimated 513,000 individuals with mobility challenges, and 5.8% of the total population have functional limitations (9). Many of these patients would benefit from prosthetic devices. A study in northwestern Tanzania reported road trauma and diabetes mellitus as the main sources of amputation (13). In low-income countries diabetic foot ulcers are indicators of an already decreasing quality of care of diabetic patients at individual and community level (13). Quality of care is largely influenced by Socio economic status of patients with access to certain quality of health care services. Low-income countries primarily see a high proportion of amputation patients who come from middle to low socioeconomic backgrounds, leading to significant physical, financial, and emotional challenges associated with the loss of a limb (14). As amputees fail to accept new realities in loss of limb and fail to become used to a new body, patients frequently experience despair and anxiety are common experiences (7). This has a significant impact on the overall quality of life experienced by individuals who have undergone amputations.

Prosthetic rehabilitation serves to attain functional mobility in diabetic foot amputees and enable a return of autonomy and ability to participate productively in communities they reside in (15). The use of prostheses can also help diabetic foot amputees avoid other complications associated with immobility, such as pressure sores, deep vein thrombosis, and pulmonary embolism (16)(17). Prosthetic rehabilitation can help to prevent these complications by improving circulation, reducing pressure on vulnerable areas, and promoting physical activity (17).

The definition of successful prosthetic ambulation varies from daily use of a prosthesis with or without external support to independence in activities of daily living with or without a prosthesis (14). Previous literature has suggested that age, level of amputation, comorbidity, and cause of amputation can affect the ability to successfully ambulate with a prosthesis (7).

According to projections made by the World Health Organization (WHO) in 2005, Eastern Sub-Saharan Africa needs 2400 prosthetists as well as affiliated facilities outfitted to provide prosthesis care. One trained prosthetist can treat roughly 250 persons yearly. Less than 25% of developing nations have training programs for

prosthetics and orthotics, despite the high burden of disability (2). Attempts have been made to close this gap by organizations like the Tanzania Training Centre for Orthopedic Technologists (TATCOT), the primary training center for prosthetics and orthotics in East Africa, however as of 2012, only around 425 prosthetists have received a comprehensive education (18). Additionally, it can be difficult to continue these therapies because industrialized countries' prosthetics are sometimes poorly constructed for the specific needs and challenges presented by low-resource environments in terms of environment and lifestyle (19)(20).

The substantial gap in meeting the needs of individuals in low-resource countries goes beyond the cost of prosthetic devices, as they also provide opportunities for people with different levels of amputation to actively participate in society and contribute economically (19)(20)(21). Due to resource constraints, limited availability of prosthetic materials and the absence of established frameworks for providing prosthetic devices contribute to the challenge of accessing prostheses, low- and middle-income countries frequently are unable to prioritize prosthesis services, leaving an estimated 29 million people in resource-constrained environments in need of orthotic and prosthetic services (20)(22).

Investigation of predictive factors is needed to estimate the prosthetic rehabilitation potential more accurately, targeting modifiable factors to optimize outcome after amputation. Ultimately, this would help establish successful prosthetic use, walking, and carrying out daily activities independently (23). Rate of wound healing, early physiotherapy and overall Education on prosthetics accessibility and multiple comorbidity may expose patients to have a more challenging time adjusting to their prosthetic device (24)(25). Individuals with a higher level of amputation, such as above-knee or hip disarticulation, may require more extensive rehabilitation and support to achieve optimal outcomes. Those with peripheral neuropathy or other complications may require additional interventions, such as wound care or glycemic control(25)(26).

Most of the shortcomings in starting the processes of prosthesis in low income third world countries goes into expertise and cost effectiveness in attaining proper and

adequate patient rehabilitation. Lack of materials necessary for prosthesis poor standing of patients in being able to afford the cost of being fitted(27). In some communities the moral and financial support from relatives proves to be of considerable lacking to accomplish adequate treatment of some of diabetic foot amputees.

A study focusing on predictive factors, optimized rehabilitation strategies, and addressing resource constraints is necessary to improve prosthetic rehabilitation outcomes in these settings. This study aims to identify and understand the predictive factors that influence the success of prosthetic rehabilitation in diabetic foot amputees. This involves investigating variables such as wound healing rate, patient-specific characteristics (e.g., age, comorbidity), and clinical factors that may impact the adjustment and acceptance of prosthetic devices. By identifying these factors, healthcare professionals can better assess patients' rehabilitation potential and tailor interventions accordingly.

**1.2 Problem Statement.**

Approximately 5-8 diabetic foot ulcer cases are admitted per week most are diabetic foot resulting in three-quarters of admitted diabetic foot patients amputation at MNH alone. Lack of prosthesis is the cause of patient physical, financial, social and emotional inadequacies. If appropriately rehabilitated, amputees can assume a near normal life of both productivity and independence. This depends on availability and successful fitting with a prosthetic device in a timely manner. While prosthetic rehabilitation is standard of care, how this is practiced in our setting has not been examined and we think patients are not adequately linked to the services. This is in spite of the near ready availability of the services at Muhimbili Orthopedic Institute within the same compound as Muhimbili National Hospital. Cursory view of data showed 9 cases per six months of diabetic amputee from MNH have attended MOI for prosthetic fitting receiving education, physiotherapy, prosthetic measurement and ongoing care to achieve mobility.

## 1.3 Rationale.

The findings of this study are expected to make a meaningful contribution to the well-being of diabetic foot amputees by establishing prosthetic rehabilitation as a vital component within a comprehensive multidisciplinary patient care approach. By setting a standard of care, this research aims to enhance the overall quality of health services provided. Additionally, this study will shed light on the Prosthesis Provision Pathway, identifying potential barriers and challenges in prosthesis accessibility and rehabilitation for diabetic foot amputees at Muhimbili Complex. The insights gained will serve as a foundation for addressing these challenges and improving access to rehabilitation services.

Furthermore, this study's outcomes will serve as a valuable reference for future research endeavors focusing on prosthetic rehabilitation for diabetic foot amputees in tertiary healthcare facilities. By establishing a baseline of data, this research will contribute to the understanding of the current state of prosthetic rehabilitation and enable comparisons in future studies. Moreover, the study will underscore the significance of prosthesis as a standard of care for surgical patients who have undergone amputation due to diabetic foot ulcers in the surgical department at Muhimbili National Hospital, reinforcing the importance of comprehensive patient-centered care.

## 1.4 Conceptual Framework.

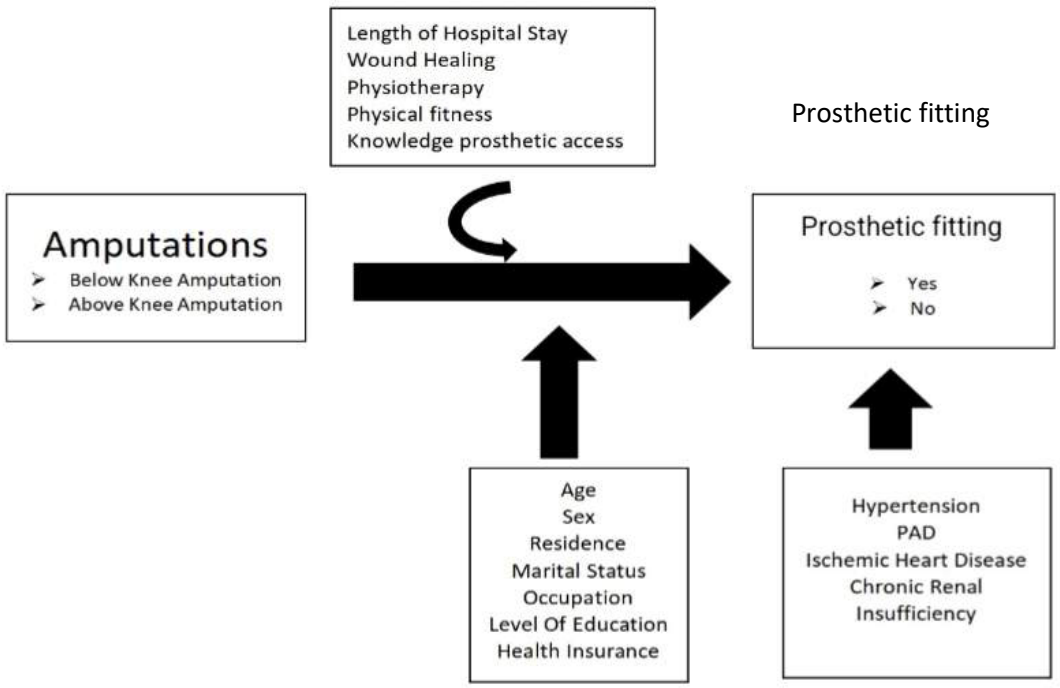



**Figure 1: conceptual framework.**

### 1.4.2 Explanation of conceptual framework.

The study's outcome variable was the number of prosthetic fittings for diabetic foot ulcer (DFU) amputations.

The independent variables were the level of amputation, either transtibial amputation (TTA/BKA) or transfemoral amputation (TFA/AKA), and their effect on patient rehabilitation outcomes. The cause of amputation was also examined, comparing emergency amputations due to gangrene with sepsis versus progressive ischemia with dry gangrene, to determine how these factors influenced prosthetic outcomes.

The factors modulating the likelihood of a successful prosthetic fitting **included** the length of hospital stay, wound healing, patient engagement in physiotherapy, physical fitness, and knowledge of prosthetic accessibility. Moderating variables affecting prosthetic rehabilitation were socio-demographic characteristics of DFU amputees, such as age, sex, education level, residency, and distance from rehabilitation services, employment status, source of income, health insurance, and the support structure available to the amputees.

Additionally, confounding variables measured included comorbidity like hypertension, peripheral artery disease (PAD), ischemic heart disease, and chronic vascular insufficiency.

## 1.5 Research Questions.

### 1.5.1 Primary Research Question.

What aspects of clinical demography of amputees predict limb prosthesis among amputees attended at **MNH/MOI** between 2021 and 2023?

### 1.5.2 Secondary research questions.

i. What are the clinical characteristics of diabetic foot amputee patients attending **MNH/MOI** for prosthetics fitting?
ii. What is the proportion of diabetic amputees fitted with a limb prosthesis at **MNH/MOI**?

## 1.6 Objectives.

### 1.6.1 Broad objective.

To study the clinical demography, prosthetic fitting and factors influencing it among diabetic foot amputees at MNH/MOI between 2021 and 2023.

### 1.6.2 Specific Objectives.

i. To describe the demography of diabetic foot amputees at MNH/MOI.
ii. To determine the proportion of diabetic foot amputees at MNH/MOI who undergo prosthetic fitting.
iii. To determine the association between clinical demography and prosthetic fitting at MNH/MOI.

# CHAPTER TWO

## 2.0 LITERATURE REVIEW.

### 2.1 Socio demographic and clinical characteristic distribution Diabetic foot amputee.

Most studies report that the mean age of diabetic foot amputees is in the fifth to sixth decade of life (Smith et al., 2015; Kumar et al., 2018). Older age is associated with a higher risk of amputation. Male-to-female ratio among diabetic foot amputees varies across studies but tends to show a higher prevalence among males (Lavery et al., 2006; Singh et al., 2019) (17). Low socioeconomic status and poverty have been consistently linked to a higher incidence of diabetic foot amputations (Kengne et al., 2017; van Battum et al., 2018). Limited access to healthcare, education, and resources may contribute to delayed presentation and inadequate management.

Longer duration of diabetes is associated with an increased risk of developing diabetic foot ulcers and subsequent amputations (Amin et al., 2017; Moxey et al., 2018). Also Coexisting conditions such as peripheral arterial disease (PAD), and neuropathy are common among diabetic foot amputees (Ahmad et al., 2016; Armstrong et al., 2017) (28). These comorbidities contribute to the severity of the foot complications. Smoking has been identified as a risk factor for the development and progression of diabetic foot ulcers, whereas alcohol intake may have conflicting effects (Apelqvist et al., 2017; Vaidya et al., 2019).

### 2.2 Prosthetic fitting of diabetic foot amputees.

Effective post-operative management after amputation involves several key aspects. Pain control is crucial to facilitate the rehabilitation process. Additionally, it is important to prevent edema, infection, and DVT to encourage early movement and mobilization of the patient. Typically, by the 3$^{rd}$ to 6$^{th}$ day following surgery, patients, excluding those with bilateral amputation, should be capable of independently standing on parallel bars and walking with the aid of crutches (1)(29).

While immediate post-operative fitting of a prosthesis has been suggested, it is recommended to wait for 7-10 days to allow for proper tissue healing (1). If there are no complications with the stump, definitive prosthetic fitting can usually be initiated within 3-4 weeks. It is worth noting that immediate and early prosthesis fitting has been associated with delayed wound healing and, therefore, caution is advised with regards to weight-bearing activities (29).

Studies have reported varying proportions of prosthetic fitting among diabetic foot amputees. The reported ranges suggest that the proportion of individuals receiving prosthetic fitting varies widely across different populations and healthcare settings (Jones et al., 2017; Chen et al., 2019). These variations may be influenced by factors such as healthcare infrastructure, availability of prosthetic services, and socioeconomic factors.n a 2018 study conducted in Tanzania by Zambula et al., the magnitude of prosthetic fitting was found to be 75% in the population, with higher rates observed for above-knee amputations (75.7%) compared to below-knee amputations (33).

### 2.3 Predictors of prosthetic fitting after diabetic foot amputation.

Several factors have been identified as influencing the proportion of prosthetic fitting among diabetic foot amputees. Limited access to healthcare facilities and specialized prosthetic services can significantly impact the proportion of individuals receiving prosthetic fitting (Mills et al., 2016; Ribeiro et al., 2018). Low socioeconomic status, poverty, and lack of health insurance coverage have been associated with lower rates of prosthetic fitting among diabetic foot amputees (Shah et al., 2019; Jiménez et al., 2020). Availability and proximity of rehabilitation centers and prosthetic clinics play a crucial role in determining the proportion of prosthetic fitting (Chao et al., 2015; Wu et al., 2017). Individual patient characteristics, including age, comorbidities, and functional status, may also influence the likelihood of receiving prosthetic fitting (Dillingham et al., 2019; Laing et al., 2020).

In a study conducted in the USA in 1993 by Stewart, it was found that 87% of individuals with transtibial amputation (TTA) wore a prosthesis, while 70% of individuals with transfemoral amputation (TFA) wore a prosthesis. Another study conducted in Chicago, USA in 2003 by Davies reported that 56% of dysvascular amputees ambulated with a prosthesis. Among amputees due to peripheral arterial disease (PAD) in a study conducted in Sao Paulo, Brazil by Chamlian, 77.4% were fitted with prostheses, however, the study found that only 35.8% of the participants were still utilizing a prosthesis by the conclusion of the research (30). Similar findings were observed in studies conducted in the Netherlands in 2009 and Nigeria in 2015, where in the majority of cases, amputees were provided with prostheses and demonstrated successful utilization of them (31)(32).

### 2.4 Standard criteria is used to assess the fitness of patient for prosthetic fitting

Diabetic foot amputees are vulnerable and experience substantial physical, psychosocial and societal suffering when prosthesis is not available. The loss of independence alone results in depression and anxiety, social isolation, with around 40 percent unable to return to work, resulting in financial strain and increased caregiver burden (39)(40). Standard criteria used to rehabilitate involves wound care, physical therapy, and prosthetic fitting and prescription including gait training support with psychological counseling (41). Occupational therapy focuses on independence, and is also important for those who do not have prosthetics to ensure that they are able to help themselves with their activities of daily living (ADLs) by providing assistive devices, and making functional changes within the home. The treatment needs regular medication checkups and other treatments including long-term care (counseling and drug therapy) (42). To increase quality of life and independence, it is necessary to provide holistic rehabilitation.

# CHAPTER THREE

## 3.0 METHODOLOGY.

### 3.1 Study design.

This was a **retrospective** cross-sectional study involving diabetic patients who had undergone an amputation of lower limbs between April 1st, 2021, and March 31st, 2023, at Muhimbili National Hospital and Muhimbili Orthopedic Institute.

### 3.2 Study Area.

This study was conducted at Muhimbili National Hospital (MNH) and Muhimbili Orthopedic Institute (MOI), both situated within the Muhimbili complex in Dar es Salaam, Tanzania. MNH held a significant position among Tanzania's tertiary hospitals, functioning as a national referral center, research hub, and university teaching hospital. With a presence in the Ilala district of Dar es Salaam, MNH was organized into eight directorates and encompassed 29 departments and 107 units. Providing services to diabetic patients with varying complications, MNH conducted amputations at a rate of 7 cases per week and 353 cases per annum by general surgeon in collaboration with orthopedic departments, often referring patients to MOI for physiotherapy and prosthetic services. MOI was the country's largest orthopedic referral center. Equipped with workshops catering to orthotic and prosthetic needs, MOI extended its services beyond MNH to other hospitals in Dar es Salaam and various regions across Tanzania. The MOI unit, comprising nine members, handled around 50 cases per month and offered below knee and above knee prostheses at affordable rates. A collaborative physiotherapy unit at MOI, supported by ten physiotherapists, provided comprehensive care in conjunction with external organizations, accommodating up to a hundred patients daily with the necessary resources for effective treatment.

### 3.3 Study population.

This study included all individuals with diabetic foot ulcers at MNH/MOI admitted from April 1st, 2021, to March 31st, 2023.

### 3.4 Study Sample.

All patients who had amputation done at MNH/MOI from April 1st 2021 to March 31st 2023.

### 3.5 Inclusion and Exclusion Criteria

#### 3.5.1 Inclusion criteria

- Lower limb amputation below or above knee Amputation.
- Amputee who consented to the study.
- Amputees at the age of 18 years or older.
- Amputees with matured stumps for a 3-month period.

#### 3.5.2 Exclusion criteria.

- Mobility problems prior to amputation; paraplegia, senility and poor performance status.
- Incomplete medical records.

### 3.6 Sample size and sampling technique.

**The sample size will be estimated using the Leslie kish formula (1965).**

$$N = \frac{Z^2 p(100-p)}{e^2}$$

Where:

Z =level of confidence interval which of 95%=1.96

p = Expected proportion (of unknown population 50%)

e = margin of error 5%

n= $(1.96)^2 x\ 0.5(1 - 0.5)/0.05^2$

n=384

using formula for adjusted sample size, nc = n/(1+n/N), where N is the size of the population from the observational pilot study which is 205 for the past 3 months for the patient who underwent lower limb amputation at MNH complex.

$$nc = 384 /(1+ 384/205) = nc = 134$$

The adjusted sample size is 134. Therefore, the minimum adjusted sample size will be 134 patients. Adjusting for the non-response rate which is 10%, the minimum sample size will be 148 patients.

### 3.7 Sampling Method

The study employed a simple random sampling technique from admission and theater registry at MNH/MOI. All patients with available records that fit the inclusion and exclusion criteria within the 2-year study period (April 1st, 2021 to March 31st, 2023) were included

### 3.8 Variables

#### 3.8.1 Dependent variable

- Prosthetic fitting.

#### 3.8.2 Independent variable

- Demographic characteristics.

  Age (years), Sex (Male/ Female), physical (Employed/ Unemployed), , Marital Status (Married/ Unmarried), Level of education (Below secondary/Above Secondary) and Residency (Dar es Salaam/ Out of Dar es Salaam).
- Clinical characteristics

  Type of Diabetes (Type 1 or 2), Surgical indication; infection, ischemia or gangrene (Wagner's classification).
- Intra operative variable

Extent of tissue injury/damage (edema, abscess or fasciitis), Type of amputation (AKA/BKA).

- Modulating variables on the prospect of prosthetic fitting are

  Length of hospital stay, Patient category, Referral to orthotics, Wound healing, Patient physiotherapy, Physical fitness and knowledge on accessibility of prosthetics.

- Control variables:

  Comorbidity such as Hypertension, Anemia, PAD, Ischemic heart disease and chronic renal insufficiency.

### 3.9 Data collection technique

Patients with diabetic foot, diabetic foot ulcer requiring surgical intervention are identified and admitted through the Hospital's outpatient clinics or emergency department. After routine laboratory and radiological investigations are done, these patients are then scheduled for emergency/ elective surgical amputation.

Intra-operatively, progress of the procedure and post-operative surgical notes are documented in the patients' medical records. Any post-operative progress and complications are documented daily until the patient is discharged. Follow up at 2 weeks then they are referred to physiotherapist and orthotic clinic for measurement of prosthetic devices depending on state of stump retained. Final follow up at 6 weeks where assessment for stump healing progressive exercises done to optimize the prosthetic device to allow adequate gait and mobility, a two minutes' walk test is administered follow-up as outpatient at 6th to 12th week done with kept clinical notes until patient archives maximum distance of mobility without any assistance.

This study included all patients admitted from April 1st, 2021, to March 31st, 2023, who had undergone lower limb amputation. Participants were captured using the theater records/registry of all lower limb amputations done at MNH and MOI within the study period. Verbal consent was obtained using subject contact numbers and telecommunication devices, and written informed consent was obtained from

subjects readily available at clinics before participating in the study and direct administration of the checklist.

A checklist adopted from a previous study and structured for this study via RedCap, an online secure web platform for building and managing online databases, was used. A survey containing all the necessary data points of dependent and independent variables was used for data collection after being tested for validity and reliability through interviews of potential respondents in a pilot study. Data collection took place from patients' files in the medical records department, with additional data on laboratory results and radiological data obtained through the hospital's online database. Intra operative information was extracted from anesthesia forms and surgeons' postoperative notes. Data collection from follow-up clinics on patient referral for prosthetic fitting and successful ambulation was conducted from clinic notes, direct observation or through telecommunication devices.

Patients of diabetic foot amputation and meeting the study's inclusion criteria were considered. The principal investigator conducted data collection from files, the online hospital database, and patient clinics or via telecommunication with the help of one trained research assistant. Data were collected using an online secure web platform for building and managing online databases and surveys.

### 3.10 Data Management and analysis

#### 3.10.1 Data management

Data was managed using an online data streamlined process, which facilitated the rapid creation and design of projects while offering a wide range of data collection tools tailored to our data collection strategy. Patient names and registration numbers were entered as numeric codes, with variables organized to indicate their corresponding code numbers.

### 3.10.2 Data analysis

After data collection, data underwent thorough examination using SPSS software version 23 to ensure completeness and accuracy before proceeding to analysis. Categorical variables were summarized as proportion, while quantitative variables were summarized as mean, odd ratios with corresponding 95% confidence intervals were calculated and significance was determined with threshold of $p \leq 0.05$ to compare categorical variables, Pearson chi square test was employed. Continuous variables **were** compared using either the t-test for independent samples or the Mann-Whitney U test in case of skewed distribution

Binary logistic regression was utilized to assess the presence of an association between the dependent variable and the study outcome variable of prosthetic rehabilitation among diabetic amputees. This analysis was adjusted for potential confounders to provide a more accurate understanding of the relationships between variables

### 3.11 Ethical considerations and Approval.

This study was presented to the ethical committee of Muhimbili University of Health and Allied Sciences and the ethical clearance was granted by the MUHAS Research Ethics Committee **(Ref No: DA.282/298/01.C/1960)**, ethical clearance number **MUHAS–REC–10-2022-1960**. Permission for Data collection was granted from the research and consultancy unit of **MNH (Ref. No.:MNH/CRTCU/Perm/2024/0013).** All ethical principles were respected during the study period. For confidentiality, the patient's names were not written on the data collection tools after obtaining informed consent. Confidentiality, anonymity, protection of privacy and personal information were observed.

# CHAPTER FOUR

## 4.0 RESULTS

### 4.1 Introduction

In Figure 2 below we display the recruitment process of diabetic foot ulcer amputees at MNH. In total, 253 patients had an amputation in which 36 died during the immediate postoperative period and another 59 did not consent hence were excluded along with 12 whose stump had not matured by the time this study was carried out. This left 146 patients available to be studied.

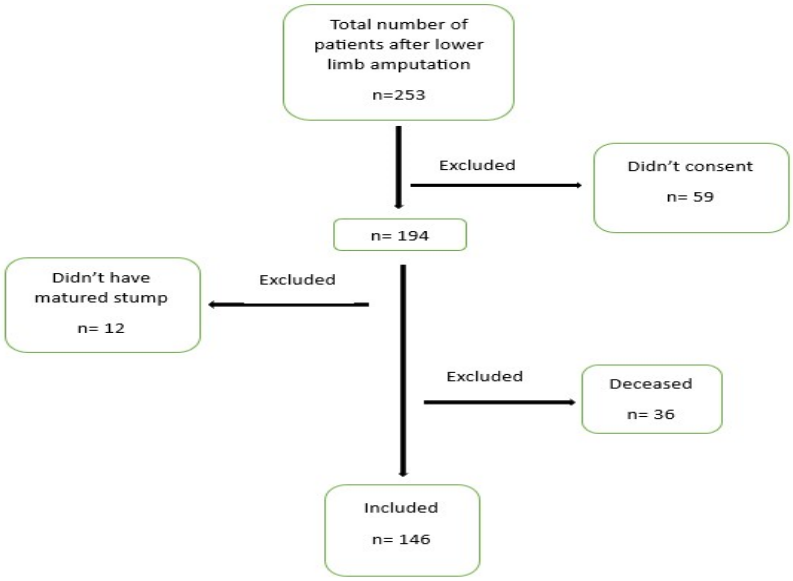



**Figure 2: Flowchart of patient exclusion and inclusion criteria in the study**

### 4.2.1 Socio - demographic characteristics of diabetic foot amputees

In **Table 1** below, we present the socio demographic features of participants under study. A total of 146 patients with diabetic foot amputation who met the inclusion criteria were admitted to MNH Complex and recruited into the study. The Median age was 61 years with IQR 28.95 and the age group of 55 years and above constituted the largest proportion, accounting for 81(55.50%) of study participants,

88(60.30%) participants were male with a male to female ratio of 1.5:1. The majority of individuals 111(76.0%) had a spouse, had education below the secondary level 88(60.30%), were employed 81(55.50%) and resided within Dar es Salaam region 106(72.60%).

**Table 1: Socio - demographic characteristics of the population under study who had diabetic foot amputation (N=146)**

| Variable | Frequency, n (%) |
|---|---|
| **Age group** | |
| < 55 years | 65 (44.50) |
| ≥ 55 years | 81 (55.50) |
| **Sex** | |
| Male | 88 (60.30) |
| Female | 58 (30.70) |
| **Marital status** | |
| With Spouse | 111 (76.0) |
| Without Spouse | 35 (24.0) |
| **Education level** | |
| Below Secondary level | 88 (60.30) |
| Secondary level and above | 58 (39.70) |
| **Occupation** | |
| Employed | 81 (55.50) |
| Unemployed | 65 (44.50) |
| **Residency** | |
| Dar-es-salaam | 106 (72.60) |
| Out of Dar-es-salaam | 40 (27.40) |

### 4.2.2 Clinical characteristics of diabetic foot amputees

In **Table 2** below, we present the clinical features and rehabilitative services rendered to diabetic foot amputees at Muhimbili. Severity of diabetic foot ulcer was graded according to the Wargner system whereby the majority were in Wagner 4 at 90(63.0%). Overwhelming majority had a closed type of amputation as was in 137(93.8%) with transfemoral amputation also leading in 76(52.1%). Majority of the patients had no comorbidity as was in 107(73.3%). Most had a hospital stay of less than a week in 78(53.4%). Utilization of rehabilitative services was observed to be low with only 21(14.4%) amputees referred for prosthesis, 28(19.2%) had anything about prosthesis, and majority of study participants 88(60.30) were not referred for physiotherapy services.

**Table 2: Clinical characteristics of the population under study who had diabetic foot amputation (N=146)**

| Variable | Frequency, n (%) |
|---|---|
| **Wagner's grading** | |
| Grade 3 | 26 (17.80) |
| Grade 4 | 92 (63.0) |
| Grade 5 | 28 (19.20) |
| **Types of Amputation** | |
| Closed | 137 (93.80) |
| Open | 9 (6.20) |
| **Level of amputation** | |
| Trans femoral | 76 (52.10) |
| Trans tibial | 70 (47.90) |
| **Comorbidity** | |
| None | 107 (73.30) |
| ≥ 1 | 39 (26.70) |
| **LOS** | |
| ≤ 1 week | 68 (46.6) |
| > 1weeks | 78 (53.40) |
| **Referral for prosthesis** | |
| Referred | 21 (14.40) |
| Not referred | 125 (85.60) |
| **Health Insurance** | |
| Yes | 67 (45.90) |
| No | 79 (54.10) |
| **Education on Prosthesis** | |
| Yes | 28 (19.20) |
| No | 118 (80.80) |
| **Physical therapy** | |
| Yes | 58 (39.70) |
| No | 88 (60.30) |

### 4.3 The proportion of diabetic foot amputees at Muhimbili National Hospital to undergo prosthetic fitting.

In the **Pie Chart** below, we present the proportion of diabetic foot amputees who underwent prosthetic fitting. Of all study participants only 17(11.64%) received prosthetic fitting with varying levels of mobility.

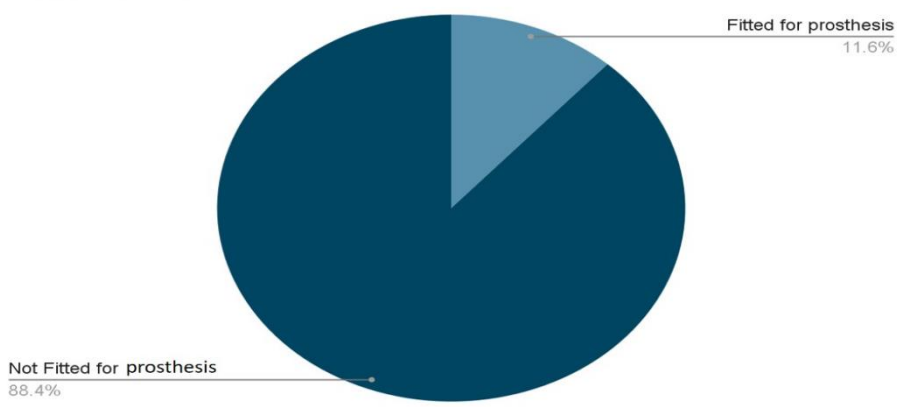



**Figure 3: Pie Chart showing proportion of diabetic foot amputees fitted with a limb prosthesis**

### 4.4 Association between clinical demography and prosthetic fitting at Muhimbili National Hospital.

In Table 3 below, we present the association between social demographic features and prosthetic fitting. Social demographic factors that were found to significantly influence the chances of a prosthetic rehabilitation at Muhimbili age below 55 years (20% vs 4.9%, P-value 0.008) and being female (19 vs. 6.8%, P-value 0.034).

**Table 3: Showing relationship between prosthetic fitting and social demography among diabetic foot amputees.**

| Variable | Fitted, n (%) 17(11..64) | Not Fitted, n (%) 165(88.36) | P value |
|---|---|---|---|
| **Age group** | | | |
| < 55 years | 13 (20.0) | 52 (80.0) | **0.008** |
| ≥ 55 years | 4 (4.90) | 77 (95.10) | |
| **Sex** | | | |
| Male | 6 (6.80) | 82 (93.20) | **0.034** |
| Female | 11 (19.0) | 47 (81.0) | |
| **Marital status** | | | |
| With Spouse | 13 (11.70) | 98 (88.30) | 0.964 |
| Without Spouse | 4 (11.40) | 31 (88.60) | |
| **Education level** | | | |
| Below Secondary level | 8 (9.10) | 80 (90.90) | 0.294 |
| Secondary level and above | 9 (15.50) | 59 (84.50) | |
| **Occupation** | | | |
| Employed | 10 (10.30) | 71 (87.70) | 0.802 |
| Unemployed | 7 (8.20) | 58 (89.20) | |
| **Residency** | | | |
| Dar-es-salaam | 15 (10.90) | 91 (85.80) | 0.156 |
| Out of Dar-es-salaam | 2 (5.0) | 38 (95.0) | |

In Table 4 below, we present the association between clinical features and services offered as predictors of prosthetic fitting. Services offered here included referral and counseling on prosthesis, and attendance for physiotherapy, all of which were found to be highly associated with a higher prosthetic fitting probability, P-value 0.001.

**Table 4: Showing relationship between prosthetic fitting and clinical characteristics among diabetic foot amputees.**

| Variable | Fitted N (%) | Not Fitted N (%) | P value |
|---|---|---|---|
| **Wagner's grading** | | | |
| Grade 3 | 1 (3.20) | 30 (96.80) | 0.366 |
| Grade 4 | 13 (11.40) | 101 (88.60) | |
| Grade 5 | 3 (8.10) | 34 (91.90) | |
| **Types of Amputation** | | | |
| Closed | 16 (11.70) | 121 (88.30) | 0.959 |
| Open | 1 (11.10) | 8 (88.90) | |
| **Level of amputation** | | | |
| Trans femoral | 6 (7.90) | 70 (92.10) | 0.197 |
| Trans tibial | 11 (15.70) | 59 (84.30) | |
| **Comorbidity** | | | |
| None | 10 (9.30) | 97 (90.70) | 0.157 |
| ≥ 1 | 7 (17.90) | 32 (82.10) | |
| **LOS** | | | |
| ≤ 1 week | 9 (13.20) | 59 (86.80) | 0.613 |
| > 1weeks | 8 (10.30) | 70 (89.70) | |
| **Referral for prosthesis** | | | |
| Referred | 13 (61.90) | 8 (38.10) | **< 0.001** |
| Not referred | 4 (3.20) | 121 (96.80) | |
| **Health Insurance** | | | |
| Yes | 11 (16.40) | 56 (83.60) | 0.123 |
| No | 6 (7.60) | 73 (92.40) | |
| **Education on Prosthesis** | | | |
| Yes | 17 (60.70) | 11 (39.30) | **<0.001** |
| No | 0 (0) | 118 (100) | |
| **Physical therapy** | | | |
| Yes | 13 (22.40) | 55 (77.60) | **0.001** |
| No | 4 (4.50) | 84 (95.50) | |

### 4.5 Independent predictors of prosthetic fitting of diabetic foot amputees at Muhimbili National Hospital.

In Table 5 below, we present the association between various factors and outcomes of prosthetic fitting among amputees with both unadjusted and adjusted odds ratios, confidence intervals, and p-values for significance. We found that females showed 2.4 higher odds than males for prosthetic fitting, but the results were not statistically significant ($p > 0.05$). Similarly insured patients had 2.9 higher odds, with borderline significance in unadjusted analysis, but this was not significant after adjustment. Longer stays were associated with lower odds for prosthetic fitting, but not significant in both analyses. Those who underwent physical therapy had significantly higher odds, both unadjusted but failed to reach statistical significance in adjusted analysis.

**Table 5: Logistic regression model of predictors for prosthetic fitting.**

| Variable | Unadjusted OR (95%CI) | P value | Adjusted OR (95%CI) | P Value |
|---|---|---|---|---|
| Sex | | | | |
| Male | Ref | | Ref | |
| Female | 2.4(0.78-7.06) | 0.13 | 2.3(0.75-7.76) | 0.14 |
| Patient category | | | | |
| No insurance | Ref | | Ref | |
| Insured | 2.9(0.9- 9.1) | 0.12 | 1.9(0.56- 6.52) | 0.3 |
| Length of hospital stay | | | | |
| < 1 week | Ref | 0.61 | Ref | |
| ≥ 1 week | 0.47(0.16- 1.4) | | 0.43(0.13- 1.39) | 0.46 |
| physical therapy | | | | |
| No | Ref | | Ref | |
| Yes | 4.7(1.4- 15.7) | 0.01 | 4.05 (1.1- 14.6) | 0.06 |

Key: odds ratios (OR) ) and confidence intervals (CI.

# CHAPTER FIVE

## 5.0 DISCUSSION.

In this study the mean age of diabetic foot amputees was in sixth decade of life 55.50% of participant at age 55 years and above with prevalence of male participants is high at 62.09% compared to female which is similar from other study which was done in Brazil in which most of amputees were male with prevalence of 66% (30). In the current study the age group of 55 years and above had the largest proportion as compared to other age groups, this finding is quite similar with findings from other previous studies (34). Most participants in this study had above knee amputation in which the proportion of above knee amputation was 52.10% similar to the study done in Brazil where the distribution of amputation by level was higher for TFA to TTA (35). These findings show the younger participants are very few in comparison to elderly with more proportion of male to female presentation in diabetic foot amputees. This is accurate to diabetic foot presentation as most of diabetic foot ulcers begin a longer duration of diabetic disease depending on diabetic control with other associated complications (12).

In this study the proportion of attendance for prosthetic fitting was 11.64% of all diabetic foot amputees. Among participants who underwent prosthetic fitting, the proportion of females is greater than male. This was a different finding compared to that observed in a study done in Tanzania where the proportion of prosthetization is high as 75% of amputees which was similar to study in Brazil 77.4% of successful prosthetic fitting in done (30)(33), But in another study done in USA for prosthetic fitting, use and satisfaction following lower limb amputation done was found that half of the study participants (50%) were fitted with prosthesis at four months follow up which was relatively lower but still higher compared to this study(36). The difference seen in prosthetic fitting in this study compared to other study may be attributed to their study focused on prosthesis alone, access to prosthetic devices and longer year follow up but might also be due to the fact that in the current study majority of participants fitted middle aged while their higher prevalence of elderly amputee

hence those rehabilitated died or higher the age the more likelihood of pre amputation immobilization, stroke, longer period of hospital stay and more complications.

Prosthesis fitting in this study, occurred in participants who had referral and education for prosthesis as referral and education on prosthetic availability has shown higher odds of prosthesis with p value of 0.001 respectively. So poor outcomes to prosthetic fitting can be associated with poor referral and poor education of patients on prosthesis which is similar to a study done in Tanzania on Trans femoral amputation and prosthesis provision where there was mismatched patient expectations and inadequate coordination of care (7). In this study physiotherapy and referral from surgeons seem to be associated with fitting and use of prosthesis. In the study done by Bhangu S. et al (2009) also showed association between prosthetic fitting and physiotherapy in patient post amputation, he also had similar results with age and level of amputation in predicting prosthetic outcomes (37). The poor patient coordination for prosthesis through referral, poor education on prosthesis and its availability whether on patient expense or charitable organization was found to be a contributor to the poor proportion of diabetic foot amputee prosthetic fitting.

Although the effect of comorbidity and clinical factors such as type of amputation and level of amputation on outcome effects has not been significantly pointed out as for other studies (37). As for this study and some authors these effects were simply not present. In this respect, and as far as prosthetic fitting is concerned, Van Eijik et al. (23) found that multi morbidity was not related to prosthetic fitting ambulation. We find our results to be in accordance with theirs. Adequate management of co-existing conditions and return to pre morbid conditions should improve patient health and alleviate patient risk for complications to be encountered due to immobility.

An association was observed in analysis for physical therapy and prosthetic fitting. Similar to a study done in Switzerland, we found an association between the presence of physical therapy and the use of prosthetic fitting. A bi variate model also showed that patients age, sex, education on prosthesis and referral status were associated with prosthetic fitting. These findings are also in agreement with those described by Rau, B et al., from Switzerland and Fajardo-Martos et al., from Brazil on age, physical therapy, after analyzing the results that variables are a predictive factor for prosthetic fitting and rehabilitation (35)(38). Finally, the logistic regression model evaluating multiple factors as predictors of prosthetic fitting at the facility found that none such as sex, insurance status, length of hospital stay, or physical therapy were independent predictors of the outcome. This contrasts with previous studies where certain factors, like the sex, age or access to physical therapy, were associated with prosthetic fitting. The lack of statistically significant predictors is likely due to a small sample size, leading to wide confidence intervals and reduced precision. A broader sample with more diverse variables is needed to enhance the accuracy and detect potential predictors of prosthetic fitting.

# CHAPTER SIX

## 6.0 LIMITATIONS MITIGATION, CONCLUSION AND RECOMMENDATIONS

### 6.1 Limitations and mitigation.

Among the limitations of the present study, the most important derives from its retrospective character, which makes it impossible to contemplate any variable not included in the patient records.

Other limitations include being a single center study and recruiting small sample sizes.

### 6.2 Conclusion.

There are lower rates of prosthetic fitting among diabetic foot amputees attending Muhimbili Complex, only 1 in 10 patients gets prosthetic fitting. Diabetic foot amputees of age below 55 years old and female sex are seen receiving prosthetic fitting despite a greater population of amputees being elderly (above 55 years) and of male sex. There are low referral rates for prosthetic fitting among limb amputees at this facility and this needs to be addressed. Only 50% of referred patients. Low number of diabetic amputees receive education of prosthesis and physiotherapy services, education of prosthesis and physiotherapy increase likelihood of prosthetic fitting at this facility.

### 6.3 Recommendation.

1. A study to look into prosthetic fitting prosthesis provision among diabetic foot amputees at this facility to create awareness on availability of the service which will make a good access of a service and prosthesis.
2. A qualitative study into age and sex of diabetic foot amputees in regards to prosthetic services in this facility to better address the population of amputees attending at this facility
3. Referral for prosthetic rehabilitation should be part of patient management at this facility, a study into service provider awareness of prosthetic services should be done.
4. A larger prospective study into associated services in prosthetic rehabilitation such as physiotherapy and education of amputees on prosthesis should be conducted to better improve access to prosthesis for patients at this facility.

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## Appendices

### Appendix I: Redcaps input data

Lower limb amputation secondary to Diabetic Foot Ulcer

Use of prosthesis among amputees due to DFU 2021 – 2023

| Identification No | Date of admission | Date of operation |
|---|---|---|
| _____ | _____ | _____ |
| **Date of discharge** | **Date of referral** | **Date of 1st clinic** |
| _____ | _____ | _____ |

**A: Socio demographic Characteristics**

| | | |
|---|---|---|
| 1. **Age of a patient (yrs)** | i. <25 | [ ] |
| | ii. 25-34 | [ ] |
| | iii. 35 - 54 | [ ] |
| | iv. 55+ | [ ] |
| 2. **Sex** | i. Female | [ ] |
| | ii. Male | [ ] |
| 3. **Marital Status** | i. Married | [ ] |
| | ii. Not married | [ ] |
| | Iii Widowed | [ ] |
| 4. **Education level** | i. Non formal | [ ] |
| | ii. Primary | [ ] |
| | iii. Secondary | [ ] |
| | iv. Post-secondary | [ ] |
| 5. **Physical status** | i. Student | [ ] |
| | ii. Unemployed | [ ] |
| | iii. Formal employ | [ ] |
| | iv. Self employed | [ ] |

| | | |
|---|---|---|
| | v. Peasant | [ ] |
| 6. **Residence** | i. Dar es Salam | [ ] |
| | ii. Outside Dar es Salaam | [ ] |
| 7. **Number of dependant** | i. None | [ ] |
| | ii. 1-2 | [ ] |
| | iii. 3+ | [ ] |
| **B: Information patterning to amputation** | | |
| 8. **Side of amputation** | i. Right | [ ] |
| | ii. Left | [ ] |
| 9. **Type of amputation (Technique)** | i. Closed | [ ] |
| | ii. Open | [ ] |
| 10. **Level of amputation** | i. Through hip | [ ] |
| | ii. Trans femoral | [ ] |
| | iii. Through knee | [ ] |
| | iv. Trans tibial | [ ] |
| | v. Through ankle | [ ] |
| | Vi. Transmetatarsal | [ ] |

**11. Clinical characteristics**

| | | |
|---|---|---|
| **Type of diabetes** | | DM1[ ] |
| | | DM2[ ] |
| **Wagner's Grading** | Grade 3 | [ ] |
| | Grade 4 | [ ] |
| | Grade 5 | [ ] |
| | Recommendation: | |
| **Intraoperative finding** | Edema | y[ ]/n[ ] |
| | Abscess | y[ ]/n[ ] |

Gangrene y[ ]/n[ ]

**12. Economic burden**

| | | |
|---|---|---|
| Do you have health insurance | Yes{ }/ No{ } | |
| How long have you been out of work,(unearning)? | 1 month | [ ] |
| | 3 months | [ ] |
| | 6 months | [ ] |
| | >12 months | [ ] |
| Can you afford all the services provided in time? | Yes { }/ No { } | |
| Do you have support? | Family | [ ] |
| | Relative | [ ] |
| | Social welfare | [ ] |
| Is your house modified to accommodate disability? | Yes{ }/ No{ } | |

Acceptance to amputation

| | |
|---|---|
| Have you been counseled? | Yes{ }/ No{ } |
| Are you okay to have amputation | Yes{ }/ No{ } |
| Have you planned for physical therapy? | Yes{ }/ No{ } |

Health seeking behavior

| | | |
|---|---|---|
| Have had teaching on/at? | Diabetic clinic | Yes{ }/ No{ } |
| | Diabetic foot | Yes{ }/ No{ } |
| | Foot care | Yes{ }/ No{ } |
| | Prosthesis | Yes{ }/ No{ } |

Prior history of surgical management

| | | | |
|---|---|---|---|
| Have you had surgical care? | Wound care | Yes{ }/ No{ } | |
| | debridement | Yes{ }/ No{ } | |
| | sloughectomy | Yes{ }/ No{ } | |
| | disarticulation | Yes{ }/ No{ } | |
| 13. **Co-existing disease** | i. None | [ ] | |
| | ii. Diabetic | [ ] | |
| | iii. Cardiac | [ ] | |
| | iv. Anemia | [ ] | |
| | v. Trauma | [ ] | |
| | vi. Others | [ ] | |
| 14. **Complications** | i. Yes | [ ] | If yes ans 15&16 |
| | ii. No | [ ] | |
| 15. **Systemic complication** | i. Cardiac | [ ] | |
| | ii. Respiration | [ ] | |
| | iii. Anaemia | [ ] | |
| | iv. Septicaemia | [ ] | |
| | v. Renal | [ ] | |
| | vi. Others | | |
| | _____ | | |
| 16. **Local complication** | i. Stump infection | [ ] | |
| | ii. Dehisces | [ ] | |
| | iii. Flap necrosis | [ ] | |
| | iv. Phantom / stump pain | [ ] | |
| | v. Others | [ ] | |
| 17. **Death** | i. Yes | [ ] | |
| | ii. No | [ ] | |
| 18. **Surgical revision** | i. Yes | [ ] | |

| | | |
|---|---|---|
| | ii. No | [ ] |
| | iii. If Yes, mention type of surgery_____ | |
| 19. **Duration of hospital stay in days** | i. 1 week | [ ] |
| | ii. 2 weeks | [ ] |
| | iii. 3 weeks | [ ] |
| | iv. 4 weeks | [ ] |
| | v. > 4weeks | [ ] |
| **C: Early function** | | |
| **Prosthesis** | Yes | [ ] |
| | No | [ ] |
| 20. **Use of walking aid** | i. Walking frame | [ ] |
| | ii. Crutches | [ ] |
| | iii. Prosthesis | [ ] |
| | iv. Wheel chair | [ ] |
| 21. **Degree of ambulation** | i. Indoor | [ ] |
| | ii. Out door | [ ] |
| | iii. Non ambulant | [ ] |

## Appendix II: Informed Consent (English Version)

### A. INFORMATION

Introduction

Hello there! I am Dr. Edmund Mujuni, affiliated with Muhimbili University of Health and Allied Sciences. I would like to extend an invitation to you to take part in a study focused on investigating predictive factors for prosthetic rehabilitation after diabetic foot amputation at a tertiary hospital. The purpose of this study is to determine factors that predict successful prosthetic fitting and rehabilitation of diabetic foot amputees at Muhimbili National Hospital.

What does your participation mean? Your participation in this study would involve your agreement to answer a series of questions that may take approximately five minutes of your time. These questions aim to gather information related to patterns and the management of diabetic foot amputees for successful prosthetic fitting and rehabilitation.

What are my benefits and risks by participating? We firmly believe that your active participation in this study is expected to make a meaningful contribution to the well-being of diabetic foot amputees by establishing prosthetic rehabilitation as a vital component within a comprehensive multidisciplinary patient care approach. Your involvement in this study will also enhance your own awareness and promote the development of positive health-seeking behaviors. We assure you that there are no anticipated risks associated with your participation in this study.

Confidentiality: Rest assured that the information you provide during the study will be treated with the utmost confidentiality. Only the researcher will have access to the questionnaires, and your identity will remain completely anonymous and undisclosed in any published materials.

Right to withdrawal: Participation in this study is entirely voluntary. You retain the right to withdraw from the study at any time, even after signing the consent form, should you change your mind. It is important to note that your decision not to participate will not in any way jeopardize your entitlement to health or social rights.

Who to contact: If you have any inquiries or concerns regarding this study, please feel free to reach out to the following individuals:

1. Dr. Edmund Mujuni (Principal Investigator)

   Department of Surgery

   Muhimbili University of Health and Allied Sciences

   P.O. Box 65001, Dar es Salaam

   Mobile phone: 0682727169

2. For questions regarding your rights as a participant, you may contact Dr. Nahya Salim

   Chairperson of the Senate Research and Publications Committee

   Muhimbili University of Health and Allied Sciences

   P.O. Box 65001, Dar es Salaam

   Telephone: (022) 2150302-6

Please don't hesitate to get in touch with them should you require any further clarification or assistance.

**B: Certificate of Consent**

I confirm that I have thoroughly reviewed the aforementioned information (which has been provided to me). I have had the opportunity to ask questions and have received satisfactory responses. I have comprehended the purpose of the study, as well as the potential benefits, risks, and my right to withdraw from participation. With this understanding, I willingly and voluntarily provide my consent to participate in this study.

Signature of participant: ……Date……

Signature of researcher: ……Date……

## Appendix II: Fomu Ya Ridhaa (Swahili version)

### A. TAARIFA KWA UJUMLA

Utangulizi:

Habari! Mimi ni Dk. Edmund Mujuni, ninashirikiana na Chuo Kikuu cha Afya na Sayansi Shirikishi Muhimbili. Ningependa kukupa mwaliko wa kushiriki katika utafiti unaolenga kuchunguza sababu za utabiri za urekebishaji wa viungo bandia baada ya kukatwa mguu wa kisukari katika hospitali ya juu. Madhumuni ya utafiti huu ni kubainisha mambo ambayo yanatabiri mafanikio ya kuwekewa viungo bandia na ukarabati wa watu waliokatwa mguu wenye kisukari katika Hospitali ya Taifa ya Muhimbili.

Je, ushiriki wako unamaanisha nini? Ushiriki wako katika utafiti huu utahusisha makubaliano yako ya kujibu mfululizo wa maswali ambayo yanaweza kuchukua takriban dakika tano za muda wako. Maswali haya yanalenga kukusanya taarifa zinazohusiana na mifumo na usimamizi wa mtu aliyekatwa mguu mwenye kisukari kwa ajili ya kufaa na urekebishaji wa viungo bandia.

Je, ni faida na hatari gani kwa kushiriki? Tunaamini kwa uthabiti kwamba ushiriki wako katika utafiti huu unatarajiwa kutoa mchango wa maana kwa ustawi wa watu waliokatwa mguu wenye ugonjwa wa kisukari kwa kuanzisha urekebishaji wa viungo bandia kama sehemu muhimu ndani ya mbinu ya kina ya utunzaji wa wagonjwa katika taaluma mbalimbali. Kuhusika kwako katika utafiti huu pia kutaongeza ufahamu wako na kuongeza tabia chanya za kutafuta huduma za afya. Tunakuhakikishia kuwa hakuna hatari zinazotarajiwa zinazohusiana na ushiriki wako katika utafiti huu.

**Usiri**: Taarifa utakazotoa katika utafiti huu ni siri. Mtafiti pekee ndiye atakayeweza kuziona taarifa hizi.Hata katika utoaji wataarifa au uchapishaji wa taarifa za utafiti jina lako halitatajwa sehemu yoyote.

**Haki ya kujitoa**: Ushiriki wako katika utafiti huu ni hiari. Unahaki ya kujitoa wakati wowote ukibadili mawazo hata kama ulisaini fomu ya idhini ya kushiriki. Hautopoteza haki yako yoyote ya kiafya au ya kijamii hata pale utakapoamua kujitoa kushiriki katika utafiti huu.

Kwa mawasiliano: Endapo utakuwa na swali lolote linalohusu utafiti huu, wasiliana na wafuatao:

Dr. Edmund Mujuni (Mtafiti mkuu) idara ya upasuaji, Chuo kikuu cha Afya na sayansi shirikishi Muhimbili, S.L.P.65001, Dares Salaam. Simu 0682727169 Kwa maswali kuhusu haki zako kama mshiriki, unaweza kuwasiliana na Dr. Nahya Salim, Mwenyekiti wa kitengo cha utafiti, Chuo cha Afya na sayansi shirikishi Muhimbili, P.O.Box 65001, Dar es salaam. Simu:2150302-6.

B: Idhini Ya Kushiriki

Nimesoma/nimesomewa taarifa hii kama ilivyoelezwa hapo juu.Nimeuliza (endapo ulipata nafasi ya kuuliza )maswali na nimejibiwa. Nimeelewa dhumuni la utafiti huu.Nimeelewa faida, athari na haki yangu ya kujitoa katika utafiti wakati wowote. Ninakubali kwa hiari yangu kushiriki katika utafiti huu.

Sahihi ya mshiriki……..Tarehe……...

Sahihi ya mtafiti…… Tarehe……...

**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/1960

Date: 31/10/2023

MUHAS-REC-10-2023-1960
DR. EDMUND MUJUNI
COLLEGE OF MEDICINE MUHAS

**RE: APPROVAL FOR ETHICAL CLEARANCE FOR A STUDY TITLED: PREDICTIVE FACTORS FOR SUCCESSFUL PROSTHETIC REHABILITATION AFTER DIABETIC FOOT AMPUTATION AT A TERTIARY HOSPITAL: A RETROSPECTIVE REVIEW.**

Reference is made to the above heading,

I am pleased to inform you that the Chairperson 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: 31/10/2023
EXPIRATION DATE OF APPROVAL: 31/10/2024

**STUDY DESCRIPTION:**
**Purpose:**
To determine factors that predict successful prosthetic fitting and rehabilitation of diabetic foot amputees at Muhimbili National Hospital.

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-%2014801.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. Kasusu Nyamuryekung'e

**Ag. Chairperson, MUHAS Research and Ethics Committee**