QUALITY OF LIFE, FUNCTIONAL STATUS AND COST-EFFECTIVENESS OF TREATMENT AFTER FEMORAL SHAFT FRACTURES IN MALAWI.

A comparison of skeletal traction and intramedullary nailing in a low resource setting.

Linda Chokotho

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Scientific environment

This study was conducted at the following hospitals in Malawi from 2015 to 2019: Queen Elizabeth Central Hospital (QECH), Kamuzu Central Hospital (KCH), Thyolo District Hospital, Chiradzulu District Hospital, Chikwawa District Hospital and Beit Cure International Hospital (BCIH). The study was funded by Norad through a Norhed Project supporting surgical specialist training in Malawi, and was a collaboration between the Department of Surgery at the University of Malawi College of Medicine, QECH and KCH in Malawi, and the University of Bergen, Centre for International Health (CIH) and Haukeland University Hospital in Norway. QECH and KCH are teaching hospitals for the College of Medicine. The study was also partly funded by the Institute for Global Orthopaedics and Traumatology, Orthopaedic Trauma Institute, University of California San Francisco and James O. Johnston Research grant through a collaboration with Beit Cure International Hospital where the author of the thesis was working.

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Abbreviations

AO	Arbeitsgemeinschaft für Osteosynthesefragen
BCIH	Beit Cure International Hospital
BIA	Budget Impact Analysis
CEA	Cost Effectiveness Analysis
CET	Cost-effectiveness threshold
CI	Confidence Interval
CUA	Cost-utility Analysis
EQ-5D	European Quality of Life 5-Dimensions
EQ-VAS	European Quality of Life 5-Dimensions- Visual Analogue Scale
GDP	Gross Domestic Product Per Capita
GLM	Generalized Linear Model
HIC	High Income Country
HICs	High Income Countries
HRQOL	Health Related Quality of Life
KCH	Kamuzu Central Hospital
IM	Intramedullary
LIC	Low Income Country
LMIC	Low- and Middle-Income Country
LV	Linguistic Validation

MCID	Minimal Clinically Important Difference
ORIF	Open Reduction and Internal Fixation
OTA	Orthopaedic Trauma Association
PROMs	Patient Reported Outcome Measures
QECH	Queen Elizabeth Central Hospital
QALYS	Quality Adjusted Life Years
RCT	Randomised Controlled Trial
REDCap	Research Electronic Data Capture
SIGN	Surgical Implant Generation Network
SMFA	Short Musculoskeletal Function Assessment questionnaire
WHO	World Health Organization
WHOQOL-BREF	World Health Organization Quality of Life-BREF
UCSF	University of California San Francisco

Abstract

Introduction

The incidence of femoral shaft fractures in Low- and Middle-Income Countries (LMICs) ranges from 15.7 to 45.5 per 100,000 people per year. A recent study in Malawi, a low-income country (LIC), estimated the national incidence of femoral shaft fractures to be 26.5 per 100,000 people per year, and the prevalence at 1.38 per 100,000 population. The femur is one of the principal weight-bearing bones in the body. Hence fractures of the femoral shaft affect weight bearing and mobility, which in turn affects various aspects of quality of life. Furthermore, these fractures occur frequently in the economically productive age group resulting in varying degrees of economic loss both for the patients, their families and the nation. The overall aim of this thesis was to compare the quality of life and functional status of adult patients with femoral shaft fractures treated with intramedullary (IM) nailing and skeletal traction.

Methods

This thesis is based on 4 studies. The first study assessed the clinimetric properties of the Chichewa EQ-5D-3L questionnaire. The questionnaire was administered to a sample of adult patients with both traumatic and non-traumatic musculoskeletal conditions. The second study translated and culturally adapted the English Short Musculoskeletal Function Assessment (SMFA) questionnaire into Chichewa using the multi-step linguistic validation (LV) method. The clinimetric properties of the Chichewa SMFA were then assessed by administering the questionnaire to adult patients with both traumatic and non-traumatic conditions. The third study assessed quality of life and functional status in adult patients with femoral shaft fractures treated with either IM nailing or skeletal traction. Quality of life and functional status were assessed using the Chichewa EQ-5D-3L and SMFA questionnaires respectively. Assessment was done at 6 weeks, 3 months, 6 months, and 1-year post injury. The

fourth study assessed the cost-effectiveness of the two treatment modalities from both the government health care payer and societal perspectives. The time horizon was 1-year. This was a cost utility analysis where QALYs were calculated from EQ-5D-3L index scores and direct treatment costs calculated using time and motion analysis were obtained from a prospective costing study. Indirect costs included patient lost productivity, and patient transportation, meal, and childcare costs associated with hospital stay and follow-up visits.

Results

Both the Chichewa EQ-5D-3L and SMFA versions were found to demonstrate adequate validity, internal consistency, floor/ceiling effects, and reliability. Hence, they were found to be valid and reliable tools for measuring quality of life and functional status in patients with musculoskeletal conditions in populations where Chichewa (or Chinyanja) is the primary language.

Patients treated with IM nailing had better quality of life and function at 6 weeks, 3 months and 6 months after injury, compared to those treated with skeletal traction. The study also found that IM nailing patients returned to work earlier than skeletal traction patients. There were no differences in quality of life and function at 1-year post injury. However, 30% of skeletal traction patients converted to IM nailing due to failed treatment; these would have ended up with poor quality of life and function at 1 year if they had continued with skeletal traction treatment.

IM nailing was found to be a dominant approach being both cost saving and more effective than skeletal traction. Furthermore, the sensitivity analysis showed more than 90% certainty of the findings.

Conclusion

In summary, the studies included in this thesis have established that the Chichewa EQ-5D-3L and SMFA questionnaires are valid and reliable tools that can be used to assess quality of life and function respectively, in adults with musculoskeletal problems who use Chichewa as their primary language. IM nailing was associated with better quality of life, better function and earlier return to work, and was more cost-effective than skeletal traction in the treatment of adult femoral shaft fractures.

Chichewa Abstract (Ndemanga)

Mwa anthu zikwi zana limodzi aliwonse mmayiko amene ali osauka ndi osaukitsitsa, anthu pakati pa khumi, asanu ndi modzi mpaka makumi anayi mphambu zisanu amakhala ndi vuto lothyoka fupa la pa ntchafu akavulala pangozi. Kafukufuku amene adachitika m’dziko la Malawi adapeza kuti mwa anthu zikwi zana limodzi aliwonse anthu pafupifupi makumi awiri mpambu zisanu ndi chimodzi amakhala ndi vuto lotchoka fupa la pa ntchafu akavulala.

Fupa la pa ntchafu ndi lofunika kwambiri chifukwa limathandiza kuti munthu azitha kuyenda bwino bwino, ndi chifukwa chake likathyoka, umoyo wa munthu umakhudzidwa mu njira zosiyanasiyana. Komanso nthawi zambiri vutoli limakhudza anthu amene ali pa msinkhu wogwira ntchito zosiyanasiyana zomwe zimathandiza chitukuko cha m’mabanja mwawo, komanso cha m’dziko. Izi zimapangitsa kuti chitukuko chibwelere mmbuyo.

Mmayiko olemera, munthu amene wathyoka fupa la pa ntchafu amapangidwa opareshoni ndikuyikidwa chitsulo mkati, kuti fupalo lilunzane mwachangu ndipo munthu yo amatha kuyamba kuyenda fupalo lisanapole. Koma ku Malawi, anthu ambiri amene ali ndi vutoli samapangidwa opareshoni ayi. Mmalo mwake fupa lothyokalo limakokedwa pogwiritsa ntchito miyala ya chitsulo kuti likhale mmalo mwake pamene likupola, ndipo munthu yo amagonekedwa mchipatala, osatha kuyenda, kwa milungu yosachepera isanu ndi umodzi.

Chikalata ichi chikufotokoza za kafukufuku yemwe cholinga chake chinali kufuna kuona kuti kodi umoyo komanso magwiridwe a ntchito a anthu akulu akulu omwe athyoka fupa la pa ntchafu amakhudzidwa bwanji pamene alandira chithandizo kuchipatala cha opareshoni kapena kuthandizidwa osapangidwa opareshoni, pongokoka fupa lothyokalo ndi miyala kuti libwerere mmalo mwake.

Kafukufuku ameneyu adachitika mzipatala za Queen Elizabeth Central, Kamuzu Central, Beit Cure, ndi zipatala za boma ku Thyolo, Chikwawa ndi Chiradzulu,

kuyambira mwezi wa April 2016 mpaka August 2018. Mu nthawi imeneyi akulu akulu omwe adapezeka ndi vuto lothyoka fupa la pa ntchafu mzipatalazi adapemphedwa kuti alowe nawo mukafukufuku yu.

Mwachidule kafukufuku yu adapeza kuti anthu omwe apangidwa opareshoni amakhala ndi umoyo wabwino, magwiridwe awo a ntchito amakhala opambana, ndipo amabwerera kukayamba ntchito mwansanga kuyerekeza ndi anthu omwe athandizidwa osapangidwa opareshoni. Komanso kafukufukuyu adapeza kuti njira ya opareshoni imagwiritsa ntchito ndalama zochepa kuti munthu akhale ndi umoyo wabwino kuyerekeza ndi njira yosapanga opareshoni. Izi zikuonetsa kuti kwa munthu amene wavulala, ndi kuthyoka fupa la pa ntchafu, njira ya bwino kuti munthuyo athandizike mokwanira ndi kuchira msanga ndikupanga opareshoni.

List of Publications

1. **Chokotho L, Mkandawire N, Conway D, Wu H, Shearer D, Hallan G, Gjertsen JE, Young S, Lau B.** Validation and reliability of the Chichewa translation of the EQ-5D quality of life questionnaire in adults with Orthopaedic injuries in Malawi. Malawi Med J. 2017 June; 29(2):84-88.

2. **Chokotho L, Lau B, Conway D, Wu H, Shearer D, Mkandawire N, Hallan G, Gjertsen JE, Young S.** Validation of the Chichewa Short Musculoskeletal Function Assessment (SMFA) questionnaire. Malawi Medical Journal. 2019;31(1):65-70.

3. **Chokotho L, Wu HH, Shearer D, Lau BC, Mkandawire N, Gjertsen JE, Hallan G, Young S.** Outcome at 1 year in patients with femoral shaft fractures treated with intramedullary nailing or skeletal traction in a low-income country: a prospective observational study of 187 patients in Malawi. Acta Orthop. 2020 Jul 23:1-8.

4. **Chokotho L, Donnelley C, Young S, Lau BC, Wu HH, Mkandawire N, Gjertsen JE, Hallan G, Shearer D.** Cost Utility Analysis of Intramedullary Nailing and Skeletal Traction Treatment for Patients with Femoral Shaft Fractures in Malawi. Submitted Acta Orthop.

Contents

1. Background and Literature Review

1.1 Definition and Anatomy of Femoral Shaft Fractures

Femoral shaft fractures occur in the long tubular segment of the bone, inferior to the lesser trochanter and proximal to the metaphyseal flair and condyles of the femur. The femur is the largest, strongest, and one of the principal weight-bearing bones in the body [1]. It is surrounded by three muscular compartments, the anterior, posterior, and medial. The muscles attached to the femur act as deforming forces on the fracture fragments, depending on the location of the fracture, tending to displace the fracture in a predictable pattern (Figure 1). Generally, the proximal fragment is flexed, abducted, and externally rotated by the iliopsoas and hip abductors. The distal fragment is displaced proximally by the quadriceps and hamstrings and adducted by the adductors [1, 2]

LATERAL VIEW **ANTERIOR VIEW**

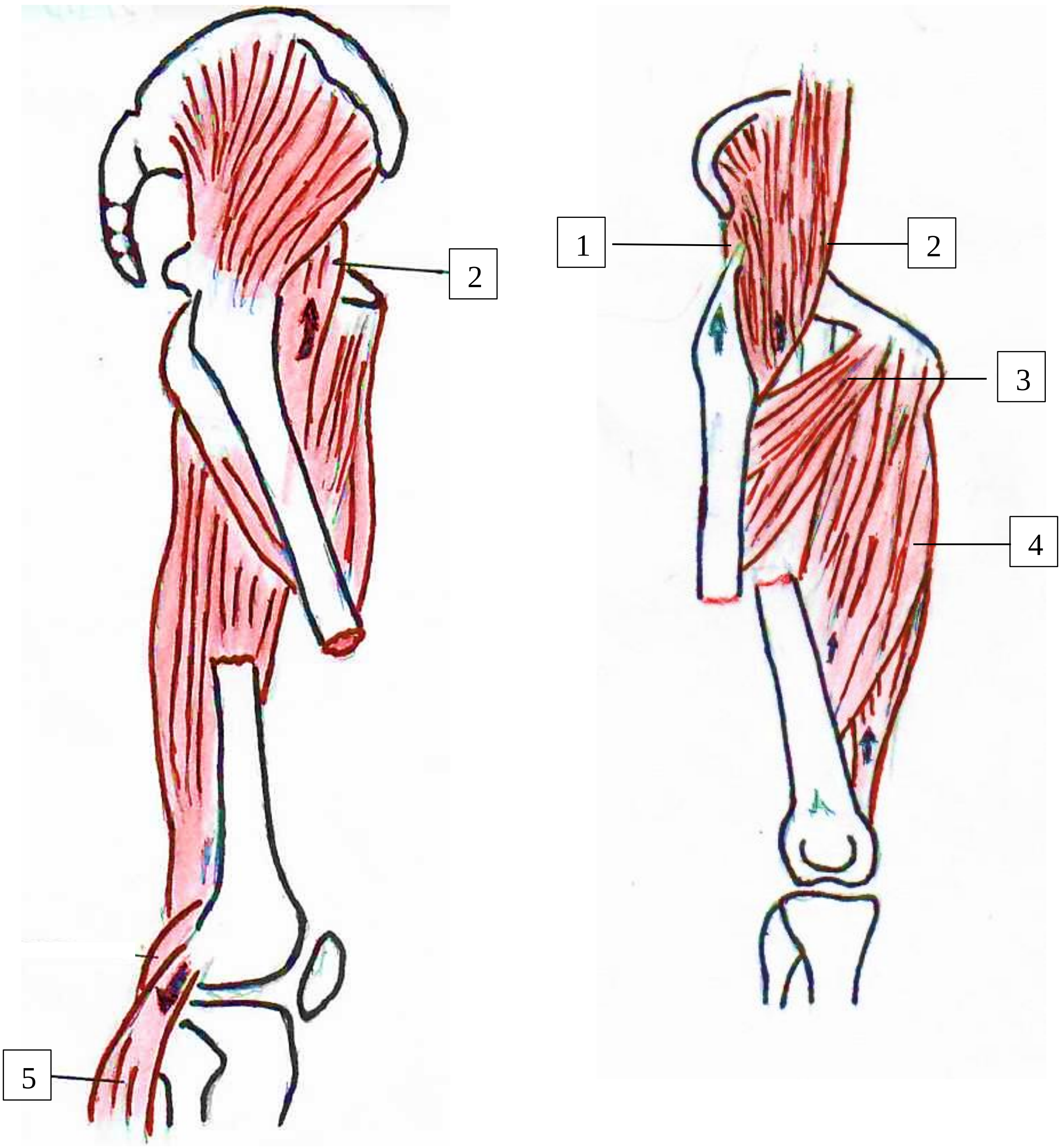

Figure 1: Lateral and Anterior views of deforming muscle forces for a shaft fracture of the femur: 1 - Gluteal and external rotators muscles, 2 - Iliopsoas, 3 - Pectineus, 4 - Adductor muscles, 5 - Gastrocnemius. (Drawing: Jesse Mbekeani. Used with permission)

The femoral shaft gets its main blood supply from one or more nutrient arteries which arise from the deep branch of the femoral artery also known as the profunda femoris artery (Figure 2). The nutrient arteries enter the shaft posteriorly in the proximal part of the shaft and supply the inner two thirds to three quarters of the cortex. The remaining part is supplied by the periosteal blood vessels. When a displaced fracture occurs, the endosteal blood supply is disrupted and the periosteal blood supply proliferates and becomes the main blood supplier of the cortex [1]. It is therefore important to preserve the periosteal blood supply during surgical treatment of femoral shaft fractures to facilitate healing. Any surgical treatment that compromises this supply has the potential of causing non-union. Due to the femur's vital role in weight bearing, shaft fractures result in significant morbidity and disability if not managed appropriately. It is therefore imperative that these injuries should be managed optimally.

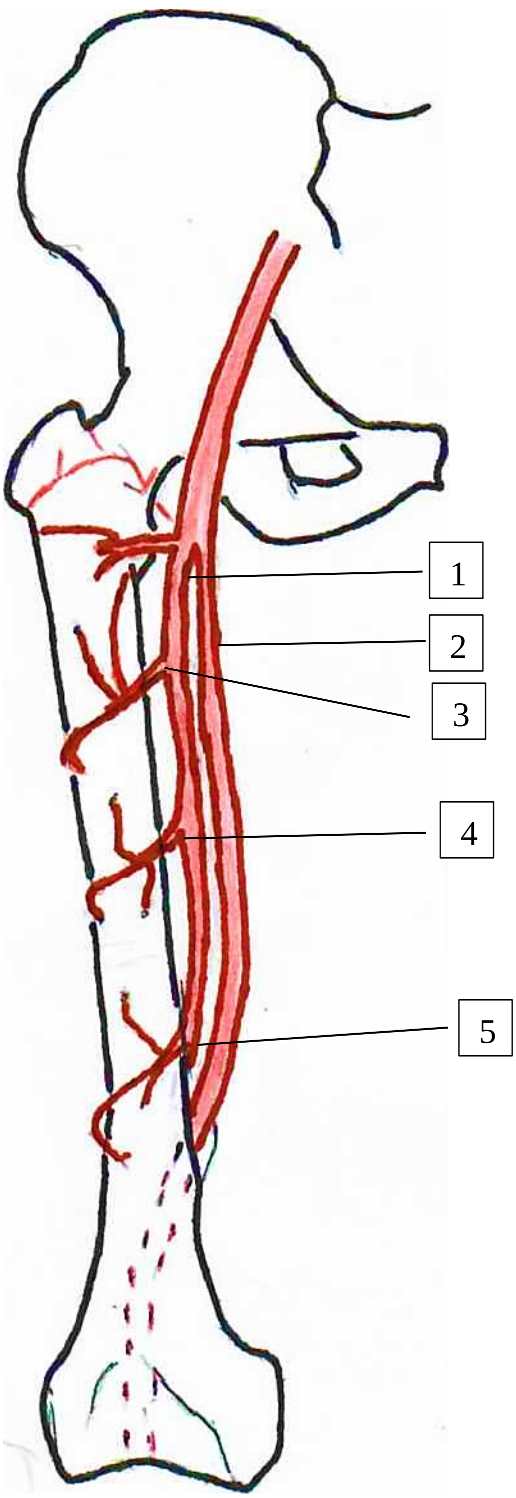

Figure 2: Blood supply of the femoral shaft. 1 - Deep femoral artery, 2 - Superficial femoral artery, 3 to 5 - Perforator arteries. (Drawing Jesse Mbekeani. Used with permission)

1.2 Classification of Femoral Shaft Fractures

Fractures are classified according to agreed classifications to facilitate communication between orthopaedic surgeons, shed light on prognosis, and guide in making decisions about treatment. In addition, use of classification systems helps in comparison of treatment outcomes. Two classification systems have been frequently used for closed femoral shaft fractures, the Winquist and Hansen and the AO/OTA Classification. Both have been found to have a good to very good interobserver agreement [3]. The femoral shaft fractures in this study were classified using the AO/OTA classification system because one of the reasons for its development was to promote standard communication in clinical research [4]. This is an alphanumeric coding system which classifies fractures according to the location in the bone and the biomechanical forces that cause different fracture patterns, and thus indirectly implies the severity of the fractures and predicts the risk of complications. Each bone in the body is numbered; the femur is bone number 3. Further, each bone segment (proximal, diaphyseal, distal) is also numbered 1 - 3 and the type of fracture (simple, wedge, complex) is coded A - C. Accordingly, a femoral shaft fracture can be classified as 32A, 32B, or 32C using the AO/OTA classification (see Figure 3). Further classification into sub-groups is coded 1 - 3 depending on whether the fracture pattern is caused by a twisting or bending force. For instance, 32-A1 is spiral, A2 oblique $\geq$ 30 degrees, A3 is transverse $<$30 degrees. Accordingly, 32-B1 is spiral wedge, B2 bending wedge, B3 fragmented wedge. Finally, 32-C1 is spiral fragmented complex, C2 segmental, C3 is irregular.

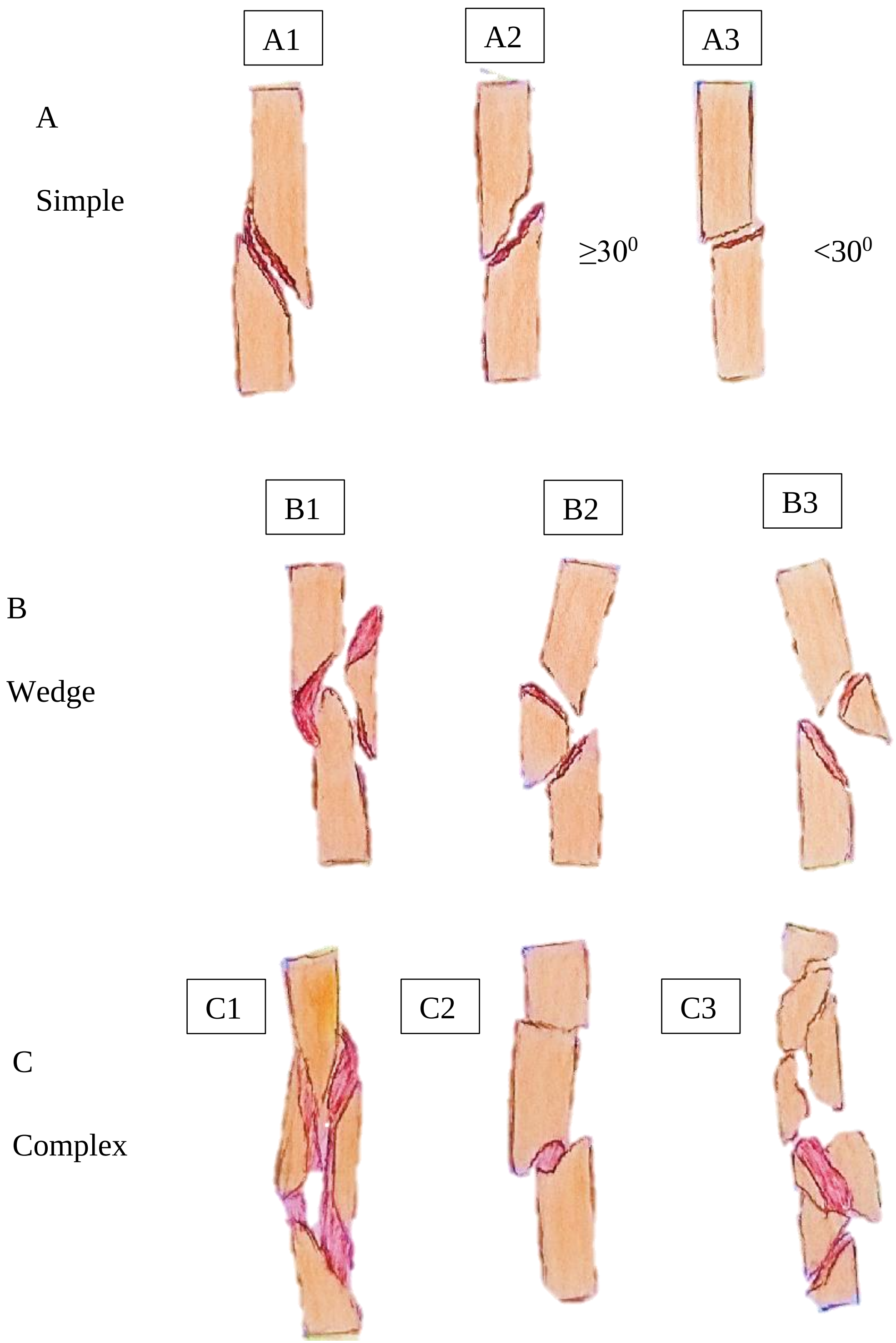

Figure 3: AO/OTA Classification. A1 - Spiral, A2 - Oblique, A3 - Transverse, B1 - Spiral wedge, B2 - Flexion wedge, B3 - Fragmented wedge, C1 - Complex spiral, C2 - Segmental, C3 - Complex irregular (Drawing: Jesse Mbekeani. Used with permission)

1.3 Epidemiology of Femoral Shaft Fractures

The incidence of femoral shaft fractures varies in different regions. In Sweden, a high-income country (HIC), the incidence of mid shaft femoral fractures was found to be 10 per 100,000 person years [5]. Conway et al. reported incidence rate ranges of 2.1 to 18.4 per 100,000 population in Tanzania [6]. Agarwal- Harding et al. 2015 [7] estimated the annual incidence range of femoral shaft fractures in LMICs from 15.7 to 45.5 per 100,000 population. A recent study in Malawi, a LIC, estimated the national annual incidence of femoral shaft fractures to be 26.5 per 100,000 population, and the prevalence at 1.38 per 100,000 population [8].

Femoral shaft fractures in adults are commonly high-energy injuries caused by road traffic collisions and falls from heights. Low-energy fractures in osteoporotic bone can occur in the elderly. There is an age- and gender associated bimodal presentation for these fractures with the high-energy injuries occurring most commonly in young adult males and the low energy ones in the elderly female population greater than 65 years of age [1,9]. Femoral shaft fractures occur frequently in the economically productive age group [1, 9-12], resulting in varying degrees of economic loss both for the patients and their families and the nation. The high-energy shaft fractures are associated with other severe injuries such as ipsilateral neck of femur fractures, tibia fractures, knee injuries and traumatic brain injury [9, 11, 13]. The proportion of patients with at least one associated injury was as high as 45% in one study from Groningen University hospital in the Netherlands [13].

1.4 Treatment of Femoral Shaft Fractures

1.4.1 Synopsis

The Hippocratic writings [14], which date as far back as 400 BC, recorded the recommended management of different types of fractures, including femoral shaft fractures, at the time. The recommended treatment for these fractures, according to Hippocrates, was manual reduction and immobilization in extension (i.e. Traction);

“for it is a great disgrace and an injury to exhibit a shortened thigh. For the arm, when shortened, might be concealed, and the mistake would not be great; but a shortened thigh-bone would exhibit the man maimed” [14]. The treatment of femoral shaft fractures has advanced over the years from the historical non-operative management with traction and plaster cast application to surgical treatment with some kind of fixation device such as IM nailing. IM nailing is now the accepted gold standard treatment method because it results in a stable fixation that allows early mobilization and rehabilitation of the patients [15, 16]. However, in LICs, non-operative treatment remains the main treatment for femoral shaft fractures. The reasons for continued use of non-operative treatment are multifactorial and include lack of expertise, implants, equipment, and theatre time [15, 17]. The following sections will discuss the different methods used to treat femoral shaft fractures and the historical background of these methods.

1.4.2 Skeletal Traction

This method of treating femoral shaft fractures was introduced by Fritz Steinmann, a Swiss surgeon, in 1907 [18]. Prior to this time, femoral shaft fractures had been treated with different forms of either manual or skin traction and splinting dating as far back as the Egyptian civilization in 1300 BC [19]. The Steinmann traction pin was a metal pin sharpened on one end that was inserted using a hand drill. It was initially inserted in the supracondylar region of the femur, then tongs were applied to both ends of the pin which were used to attach the cord for the traction weights. In the current practice, the distal femur insertion site is indicated for the fractures of the proximal third of the femoral shaft and fractures with associated knee ligament injuries. The proximal tibia insertion site is indicated for fractures in the distal two thirds of the shaft. Skeletal traction applies a pulling force on the fractured limb, thereby causing tension in the surrounding soft tissues which if successful maintains length and acceptable alignment as the fracture heals. Conservative treatment using skeletal traction for at least 6 weeks is the mainstay treatment option for femoral shaft fractures in LICs (Figure 4). However, it is associated with complications such as muscle wasting, joint stiffness, venous thrombo-embolism, traction pin site infection, pressure sores, malunion, and non-union [1]. Although studies have reported good fracture union rates of greater than 90% in patients treated with skeletal traction [20,21], a considerable proportion of these patients experience these complications. In a study evaluating the management of isolated femoral shaft fractures in a district hospital in Malawi, 11 out of 20 patients treated with skeletal traction had complications such as traction pin site infection, leg length discrepancies of >2cm, delayed union, and malunion [20]. Bezabeh et al. (2012), found similar complications in their cohort of femoral shaft fractures treated with Perkins traction, with pin site infection in 11.8%, shortening of more than 2cm in 16.2%, and knee stiffness of varying degrees in at least 72% [21].

Figure 4: Patient on Skeletal Traction (Photo: Thokozani Masina. Used with permission and consent from the patient)

Various skeletal traction techniques and modifications have been developed over the years to try and improve knee range of motion and prevent angulation deformities (Figure 5) [22]. In some instances, a plaster spica is applied once no further displacement of the fracture fragments can occur. Skeletal traction treatment is likely to be costly as the patients have to stay in hospital for a long period of time. Both patients and their guardians are likely to experience loss of income when they stay away from work or other income generating activities for a long time [23, 24]. Thus, skeletal traction has both medical as well as socioeconomical complications which are likely to affect quality of life even when one has complete bony union.

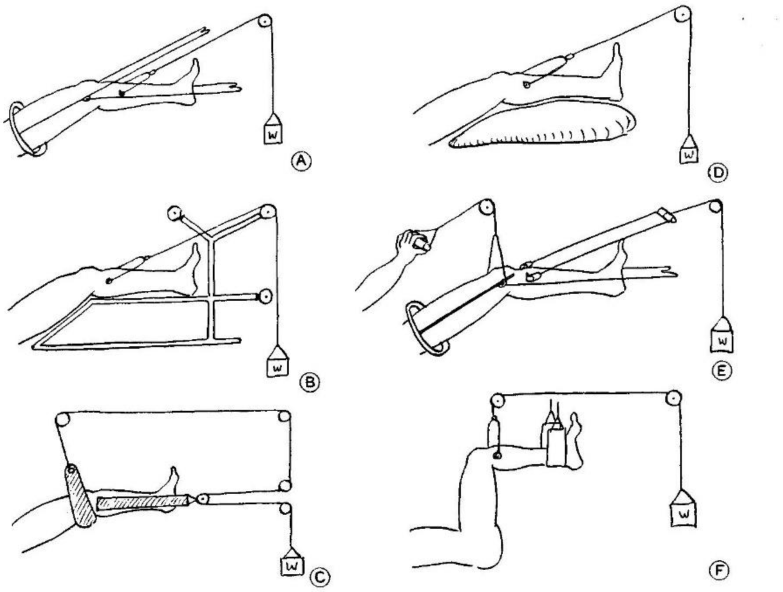

Figure 5: Different types of Skeletal Traction. A- Thomas splint and Pearson-Flexion piece, B- Braun Frame, C- Russell Traction, D- Perkins, E- Fisk, F – 90-90-0. (Source: Charnley J. The closed treatment of common fractures. Cambridge University Press, 2005 [22] Used with permission from the publisher).

1.4.3 Intramedullary Nailing

An intramedullary (IM) nail is a load sharing device that is inserted into the medullary cavity of a long bone to provide fracture reduction and relative stability while the fracture heals (see Figure 6). The use of IM nails in treating femoral shaft fractures has evolved over the years in terms of design, materials, basic science principles and methods of insertion [25]. The IM nailing method has the advantage of early mobilization for the patient, which reduces complications from prolonged immobilization associated with non-operative treatment.

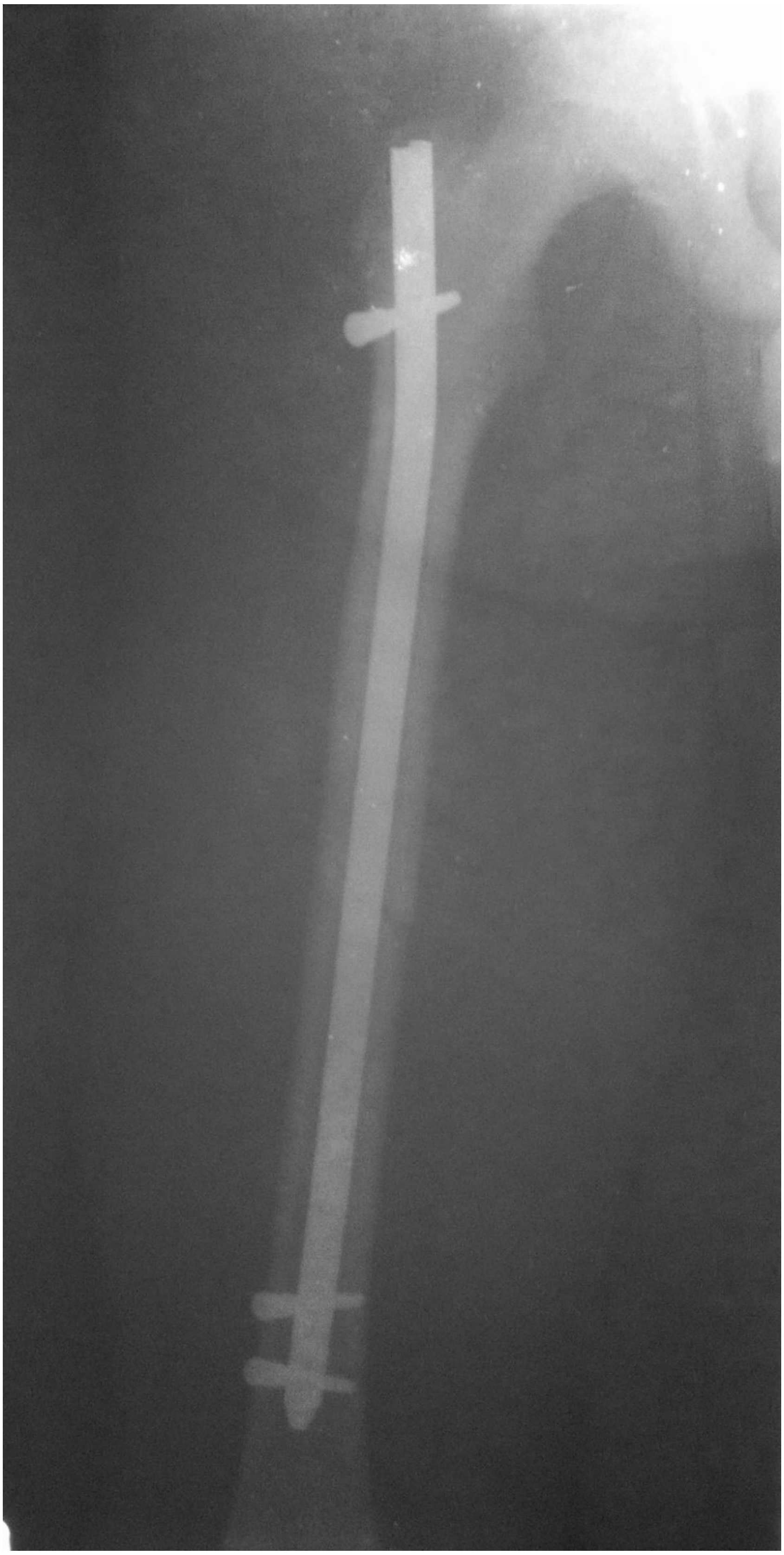

Figure 6: Femoral shaft fracture fixed with an IM nail (Photo: Sven Young. Used with permission)

The use of IM devices to treat long bone fractures was first recorded as far back as the 16th century where doctors in Mexico used wooden sticks to treat non unions of long bone fractures [26]. In 1917, Hoglund from the United States of America, used autogenous bone as an IM implant (as quoted by Bong et al. [25]). Hey Groves from England also reported use of IM devices to treat gunshot shaft fractures of the femur, humerus and ulna in 1918 [27]. Hey Groves described the technique of open IM nailing through the fracture site "*After preparing at least three or four inches of the distal fragment, the proximal one is drilled by a special drill, 12 inches long. This is driven right up through the trochanter, the top of which is exactly in line with the axis of the femur. The tip of the drill is made to emerge against the skin of the buttock and then cut down upon. The drill is removed and the peg, 6 to 9 inches long, is then pushed up the proximal fragment until its upper end emerges from the buttock wound and its lower is left about half an inch from the bone end. The two fragments are now brought into apposition and into line, and the peg is hammered down until it engages the lower fragment by several inches*" [27]. This technique of IM nailing was met with skepticism in Europe and North America due to several limitations such as use of rods not long enough to give stability, rapid absorption of the materials used to make the rods, bone reaction to the non-inert metals causing resorption and high infection rates [25, 28, 29]. Different types of materials were used to make the IM rods including non-inert metal, ivory, animal, and human bones. Interest in IM nailing was revived after the development of inert alloys such as stainless steel. Smith-Petersen's report of his five-year series of successful fixation of neck of femur fractures with a flanged nail that afforded absolute stability and excellent fracture union with minimal complications, also contributed to the renewed interest [30]. In the United States of America, the Rush brothers described use of metal pins which they had made to treat fractures of the proximal ulna and proximal femur [31], whereas in England use of intramedullary Kirschner wires was promoted by Lambrinudi [32]. However, these devices still lacked adequate mechanical stability. It was only when wide nails which occupied the whole of the medullary cavity were introduced by Gerhard Küntscher from Germany during World War II, that the technique received some credit.

Küntscher Nails

Gerhard Küntscher further developed the use of IM nailing by introducing the reaming technique and rigid nails [33]. Küntscher's work started before World War II and in 1939 he published his first cases with his "Marrow nail" and later, in 1940, presented his work at the German Surgical Society meeting in Berlin (as quoted by Watson-Jones et al. [28], Vécsei et al. [29]). Unlike Hey Groves, Küntscher advocated a closed nailing technique under fluoroscopic guidance and strict aseptic technique during the operation. The Küntscher nail design was a non-locking nail which was ideal for fixing stable transverse fractures of the middle third of the femur. However, his initial work was not accepted, and it was only during the World War II in 1942, when his nail was used to successfully treat wounded German soldiers, that his work started to be recognized as an important advancement in the treatment of femoral shaft fractures in Germany and other parts of Europe (as quoted by Bong et al., Watson et al., and Vécsei et al. [25, 28, 29]). By 1950, most large hospitals in Germany were using IM nails to treat acute diaphyseal fractures. However, in the US, there was still skepticism as seen by an article that was published in Time Magazine of March 12, 1945 entitled 'the Amazing Thighbone'. The article highlighted the criticism of the Küntscher nail by the American surgeons who discovered metal rods in the femurs of US soldiers who had been treated in Germany during World War II [34].

The Küntscher nail had limited ability to provide rotational stability and maintain axial length, especially in communited fractures. Later nail designs have improved greatly in this respect as will be discussed below, but the basic concepts that were introduced by Küntscher have remained the same.

Locking Intramedullary Nails

IM nails with locking screws to improve stability of the nail-bone construct were introduced in the 1950s [35]. Locked nailing has resulted in an expansion of indications for IM nailing to include comminuted, segmental fractures, fractures with bone loss, and metaphyseal fractures whose stability and length could not be maintained by non-locked nails. The locking mechanism provides less tensile and shear stresses than plates and screws. Locking nails have become the gold standard treatment for femoral shaft fractures because they secure stability of the fracture and allow for weight bearing thereby facilitating early mobilization and rehabilitation. Studies have reported union rates as high as 90% or more as well as low complication rates [36-38]. The cost of locking nails and the special equipment needed during insertion, such as fluoroscopy and special operation tables, are some of the limiting factors for patients in most LICs to access them. Recognition has emerged for the need of a low-cost IM nailing system, that is affordable and appropriate for use in LICs, taking into consideration the budget and infrastructure constraints of low resource settings. One such nail is the Surgical Implant Generation Network (SIGN) IM nail, which is designed specifically to be used in limited resource settings.

SIGN Nail

Surgical treatment of long-bone fractures in many LMICs improved with the introduction of the SIGN IM nail system [39, 40]. SIGN is a humanitarian non-profit organization that has manufactured and donated IM nails free of charge for use in LMICs since 1999. SIGN's aim is to promote equality in fracture care and currently donates free implants to 53 LMICs. The SIGN system differs from other IM nail systems in that it uses an external jig that directs both proximal and distal locking (Figure 7), allowing insertion of the nail without the use of fluoroscopy, a fracture table, or power instruments. This is an important modification, as in many low resource settings, a C-arm, fracture tables, and power instruments are not always available. However, when performing IM nailing without these modern tools, the fracture site normally needs to be surgically exposed, theoretically increasing the risk of infection. The nail was initially designed as a tibia IM nail but is used in the same configuration in the femur and humerus. The donations of SIGN IM nails allow increased access to operative treatment of long bone fractures by decreasing cost to patients and the health care systems in resource-poor environments. Outcomes in terms of clinical and radiographic healing, weight bearing, knee range of motion and complications after SIGN IM nailing have been found to be comparable with those achieved after use of other locked IM nails inserted with guidance of fluoroscopy without opening the fracture site [41].

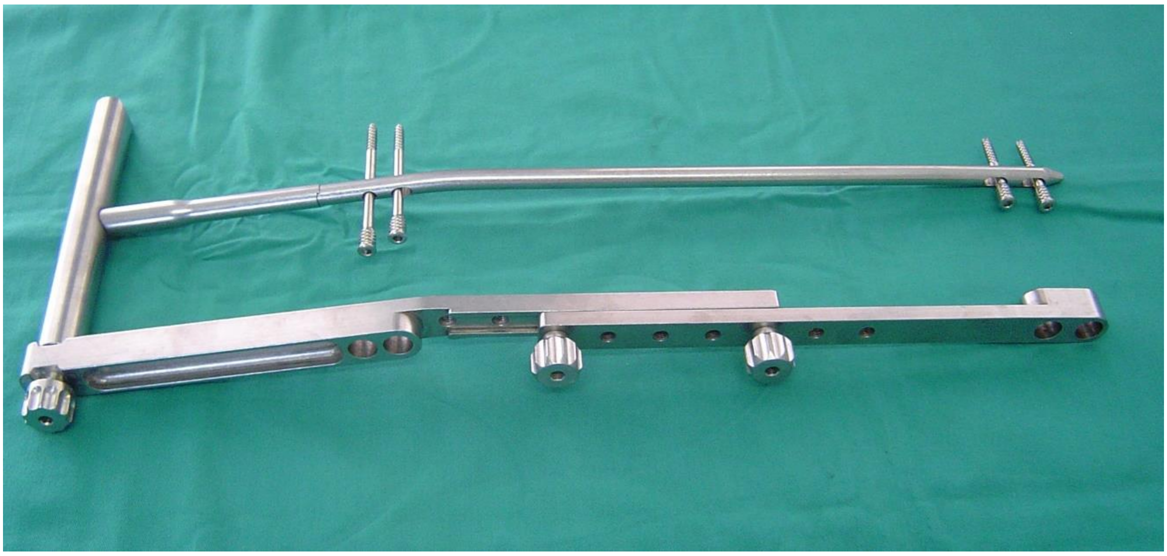

Figure 7: The SIGN nail construct showing the nail with locking screws and its insertion jig (Photo: Jes Bates. Used with permission).

Despite the availability of free IM implants in some hospitals, non-operative treatment using skeletal traction remains the main treatment option in some LICs due to reasons already explained. Presently there are no published prospective clinical studies evaluating patient reported outcomes of IM nailing compared to skeletal traction.

1.4.4 Plates and Screws

Plates are load-bearing devices, screwed directly onto the surface of the bone, which cause stress shielding and therefore result in cortical osteopenia or bone loss, hence more prone to failure than nails [1]. Use of compression plating for shaft fractures of long bones was popularized in the 1960s when the AO (Arbeitsgemeinschaft für Osteosynthesefragen) group introduced compression plating for long bone fractures [13, 42]. In some settings, as many as 50% of femoral shaft fractures were treated with the compression plates during 1968 and 1969 [13]. However, due to advances in IM nailing technique increasing the ease of insertion and the superior outcomes of nailing, plating did not gain momentum and the interest diminished.

1.4.5 External Fixator

The main indication for using an external fixator in femoral shaft fractures is when there is a Gustillo and Anderson Grade III open fracture where the wound is greater than 10 cm and where the fracture may be associated with extensive stripping of the periosteum or vascular injury requiring repair [1]. External fixators can also be used temporarily in damage control orthopaedics in severely injured unstable polytrauma patients when rapid rigid stabilization is required while waiting for definitive treatment [43-45]. However, there are reports in the literature of use of external fixators as definitive treatment for femoral shaft fractures [46, 47].

1.5 Outcomes of Femoral Shaft Fractures

The femur is a principal weight bearing bone and its fracture, if not managed well, may result in weight bearing and mobility problems which in turn will affect most aspects of quality of life. Femoral shaft fractures take 3 to 6 months to unite, but the healing process may be affected by fracture characteristics, as well as patient and treatment factors. Multifragmentary, segmental, and open fractures will take longer to heal due to more severe soft tissue injury with compromised blood supply which is likely to be disrupted because of the high energy impact. Patient-related factors that can affect clinical outcomes after treatment include, age, smoking, comorbidities, and some medication use [48, 49]. Some clinical studies have shown excellent union rates of femur fractures in patients treated with either IM nailing or skeletal traction [21, 36-38]. Low rates of major complications such as infection and non-union in patients treated with IM nailing have also been reported [50, 51]. However, complication rates as high as 36-55% of all patients treated with skeletal traction have been reported in some small sample size studies [20,21, 52]. These complications include malunion, pin site infections, leg length discrepancy, and knee joint stiffness.

Delayed union or non–union of femoral fractures in patients initially treated with skeletal traction should be treated with IM nailing. There is no clear consensus among clinicians with regards to the definition of delayed union and non-union. Delayed union in long bone fractures, has been defined as no clinical or radiological evidence of fracture union 4 months after the injury [53]. Tsang et al. (2016), defined non union as no radiological evidence of fracture healing by 12 -16 weeks for low energy fractures and 6 months for high energy fractures [54], whereas Gomez-Barrena et al. (2015), defined non union as no evidence of healing 6 months after injury irrespective of severity [53]. Patients initially treated with IM nailing who end up with delayed union or non-union can be treated with exchange nailing. In addition, bone grafting, or dynamization (where a distal interlocking screw is removed to allow the nail to move so compression is allowed at the fracture site) or a combination of any of these is often done, depending on the cause of the problem. In most cases, secondary treatments help to resolve the complications, however, in some patients, complications persist or are left untreated. Complications such as non-union, angular deformities, limb shortening, pain, and joint stiffness, may cause significant physical impairment and have a considerable bearing on a person's quality of life. Furthermore, the effects on quality of life and function may persist beyond the normal clinical recovery period. There is a paucity of studies that have looked at how quality of life and function assessed using patient reported outcome measures, is affected after treatment of femoral shaft fractures.

1.6 Outcome Measurements

1.6.1 Patient Reported Outcomes Measures (PROMs)

There is evidence that diaphyseal fractures treated with IM nailing have better outcomes than those treated non-operatively [52, 55- 57]. High rates of fracture union have been reported with both open and closed intramedullary nailing [36-38, 50]. However, outcome assessment in these studies was reported in terms of fracture union, clinical complications, return to work, and mobility and was not based on PROMs. Medical technology, with all its advances over the decades, is not able to give complete information on the impact of disease or treatment. Some information can only be obtained from the patient. The clinical outcome measures do not address all issues that matter to the patient. Patients are concerned with how their condition is going to affect daily activities, functional status and mental health. Thus, PROMs can provide the missing link in defining a good outcome by capturing quality of life issues that patients care about, thereby bridging the gap between the clinical reality and the patient perspective [58]. Therefore, assessment of treatment effectiveness or impact should ideally include both clinical effectiveness as well as benefits as felt by the patient [59]. In some low resource settings where comprehensive clinical assessment is limited by lack of resources, PROMs may assist to assess effects of treatment on the patient's life.

A patient reported outcome is any report of the status of a patient's health condition that comes directly from the patient, without interpretation of the patient's response by a clinician or anyone else [59, 60]. "Quality of Life is defined as an individual's perception of their position in life in the context of culture and value systems in which they live and in relation to their goals, standards and concerns. It is a broad ranging concept affected in a complex way by the person's physical health, psychological state, level of independence, social relationships, and their relationship to salient features of their environment" [61].

PROMs are the tools used to measure these outcomes. The tools can be designed to measure the general health of a patient (generic), or they can be disease specific, dimension specific, region specific, or individualized. They may measure health related quality of life, functional status, symptoms and the extent of the associated limitation, personal experience of care, and anxiety and depression related to the condition [59, 60].

PROMs are gaining popularity and there is a growing opinion that measures of quality of life should be used to evaluate health care interventions [58, 62] and help to plan treatment that will address patient's needs and preferences [63]. Patients' rating of their illness significantly differs from the doctors rating with more patients rating their physical and emotional limitations as major compared to physician's rating [64, 65].

The importance of incorporating the patients' perspective of the outcome of treatment has not been given much attention in LMICs. As such there are no studies that have assessed and compared health related quality of life (HRQOL) and general function in patients with femoral shaft fractures treated using the different treatment modalities. HRQOL consists of multiple domains such as physical, psychological, and social, and the patient states how these domains have been affected by the illness or the treatment [60,61]. Figure 8 shows some other aspects like financial status, and cultural setting that may also affect HRQOL. One of the tools used to measure HRQOL is the EQ-5D

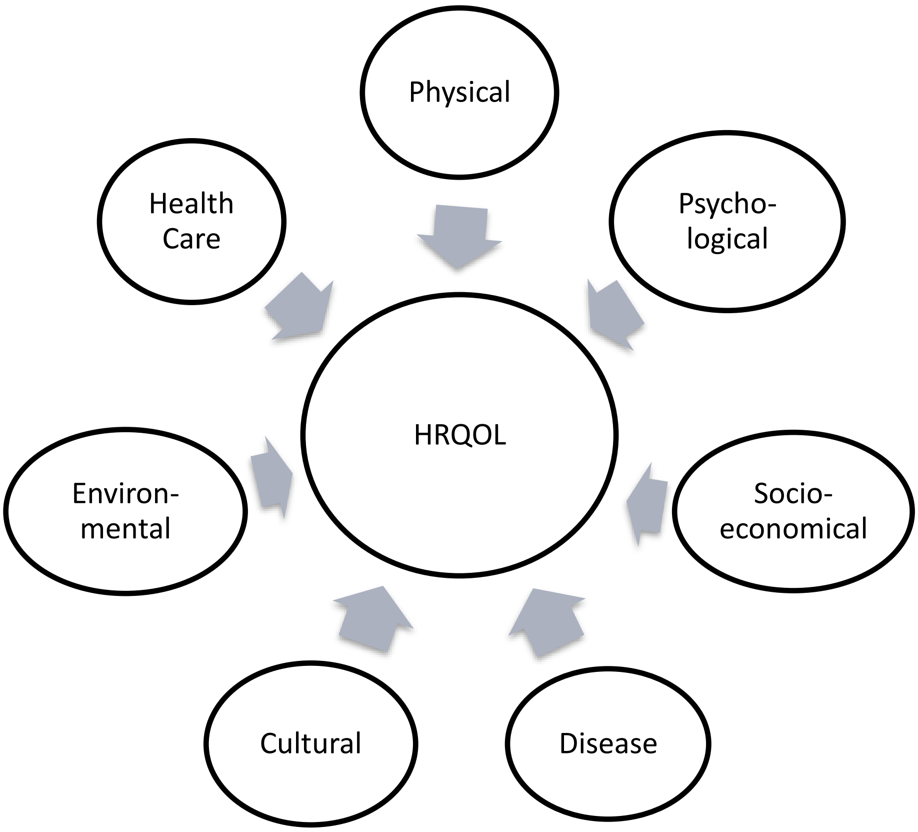

Figure 8: Factors Influencing Health Related Quality of Life. (Source: Deshpande PR, Rajan S, Sudeepthi BL, Nazir CA. Patient-reported outcomes: a new era in clinical research. Perspectives in clinical research. 2011 Oct;2(4):137) [60]

1.6.1.1 EQ-5D

The EQ-5D is a standardised tool that measures general health status. It has two versions, namely the EQ-5D-3L, which has three responses for each domain, and the newer EQ-5D-5L which has five responses for each domain [66]. The tool has 2 parts, the descriptive system and the EQ Visual Analogue Scale (EQ-VAS). The descriptive system has five domains namely mobility, self-care, usual activities, pain/discomfort, and anxiety/depression (See Section 10.1). In this study, the EQ-5D-3L was used to assess quality of life, hence the rest of the description will be for this version. A person is asked to indicate whether he/ she has no problem, some/moderate problem, or severe/ extreme problems for each of the five domains and each response is scored from 1 to 3. Each health state is represented by a five-digit number, one from each of the five domains. For instance, 11111 indicates a state of perfect health where a person has no problems in each of the five domains, whereas 23221 indicates that a person has some problems with mobility, extreme problems with self-care, some problems with usual activities, some pain/ discomfort but is not anxious/ depressed. These responses result in a total of 243 (3^5) possible health states and each state is linked to a predetermined single summary index value [66]. These index values range from -0.145 to 1, where negative values are equivalent to a health condition worse than death, zero is equivalent to death, and 1 equivalent to perfect health. The value sets measure people's preferences with respect to health, i.e. how health is valued. The values are generated from a sample of the general population using either the time trade off (TTO) or the Visual Analogue Scale (VAS) valuation techniques. There are a number of countries/ regions with these value sets. This study used the valuation set for the Zimbabwean population [67] since it has a similar socioeconomic profile as Malawi. The EQ-VAS requires that a person rates his/her own health status on a scale of 0 to 100 where 0 is the worst imaginable health state and 100 is the best imaginable health state. The validity and reliability of both the EQ-5D-3L and EQ-5D-5L have been tested and found to be good in measuring, comparing and valuing health related quality of life in patients with different disease conditions [68, 69]. In addition, instruments like the EQ-5D are preference based and give an overall score from which quality of life adjusted years (QALY) can be calculated. QALY is frequently used in cost effectiveness analysis, important in informing health policy and making resource allocation decisions (70-72].

1.6.1.2 Short Musculoskeletal Function Assessment (SMFA)

The SMFA is one of the disease specific PROMs intended for use in adult patients presenting with general musculoskeletal disease [73]. This questionnaire was derived from the longer 101-item Musculoskeletal Function Assessment (MFA) version.

The SMFA is a two-part 46 item questionnaire, with the questions grouped in four categories namely, daily activities, emotional status, function of the arm and hand, and mobility. The first part has 34 questions, 25 of which assess how difficult it is for patients to perform certain activities, and the other 9 assess how often patients have difficulty when doing certain activities. Each item has 5 responses scored from 1 to 5, with the lower scores indicating good function and the higher ones indicating poor function. The cumulative scores derived from these thirty-four questions gives the dysfunction index. The second part has 12 questions which assesses how much patients are bothered by functional problems in areas such as recreation, leisure, sleep, rest, work, and family. There is also a 5-level response format for each question with 1 indicating “not at all bothered” and 5 indicating “extremely bothered”. The total scores from the 12 questions gives a bother index. The dysfunction and bother index scores are standardized using a formula so that the values should range from 0 to 100, with the lower scores indicating better function. Psychometric properties of the SMFA have been studied and has been found to be valid, reliable and responsive, and proven to be consistent across gender and age categories for patients with musculoskeletal disorders [73, 74].

1.7 Translation

Both the EQ-5D and SMFA are used widely in English speaking countries. Translated versions of these forms are needed to allow for cross-cultural comparisons. If questionnaires are to be used across cultures, they must not only be translated well but also adapted for a particular culture to maintain content validity of the instrument [75]. Cultural adaptation of the questionnaires is important as some content may not make sense in other settings, and therefore will compromise validity [76, 77]. Thus, translation and testing of PROMs must not only focus on comprehension but cultural relevance as well and adapted accordingly.

There is no gold standard methodology for the translation of PROMs [78]. However, there seems to be a consensus in the literature that the process of translation and cultural adaptation needs to follow a structured multi-step procedure [76-79] also called linguistic validation (LV). One such structured methodology is the forward and back translation procedure where a series of steps are followed to get the final translated version [75, 78, 81]. The first step is preparation during which permission to translate the tool is obtained, translators identified and key local personnel recruited to help with the translation process. In addition, the method to be used is identified and a clear plan of the steps to be followed is outlined. All initial work that needs to be done before translation begins is carried out in the first step. The second step is forward translation where the tool is translated to the target language by two independent translators. Thirdly, reconciliation of any differences between the two translators is done to come up with one version. Back translation is then done in the fourth step where two other independent translators who are not aware of the contents of the tool translates the reconciled version back to its original language and after consensus, they come up with one back translated version. Any discrepancies between the original and the back-translated version are discussed and resolved. In the fifth step, the translated tool is then discussed by a panel of experts which comprises methodologists, health professionals, language experts, and both sets of translators and original developers of the tool if possible. The committee’s role is to ensure that there is equivalence between the original tool and the translated tool and that it is culturally adapted accordingly. The committee will then come up with a pre-final version which is then pre-tested using cognitive interviewing on a sample from the target population to evaluate patient's comprehension, interpretation and cultural relevance. The pre-final version is then revised accordingly based on the findings of the pre-testing, to come up with the final version. Pre-testing is usually the final step but other additional steps may be added such as international harmonization to check for consistency and conceptual equivalence if the tool is being translated into several languages and proof reading of the translated tool to correct errors. At each step there is need to have a written report with details on how each step was carried out, what discrepancies were encountered and how these were resolved. These reports are then handed over to the developers or the expert committee at the end of the translation process in case there is need to verify that the recommended steps were followed [75]. It is recommended that the psychometric properties of the final translated version are evaluated to ensure validity, reliability and responsiveness of the tool [75, 76]. Another method of translating PROMs is the two panel approach where professional and lay panel meetings are used [82, 83], or where only forward translation is done by either one or two persons.

1.8 Health Care Setting in Malawi and Fracture Care Services

Malawi has a population of 17.5 million, 84% of which live in rural areas [84]. The health system in Malawi has three levels, primary, secondary, and tertiary. The primary health care level consists of health centres, the majority of which are rural and are managed by medical assistants and nurses. Medical assistants are non-physician personnel who get two years of post-secondary school training in clinical medicine before qualifying. The health centres offer mostly outpatient services, except for uncomplicated obstetric deliveries where patients are offered short stay admission. No primary care facilities in Malawi have available x-ray machines, and consequently no fracture care service is available, even for common simple fractures. The next level of health care is the secondary care facilities, which are district hospitals. The district hospitals are also mostly located in the rural areas of the country. There are 28 districts in Malawi, and 26 district hospitals which act as referral facilities for the health centres. Each district hospital has between 11 and 40 health centres within its catchment area [85]. Orthopeadic services in district hospitals are provided by Orthopaedic clinical officers who are either medical assistants or clinical officers (have 3 years of post-secondary education in clinical medicine) who then undergo a further 18 months of orthopaedic training in non-operative fracture management and operative management of orthopaedic emergencies. Use of orthopaedic clinical officers to provide orthopaedic care in a limited resource setting has been found to be cost-effective [86]. All district hospitals have x-ray machines although their condition and availability vary [87].

The district hospitals are the first level where fracture care is offered. The majority of fractures managed at the district hospitals do not need anaesthesia [88]. The patients with fractures that need anaesthesia at this level of care are treated with either fracture manipulations, which are all done closed with no aid of an image intensifier, or surgical debridement of open fractures. The tertiary level consists of four central hospitals, located in the largest cities, and these are referral centres for the district hospitals in their administrative region. Currently, the few available orthopaedic surgeons are all based at central hospitals, and surgical fixation of fractures is offered only in these tertiary care facilities. In some instances, patients bypass the lower levels of health care and report directly to central hospitals [85]. As of October 2020, Malawi had 14 orthopaedic surgeons serving a population of approximately 17.5 million.

2. Aims of the study

The main aim of this study was to assess the quality of life and functional status of patients with unilateral closed femoral shaft fractures treated with skeletal traction compared to those treated with intramedullary nailing. In order to achieve this main aim, we needed to identify suitable patient reported outcome measure tools which were valid and could be administered in the local language of Chichewa.

The specific aims of the four papers included in the thesis were:

I. To validate a Chichewa version of European Quality of Life 5-Dimensions questionnaire (EQ-5D-3L) (Paper I)
II. To translate and validate a Chichewa version of the Short Musculoskeletal Functional Assessment (SMFA) questionnaire (Paper II)
III. To assess the quality of life and functional status of adult patients with closed femoral shaft fractures treated with skeletal traction or with an IM nail using the EQ-5D-3L and the SMFA (Paper III)
IV. To evaluate and compare the cost-effectiveness of IM nailing and skeletal traction in the treatment of adult femoral shaft fractures (Paper IV).

3. Methods

This section summarizes the methods used for the studies in Papers I – IV. A detailed description of the methods and analyses that were done are explained in each paper (See Section 9, Papers I-IV).

3.1 Translation and Evaluation of Psychometric Properties for the Patient Reported Outcome Measures (Paper I and II)

The translation and cultural adaptation of the English version of the EQ-5D-3L into Chichewa (Chinyanja) language (Section 10.1), was commissioned by the developers of the tool, the EuroQOL group in 2012, and the procedure is described elsewhere [89]. However, its clinimetric properties had not been evaluated before. Permission to use the already translated questionnaire was obtained from the EuroQol group, and its clinimetric properties were evaluated.

The SMFA was translated and culturally adapted into the local language of Chichewa, using the multi-step LV procedure shown in Figure 9.

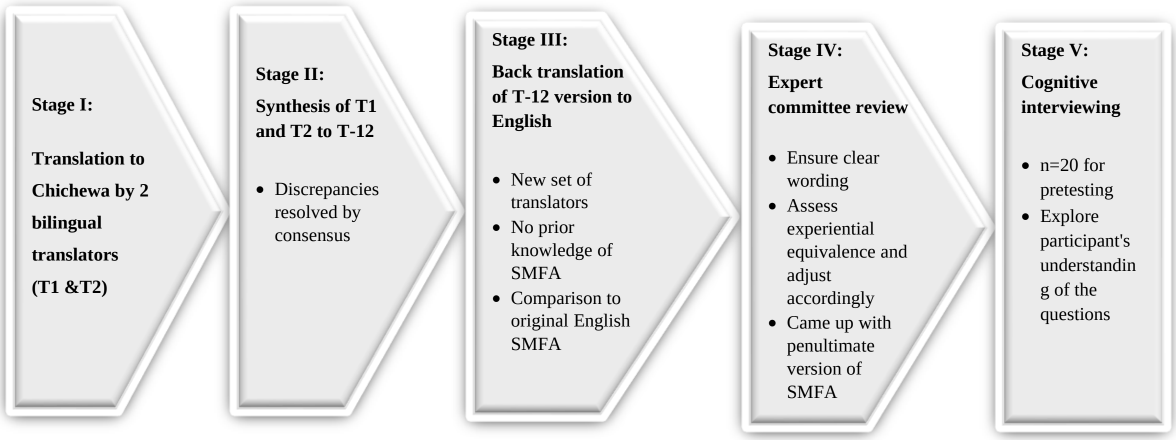

Figure 9: Steps Followed in the Translation and Cultural Adapation of the SMFA

The multi-step translation procedure included firstly, independent forward translation to Chichewa by two bilingual translators and resolving any differences by consensus. Secondly, back translation into English by another set of two independent translators, with no prior knowledge of the contents of the SMFA questionnaire. The back translated version was then compared with the original English version to ensure that they had the same content. A committee comprising orthopaedic surgeons, research assistants and lay people then assessed the questionnaire to ensure that the wording was clear and the questions were culturally relevant. Tasks not experienced by the target culture were replaced by a similar task experienced in Malawian culture. The translated version that was passed by the committee was then pre-tested on a purposive sample of 20 non-study participants with different musculoskeletal problems at Queen Elizabeth Central Hospital, Blantyre. Pre-testing was done to explore how the participants interpreted the items on the questionnaire and whether they understood the meaning of the questionnaire items but also to probe the meaning of their responses. Findings of the pre-testing exercise were used to revise the form accordingly and come up with a final Chichewa SMFA (Section 10.2).

In order to evaluate the clinimetric properties, both the Chichewa SMFA and EQ-5D-3L, were then administered to 53 patients with various traumatic and non-traumatic conditions. Another sample of 20 participants separate from the initial population answered the questionnaire twice at an interval of 2 weeks apart to test for repeatability. The respondents were consecutive patients presenting at Queen Elizabeth Central Hospital's orthopaedic wards or outpatients' clinic. Concurrent administration of the World Health Organization Quality of Life -Bref (WHOQOL-BREF) questionnaire was done to assess construct validity. The WHOQOL-BREF (Section 10.3), is a shorter version of the WHOQOL-100, a quality of life tool developed by World Health Organization, that measures quality of life in four domains namely physical, psychological, social and environmental [90]. The results of the validation of the Chichewa version of WHOQOL-BREF are published elsewhere [91].

3.2 Assessment of Quality of Life and Functional Status (Paper III)

A prospective observational study design was used to assess quality of life and functional status in patients with femoral shaft fractures treated with either skeletal traction or IM nail. Adult patients aged 18 years or older with unilateral femoral shaft fracture (AO/OTA class 32) treated either with IM nail or skeletal traction were recruited. The cases were recruited from six hospitals: 2 Central hospitals (QECH and KCH), 1 non-governmental hospital (BCIH) and 3 district hospitals (Chiradzulu, Thyolo and Chikwawa). In district hospitals all patients with femur shaft fractures were treated with skeletal traction whereas in Central hospitals they were treated with either IM nailing or skeletal traction. Treatment assignment was based on the treating clinician's assessment, which was based largely on surgical capacity of the hospital at that time. IM nailing patients who met the inclusion criteria, were recruited if they had surgery within 6 weeks from the time of injury. Skeletal traction patients either continued with skeletal traction until clinical and radiological signs of fracture union were present or were offered IM nailing if in the opinion of the treating clinician, union was unlikely without further intervention. The diagnosis of delayed union was made by the treating clinician, if at 6 weeks or more post injury, there was still tenderness and mobility at the fracture site, and no radiological evidence of callus formation. Non-union was defined as no evidence of fracture healing both clinically and radiologically after at least 3 months on skeletal traction or 6 months after IM nailing. Consequently, the skeletal traction group had 2 sub-groups: those who started with skeletal traction but later converted to IMN because of either delayed union or non-union, and those who had skeletal traction as definitive treatment until union. Patients with associated major injuries, pathological or open fractures, infection at the surgical site, or prior surgery involving the affected femur were excluded. The primary outcome was quality of life at 1-year post injury, evaluated using the Chichewa EQ-5D-3L questionnaire and function status using Chichewa SMFA questionnaire. In addition, details on demographics, "fracture personality" and return to work after the injury were collected. Patients were followed up at 6 weeks, 3 months, 6 months, and 1year post injury.

3.3 Cost Effectiveness of Skeletal Traction and IM Nailing in the Treatment of Femoral Shaft Fractures (Paper IV)

This part of the study was a cost-utility analysis that compared IM nailing and skeletal traction for treatment of adult femoral shaft fractures in Malawi. Data obtained for patients in Paper III was used to calculate effectiveness of the two treatments modalities. Thus, the study design, regarding data collection and the setting, was the same as described in paper III. Cost data were collected independently by another investigator on a subset of patients in the main clinical study at one of the six sites (QECH) [92] from April 2016 to November 2016. Direct costs were estimated using time and motion analysis, and included procedure personnel and supplies, ward personnel, medications and investigations, surgical implants and instruments. Overhead costs included food, building maintenance, renovation, cleaning and sanitation, beddings, stationery, uniforms, protective wear, and staff training. Further details on how the costs were calculated are published elsewhere [92]. Outpatient costs included clinic personnel, physiotherapy, and X-ray costs. Indirect costs included patient lost productivity, and patient transportation, meal, and childcare costs associated with hospital stay and follow-up visits. Costs associated with lost productivity were calculated for patients who reported either formal or informal employment prior to injury. Patients were interviewed to estimate transportation, meal, and childcare costs.

Effectiveness Data

The effectiveness of each treatment strategy was measured using QALYs based on the EQ-5D-3L descriptive scores. At each follow up time, research assistants administered the EQ-5D-3L questionnaire to the study participants. Utility scores were calculated using EQ-5D-3L responses based on data from the Zimbabwean population value set [67]. QALYs were calculated from the utility scores using the area under the curve method [93]. Due to several factors discussed below, there was no measurable difference between groups in EQ-5D score at 1 year after treatment, hence a 1-year time horizon was used.

3.4 Statistical analyses

Paper I

Mean and standard deviation were calculated for continuous demographic variables, whereas categorical variables were presented using frequencies and proportions. The EQ-5D-3L health states were converted to Descriptive Index scores using Zimbabwean population value set [67]. Mean scores and standard deviations or 95% confidence intervals (CIs) were calculated for both the EQ-VAS and the descriptive index scores. Construct validity, floor/ceiling effects, and repeatability for both the VAS and the Descriptive index, and internal consistency for the descriptive index were calculated. Definitions and details of each of these parameters are outlined in Paper I. (Section 9.1)

Paper II

The raw scores for each patient's dysfunction and bothersome index were calculated by summing up scores for questions 1- 34; and 35-46 respectively. The total raw scores for each sub scale were then standardized using the formula: *(Actual raw score – lowest possible score / possible raw score range) x 100*. Construct validity, internal consistency, floor/ceiling effects, and repeatability for both Dysfunction and Bothersome indices were calculated. Mean scores and standard deviations or 95% confidence intervals were calculated for both indices. (See Section 9.2, Paper II, for detailed description of all the analyses).

Paper III

EQ-5D-3L descriptive index scores and standardized SMFA function and bothersome index scores were calculated. Unadjusted analysis of numerical data between the two treatment groups was done using Satterthwaite's t-test, with unequal variances. Comparison of categorical data was done using chi square test and where the expected cell frequency was less than 5, Fischer's exact test was used. Adjusted analyses were done using generalized linear regression models to adjust for possible confounders. Findings were considered statistically significant if the p value was less than 0.05, and estimates were presented with their 95% CI. Clinical significance for the EQ-5D-3L was defined as Minimal Clinically Important Difference (MCID) of 0.1 or more [94, 95].

Paper IV

A simple decision tree model (Figure 10) was constructed to compare the two treatments using Treeage software [96]. In the ST treatment strategy, there were two potential outcomes: (1) successful traction or (2) failure of treatment with conversion to IMN. Successful traction was defined as complete fracture union after treatment with ST. Failure of ST treatment was defined as either delayed union or non-union of the fracture requiring conversion to IMN. Patients treated in the IMN group had two potential outcomes: (1) successful IMN or (2) failure of treatment with reoperation.

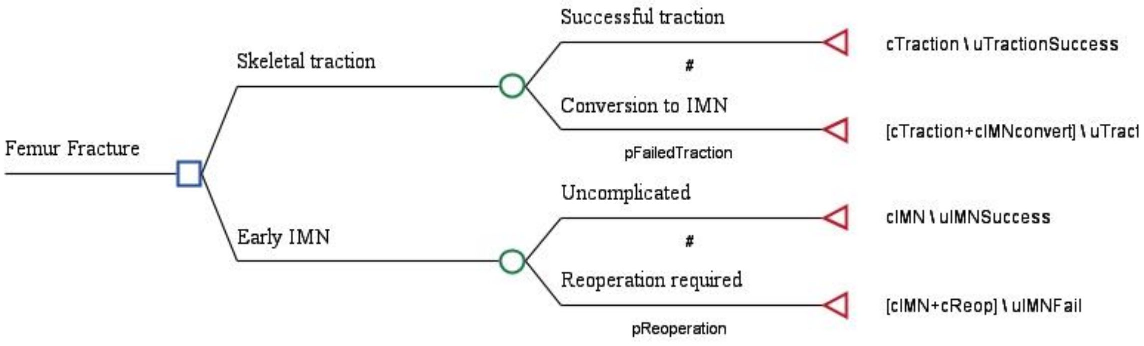

Figure 10: Decision tree model of possible outcomes after ST and IMN treatment of femoral shaft fractures. The costs and effectiveness of each pathway are presented at the end of each potential pathway

The primary outcome of the analysis was the Incremental Cost-effectiveness Ratio (ICER), which was calculated by dividing the difference in cost by the difference in utility between the two treatment groups. Most of the utilities and probabilities were obtained from the observational study that assessed the quality of life and function in adult patients with femur fractures treated with IM nailing or skeletal traction [97]. The utility for reoperation after IM nailing was obtained from another study [98]. Direct costs for IM nailing and skeletal traction were estimated using time and motion analysis [92]. Outpatient costs associated with follow up visits were calculated and included clinic personnel, physiotherapy, and X-ray costs. Indirect costs included patient lost productivity, and patient transportation, meal, and childcare costs. The costs associated with productivity loss were calculated using a standardized wage for Malawi, adjusted using purchasing power parity to USD (99). Patients were interviewed to estimate transportation, meal, and childcare costs. Both payer and societal perspectives were considered in the base case.

Sensitivity Analysis

Multiple one-way sensitivity analyses assessing the relative influence of each model input on the ICER across a range of plausible input values based on the upper and lower limits of 95% confidence intervals were done. A multivariate probabilistic sensitivity analysis (PSA) was also performed by performing 10,000 iterations of the model with a unique value for each input drawn from a probability distribution. In general, costs were represented using a gamma distribution (range 0 to ∞) while probabilities and utilities were represented with a beta distribution (range 0 to 1). The results of the PSA are presented as an ICER scatter plot.

3.5 Ethical Considerations

The study was approved by College of Medicine Research Ethics Committee, in Malawi, the University of Bergen Institutional Review board and the University of California San Francisco institutional review board. Written informed consent was obtained from all patients in the study.

Permission to conduct the study at KCH, QECH, Chikwawa, Chiradzulu, and Thyolo district hospitals was obtained from the hospital management team of the hospitals.

The use of skeletal traction treatment presents an ethical challenge, considering that it has been clearly shown in the literature that IMN is associated with better outcomes and is more cost-effective (52, 55-57). The Universal Declaration on Bioethics and Human Rights Article 15 states that: "Benefits resulting from any scientific research and its applications should be shared with society as a whole and within the international community, in particular with developing countries" [100]. Based on this declaration, one could argue that it is mandatory for doctors to provide the best available treatment to all eligible patients. However, due to limited resources not all best treatments are available to patients in LICs. The, admittedly theoretical, dilemma is whether to just provide the best treatment option to the few patients where resources allow and leave the others untreated, or to still provide the less effective option to those who would otherwise remain untreated. Thus, from a broader public health perspective, it is still better to use the less effective treatment option of skeletal traction to patients who would otherwise be untreated if only IMN was offered as it cannot be made available to all eligible patients. A cost-effectiveness study locally of the two treatment modalities will help determine which treatment offers best value for the limited resources in Malawi and should therefore be prioritized. The other ethical challenge in this study was that, in order to get comparable outcomes, patients who had unsuccessful traction would need to be left untreated with a useless leg. However, this would be clearly unethical, and consequently all patients with failed traction had to be converted to IM nailing.

4. Summary of Papers

4.1 Paper I

Chokotho L, Mkandawire N, Conway D, Wu H, Shearer D, Hallan G, Gjertsen JE, Young S, Lau B.

Validation and Reliability of the Chichewa Translation of the EQ-5D Quality of Life Questionnaire in Adults with Orthopaedic Injuries in Malawi

Malawi Med J. 2017 June; 29(2):84-88

Background: Quality of life assessment is a useful addition to measuring functional and clinical outcomes of a health care intervention and can assist in resource allocation by prioritising those interventions that result in better quality of life. The EQ-5D-3L is a standardized instrument that measures health-related quality-of-life and explores cost-effectiveness of treatments.

The clinimetric properties of Chichewa version of the EQ-5D-3L developed by Europol group are not known. Psychometric evaluation ensures validity, reliability and responsiveness of the tool. The purpose of this study was to evaluate the clinimetric properties of the Chichewa EQ-5D-3L.

Methods: Fifty-three patients with various musculoskeletal problems from QECH, Blantyre Malawi, were administered the Chichewa EQ-5D-3L and WHOQOL-BREF questionnaires. Patients were recruited from Orthopaedic outpatient clinic and wards. To assess repeatability, a separate test-retest population of 20 patients were also selected from orthopaedic clinics and wards to fill out the questionnaires twice with a time interval of two weeks in between.

The health profiles from the descriptive system were converted to index scores, calculated using the Zimbabwean population–based time trade off (TTO) value set. The possible index scores range from -0.145 to 1.0 where negative values are equivalent to a health condition worse than death, 0 is death and 1 is the best possible health state Floor and ceiling effects, repeatability and construct validity for both the

descriptive index and the EQ-VAS were calculated. Internal consistency was evaluated for the descriptive index only as the EQ-VAS is just a single construct with no sub items.

Results: Convergence construct validity determined with each of the WHO-QOL-BREF domains and the EQ-5D Descriptive index and EQ-VAS with good to moderate correlation (r = 0.3-0.7). Internal consistency was measured for the Descriptive index and the Cronbach's alpha was 0.7. The ceiling effect for the Descriptive Index and the EQ-VAS were 9.4% and 0% respectively. No respondents reached floor effect for the descriptive index or the EQ-VAS. The test-retest intraclass correlation coefficient reliability at 14 days was 0.984 for the EQ-VAS and 1 for the Descriptive Index with all twenty respondents providing the same responses.

Conclusion: The Chichewa EQ-5D-3L version was found to demonstrate adequate validity, internal consistency, floor/ceiling effects, and reliability.

4.2 Paper II

Chokotho L, Lau BC, Conway D, Wu H, Shearer D, Hallan G, Gjertsen JE, Mkandawire N, Young S.

Validation of Chichewa Short Musculoskeletal Function Assessment (SMFA) Questionnaire

Malawi Medical Journal. 2019;31(1):65-70.

Background: The Short Musculoskeletal Function Assessment (SMFA) tool measures functional status in patients with musculoskeletal conditions. There are several non- English versions of the SMFA that have been cross-culturally adapted, but to our knowledge there is no Chichewa version of the SMFA adapted for the Malawian community. This study translated and culturally-adapted the SMFA into Chichewa, and assessed its clinimetric properties as complete adaptation of a translated tool requires that its clinimetric properties should be evaluated.

Methods: The English SMFA was translated to Chichewa using a multi-step linguistic validation method. The translated Chichewa-version was then administered to 53 patients with musculoskeletal disorders from orthopaedic outpatient's clinic and wards at QECH, Blantyre Malawi. The WHOQOL-BREF was also administered concurrently to assess convergent construct validity. To assess repeatability an additional 20 patients answered the questionnaire twice over a time-interval of two-weeks. Internal consistency, floor and ceiling effects, and repeatability were tested.

Results: The mean age was 36.5 years in the initial population and 43.4 years in the test-retest population. Eighteen (90%) of respondents in the test –retest population were males. The question on how difficult it is to open medicine bottles or jars was adapted because in Malawi medicines are dispensed in packets rather than bottles or jars. The respondents were asked to say how difficult it is for them to open other small bottles or jars. The question regarding driving a car was not applicable to 75% of all study participants. There was good internal-consistency for both Dysfunction and Bothersome indices (Cronbach's alpha 0.90) and good construct-validity between both indices with the WHOQOL-BREF. Pearson's correlation coefficient and Intraclass Correlation Coefficient (ICC) for repeatability for the Dysfunction Index were 0.941 and 0.922 (95% CI: 0.772, 0.971), and Bothersome Index was 0.877 and 0.851 (95% CI: 0.629, 0.941). The Bothersome Index had 9.4% (5/53) ceiling effects.

Conclusion: The translated Chichewa SMFA is a valid and reliable tool for measuring functional status in patients with musculoskeletal conditions in populations that Chichewa is the primary language.

4.3 Paper III

Linda Chokotho, Hao-Hua Wu, David Shearer, Brian C Lau, Nyengo Mkandawire, Jan-Erik Gjertsen, Geir Hallan & Sven Young

Outcome at 1 year in patients with femoral shaft fractures treated with intramedullary nailing or skeletal traction in a low-income country: a prospective observational study of 187 patients in Malawi

Acta Orthop. 2020 Jul 23:91.

Background: Intramedullary nailing, the gold standard treatment for femoral shaft fractures is underutilized in LICs where skeletal traction remains the standard of care for femoral shaft fractures. This prospective observational study compared patient-reported quality of life and functional status after femoral shaft fractures treated with IM nailing or skeletal traction in Malawi.

Methods: Adult patients aged 18 years or older with femoral shaft fractures (AO/OTA class 32), managed by IMN or skeletal traction were enrolled from six hospitals. Quality of life was assessed using EQ-5D-3L, and functional status using the SMFA. Patients were followed up at 6 weeks, 3, 6, and 12 months post injury.

Results: A total of 248 patients were enrolled (85 IMN, 163 skeletal traction), 187 (75%) completed one-year follow-up (55 IMN, 132 skeletal traction). There was 1case out of 55 with non-union for IMN compared to 40 (30%) out of 132 skeletal traction cases that failed treatment and converted to IMN ($p<0.001$). Quality of life and SMFA Functional Index Scores were better for IMN than skeletal traction at 6 weeks, 3 and 6 months, but not at 1 year. At 6 months, only 24 out of 51 patients in the skeletal traction group had returned to work, compared to 26 out of 37 in the IMN group ($p= 0.02$).

Conclusion: Treatment with IM nailing improved early quality of life and function and allowed patients to return to work earlier compared to treatment with skeletal traction. Approximately 1/3 of patients treated with skeletal traction failed treatment and were converted to IM nailing.

4.4 Paper IV

Chokotho L, Donnelley C, Young S, Lau BC, Wu H, Mkandawire N, Gjertsen JE, Hallan G, Shearer D.

Cost Utility Analysis of Intramedullary Nailing and Skeletal Traction Treatment for Patients with Femoral Shaft Fractures in Malawi

Manuscript submitted to Acta Orthopaedica

Background: A previous study done in Malawi showed that skeletal traction was more costly than IM nailing in the treatment of adult femoral shaft fractures. In Malawi, IM nailing has improved outcomes in the treatment of femoral shaft fractures compared to skeletal traction. We report the results of a cost-utility analysis (CUA) that compared treatment of adult femoral shaft fractures using either IM nailing or skeletal traction.

Methods: A CUA was done using a decision tree model from the government health care payer and societal perspectives and a 1-year time horizon. EQ-5D-3L utility scores and probabilities were obtained from a prospective observational study. QALYs were calculated from the utility scores using the area under the curve method. Direct treatment costs calculated using time and motion analysis were obtained from a prospective costing study. Outpatient costs associated with follow up visits were calculated. Indirect costs included patient lost productivity, patient transportation, meal, and childcare costs associated with hospital stay and follow-up visits. Multiple sensitivity analysis assessed the model's uncertainty.

Results: The total cost of treatment was higher in the skeletal traction group compared to IM nailing, $1,348.81 and $1,121.97 respectively. The QALYs for skeletal traction was lower than for IM nailing, 0.71 (95% Confidence Interval (CI): 0.66 – 0.76) and 0.77(CI: 0.71-0.82) respectively. IM nailing was the dominant strategy, based on lower cost and higher utility. Sensitivity analysis showed that IMN remained the dominant treatment method in 93.8% of the simulations. IM nailing was

less cost-effective than skeletal traction at a total procedure cost exceeding $880 from the payer perspective or $1,035 from the societal perspective.

Conclusion: IM nailing was a dominant approach being both cost saving and more effective than skeletal traction. Thus, treatment of femoral shaft fractures with IM nailing can be argued to be an efficient use of limited health care resources.

5. Discussion

5.1 Methodological Considerations

5.1.1. Linguistic Validation and Psychometric Evaluation

Translation of patient reported outcome measurement tools from source language to target language is important to ensure conceptual equivalence with the original tool and cultural relevance for the target population [78, 79,101]. The translation process involves looking at concepts in the source language that can be translated literally without losing their meaning, and those that need to be adapted to suit the cultural context of the target population. For instance, in translation of the SMFA, the question about how difficult it is to open medicine bottles or jars was not culturally relevant for the Malawian setting as medicines are dispensed in small plastic bags or packets, hence it had to be adapted to suit the context. Thus, translation of PROMS does not just involve simple word for word translation, but aims to achieve a balance between conceptual equivalence and cultural adaptation. The translation process needs to be thorough and transparent to ensure that any differences detected for a particular tool are not due to translation errors. However, there are no gold standard guidelines for instrument translation and as such varied methods are used. The International Society for Pharmacoeconomics and Outcomes Research (ISPOR) task force for Translation and Cultural Adaptation of PROM published the 'Principles of Good Practice' for the translation and cultural adaptation of patient-reported outcome measures [80]. They recommended a multiple step process of translation. Multiple step translation process also known as Linguistic Validation (LV) is also recommended by World Health Organization [81], and the Patient-Reported Outcome (PRO) Consortium [78]. LV was used to achieve a balance between conceptual equivalence and cultural relevance in the translation of the SMFA in our study. This methodological approach is more transparent as it provides clear documentation of all the steps used in the translation. Other methods of translation, are simple and time and cost saving [102], but are less transparent. Such methods include forward translation only, by one or more translators, or an expert committee that translates and then review their own translation or use a single peer review. In addition, such methods may be biased and may not be able to pick up vague or ambiguous expressions identified during pretesting or cognitive interviewing. Members of a committee translating a tool, may not give independent verification due to shared misunderstandings. Some may not feel free to criticize or correct each other thereby compromising validity. Back translation is commonly used in translation of tools. Maneesriwongul et al. (2004) reviewed translation studies and found that 38 of the 47 studies had used both forward and back translation method [102]. McKenna et al. (2005) criticized the back-translation step that it lacks scientific basis [103]. However, back translation is just one of the steps in the translation process and was never used alone in our study. One of the advantages of back-translation is that it allows comparison of the original source language version with the version which was back-translated into the source language. Such a comparison ensures that the instrument to be used in the target population is the same as the source language. In addition, back translation allows for cross-cultural comparisons which are limited in forward translation alone [102, 104]. Cognitive debriefing is one of the steps in LV method. During this step the translated questionnaire is administered to a small sample of patients from the target population or from the general population to assess clarity, comprehension, interpretability, and cultural relevance of the questions [80, 105]. Cognitive debriefing was also used in the translation of the SMFA, and the questions were adjusted accordingly. Thus, cognitive debriefing improved the validity of the Chichewa SMFA further. The multi-step approach that we used in our study, requires considerable financial and time resources, but has been found to be a more rigorous and valid method for cultural adaptation than other methods [80, 102]. Psychometric evaluation after translation showed that the Chichewa PROM used in this study were valid and reliable. Both linguistic validation and psychometric assessment are required in complete adaptation of a translated tool. Thus, we are confident that the translated tools in this study are conceptually equivalent to the English version, culturally relevant for the Malawian population, and are valid and reliable.

5.1.2. Use of PROMs as an Outcome Measure

Paper III used patient reported outcomes as the primary outcome measure to compare the effectiveness of IM nailing and skeletal traction in the treatment of femoral shaft fractures in adults. Previous studies that have compared the outcomes of IM nailing and skeletal traction have traditionally used conventional outcome measures assessed by the clinicians [52, 55-57]. Such outcome measures have included fracture union (clinical and radiographic) and complications after treatment. Hence conclusions on outcomes were made based on the clinicians' findings and assessment. However, such outcome reporting does not include what happens outside the clinical encounter, which in some instances is what matters more to the patients and their families [58]. There are other aspects of life that are affected by an illness or its treatment and the clinician's understanding of the impact on these aspects is limited. Only the patient can report how the illness or its treatment impacted his or her socioeconomic status, or psychological well-being, or activities of daily living. Thus, effectiveness of treatment is multidimensional and ideally should include assessment from both the clinician's and patient's perspective. Value based health care promotes maximization of value for patients. Value is defined as health outcomes that matter to patients and the associated costs used to achieve those outcomes [106]. Use of PROMs is therefore key in value-based health care delivery system. Combining both clinical and patient reported outcomes provides a more holistic assessment of the effectiveness of treatment. Most fractures are not life threatening and the goal of treatment is not to prevent deaths but to achieve healing as quickly as possible and to minimize disability so that a person can go back to his/her preinjury life. Even when clinicians assess fracture union after treatment, the implications of their findings are whether the patient is fit to go back to preinjury life or not. Thus, treatment of fractures aims to improve quality of life. Lack of disability and impact of treatment on quality of life are aspects that only patients can report [107].

One of the challenges that we faced during the study was the lack of adequate post treatment radiographs to assess radiological union using standard criteria. Most patients who came for follow up had only a single view radiograph, as it is common practice in Malawi for radiographers to take only one view. Further, quite a significant proportion of patients missed their follow up appointment (51% at 6 months) and therefore could not be assessed clinically to determine the outcome of treatment. Some of those who missed their appointments were followed up by telephone during which the EQ-5D-3L and SMFA were administered. Use of PROMs other than in research setting is still limited [58]. In a setting like Malawi where follow up rates are low and x-rays mostly not adequate, use of PROMs that include the mobility domain and other outcome measures such as activities of daily living, can give an indirect indication of fracture union depending on how these domains are affected. Therefore, use of PROMs, though not integrated in most clinical care settings, should be considered to be integrated in fracture care outcome assessment in low resource setting, where there are barriers for patients to come to hospital. Even when patients come for follow up, x-rays are not always adequate to make comprehensive assessment of fracture union. In such settings PROM can complement clinical assessment and help the clinician to determine whether treatment is being effective or not. PROMs can be administered either using a telephone for patients who are unable to report for follow up appointment or through direct interview in clinic. Use of PROMs to complement clinical assessment may also be explored for other conditions that impact quality of life not just in fractures. PROMs also limit observer bias [107]. Clinicians may have preferences when it comes to treatment methods and therefore have a biased assessment.

5.1.3. Use of a Prospective Observational Study to Assess Quality of Life and Functional Status

Quality of life and functional status were assessed using a prospective observational study in Paper III, as such assignment of treatment was beyond the control of investigators. Randomized Controlled Trials (RCTs) give the best quality evidence compared to observational studies as the randomization process eliminates selection bias and confounding by ensuring equal distribution of measured and unmeasured participant's characteristics [108]. RCTs are ideal for studies comparing the outcomes of different treatments, because in such studies, one would like to be more confident that any success or failure is attributed to the treatment alone and not any other factors. Theoretically, our study was suitable for RCT, patients would have been randomized to either IM nailing or skeletal traction. Such an approach would have optimized the benefits of randomization and minimized the risk of bias and confounding. However, our study was done in a limited resource setting where the majority of fracture patients are treated with non-operative methods because of limited surgical capacity. Thus, it would not have been possible that every patient randomized to the IM nailing group should have surgery. Hence, due to resource constraints, an RCT study design was not practical. Inability to conduct an RCT due to resource constraints may partly explain why more than eighty percent of clinical trials are done in HICs [109, 110]. We therefore opted for an observational study, to ensure that the study did not disturb or put extra work on the system in any way but rather following the already established routine of treatment assignment by clinicians in the participating hospitals. There was therefore some inherent bias, due to the nature of the study design. We adjusted for the measured confounders using regression analyses, however residual confounding was likely present as it was not possible to adjust for unmeasured confounding. Information bias can result if measurement of outcomes of interest is done differently in the two groups, or there are disparities in accessing other treatment that may affect outcome. All data collectors in the study underwent training to ensure standard administration of both questionnaires in both groups, thereby reducing information bias. In addition, all patients had similar post-operative rehabilitation, so there was no differential treatment which may have confounded the outcome results. In this study we minimized loss to follow up by active tracing of participants if they missed their appointments. There were still some patients who could not be traced, but there was no difference in the loss to follow up between the study groups.

5.2. Discussion of Results

5.1.1. Paper I and II

The psychometric evaluation of the Chichewa versions of both the EQ-5D-3L and SMFA found that both tools were valid and reliable. Our findings for both tools compare satisfactorily with other validation studies. Garcia-Gordillo et al. (2015) in their study of validation of the Spanish EQ-5D-3L found 13.5% ceiling effects and 0.8% floor effects for the descriptive index [111]. These findings compare satisfactorily with our results of 9.4% for ceiling effects and no floor effects. The Cronbach's alpha of ≥ 0.70 signifying a good internal consistency of the Chichewa version was also reported by Tripathy et al. (2015) in their validation of the Odi EQ-5D-3L in India [112]. However, they reported lower repeatability correlation coefficients compared to our study when the questionnaire was administered 2 weeks apart. The correlation coefficients were 0.72 in general surgical patients and 0.55 in cancer patients compared to 1 in our study for the same duration of time in between questionnaire administration. This difference could be due to differences in patient population and nature of disease, as their study recruited admitted cancer patients and general surgical outpatients with varying surgical conditions. The validation results for the Chichewa SMFA indices are consistent with original validation study by the developers of the questionnaire [73] as well as several translated versions of the SMFA [113-115]. Consistency of scores over time or repeatability assessed using intraclass coefficient compared satisfactorily with the validation of the Portuguese, Swedish and Dutch versions [113-115] even though the time in between questionnaire administration ranged from 7 days to 1 month in these studies. Our study found 9.4% ceiling effects for the Bother index only. Lack of ceiling effects for the dysfunction index of the SMFA and minimal ceiling effects for the bother index has also been reported by Swiontkowski et al. (1999) in the initial validation of the SMFA [73]. Minimal ceiling effects for the bother index only could be explained by the fact that most of our patients were recruited from outpatient orthopaedic clinics and some of them may have been coming for review having been healed. However, since we did not record the duration of symptoms, this proposition could not be confirmed. The question regarding driving a car was not applicable to 75% of our patients because they did not know how to drive a car. We did not remove the question but rather replaced the missing values with the individual's mean score for that category as recommended by Swiontkowski et al. (1999) [73].

Validity of the translated tool is key to ensure that the instrument measures what it is supposed to measure. In our study there was good construct validity of the Chichewa SMFA as it correlated well with the WHOQOL-BREF general health score. However, there was a moderate correlation with the psychosocial domains, a finding that was also reported by the Swedish, Portuguese and Dutch validation studies with SF-36 questionnaire for both dysfunction and bother indices [113-115]. Good and moderate correlation with the WHOQOL-BREF general and psychosocial domains respectively, suggests that the Chichewa SMFA can be used to measure the general health of a patient but may not be a valid tool to specifically assess psychosocial aspects of health. Convergent construct validity of the Chichewa SMFA was assessed by correlation with the WHOQOL-BREF questionnaire only. Other measures of assessing convergent construct validity such as subjective rating of patient's function by an orthopaedic surgeon, clinical measurements and analysis of potential confounders of function were not assessed in this study. Ponzer et al. (2003), compared patient reported outcome measures with clinician's ratings and found weaker associations than when comparing indices from different PROM tools [113]. The lack of strong associations was attributed to different data collection methods. Swiontkowski et al. (1999) reported varying results between SMFA indices and clinical measures of patient function, with some measurements being significantly correlated with the SMFA indices while others had no significant correlation [73]. Discriminant construct validity where patients with different levels of baseline overall health status are expected to have significantly different SMFA index scores was also not assessed in our study. Both convergent and discriminant validity are important in establishing excellent construct validity. Furthermore, we did not assess responsiveness of the tool i.e. ability of the translated tool to detect clinical change as we did not collect information on baseline and follow up health status as perceived by the patients which then could be correlated with the SMFA scores at baseline and follow up. Hence, we cannot make any statement about the responsiveness of the Chichewa SMFA.

Translation is just one of the steps in development of a target language PROM. There is need for psychometric evaluation of the translated tool to assess responsiveness, internal consistency of the items, validity and reliability. McKenna et al. (2005) emphasizes that it is not good practice to assume that the translated version has the same psychometric properties as the source version [103]. Thus, the Chichewa versions developed in our study were fully adapted for use in relevant setting by including the psychometric assessment.

Notwithstanding the limitations of our studies, the two validation studies found that both the Chichewa versions of the EQ-5D-3L and the SMFA are stable and valid tools that can be used to measure quality of life and function respectively in populations whose main language is Chichewa. This is an important finding as these tools can then be used in other studies in Chichewa speaking populations. Results from any future studies using these tools can be compared with results from other languages using the same tool.

5.1.2. Paper III

The study found significantly better early quality of life and function and earlier return to work in patients treated with IM nailing compared to those treated with skeletal traction. However, there was no significant difference in quality of life and function at one-year post injury. Approximately a third of the patients treated with skeletal traction had treatment failure and needed IM nailing. These patients would have experienced a poor outcome at 1 year if they had not been treated with IM nailing. Hence the conversion resulted in a biased estimate towards the null hypothesis of no difference between the 2 groups. However, despite this considerable bias, IM nailing was still associated with better quality of life and function than skeletal traction at earlier time points.

Earlier improvement in quality of life and function has significant implications in a country like Malawi where 89% of those employed in the working age population are in informal employment with no access to employment benefits or any social protection [116]. They are only able to get income when they are physically present at work. In our study the majority of patients with femoral shaft fractures were in the economically active age group (median age 37 years in both groups). Thus, even though the function and quality of life were comparable at one year, IM nailing is the better option as it has the potential of averting the problem of loss of income due to prolonged absence from work or other income generating activities for both the patients and their families. Furthermore, the hospital stay and the suffering is shorter.

The finding that thirty percent of skeletal traction patients converted to IM nailing, highlights the lack of operative fracture care in Malawi. There is clear evidence that operative treatment produces better results than non-operative treatment for femoral shaft fractures [38, 41, 52, 56, 57, 117]. However, the majority of patients are still offered the inferior treatment method initially because of limited surgical capacity. Only when the inferior method fails, are they offered operative treatment. Sub optimal treatment of fractures in most LMICs results in avertable DALYS being incurred as a result of poor quality of life and functional outcomes. Stewart et al. (2016), found that lower extremity fractures accounted for 51% and 59% of all DALYS in Sierra Leone and Nepal respectively [118]. They further projected that a total of 4.5 million avertable DALYS will be incurred in these two countries by 2025 if fracture care capacity is not improved.

Our study is the first to compare quality of life and function of patients with femoral shaft fractures treated with IM nailing and skeletal traction. Previous studies compared clinical outcomes between these two treatment modalities and found increased union rates, less deformities, and better knee range of motion in patients treated with IM nailing than skeletal traction (52, 56, 57). The main strength of this study is that it was patient-centered rather than disease-centered, in that it assessed patient reported outcomes. Problems that persist after treatment of a fracture may not be captured by assessment of clinical outcomes alone such as fracture union, joint range of motion or presence or absence of malunion. Furthermore, diseases do not occur in a vacuum and therefore assessment of clinical outcomes alone does not include how a patient's social, psychological and physical life is affected by the disease or its treatment. Thus, using patient reported outcomes ensured that issues that are important to patients were less likely to be overlooked. Use of patient reported outcomes also help base treatment on patient's priorities and preferences [119]. However, PROMs are not a substitute for clinical outcome assessment, but rather supplementary, as the additional information that they provide is what is important [119]. The limitations of this study are discussed in full in paper III (Section 9.3).

In summary this study found that IM nailing in adult femoral shaft fracture patients resulted in better quality of life and functional outcomes than skeletal traction.

5.1.3. Paper IV: Cost-effectiveness results

This study found that treatment of adult femoral shaft fractures with IM nailing was more cost-effective than with skeletal traction in Malawi, from both the government health care payer and societal perspectives. IM nailing was both cost saving and more effective. Furthermore, the sensitivity analysis showed that there was more than 90% certainty that this conclusion is true and also that this conclusion will remain true if the total cost of IM nailing is less than $880 from the payer perspective or $1,035 from the societal perspective. Modification of the parameters in the model had little impact on the cost-effectiveness of IM nailing, showing that the model was stable.

IM nailing is the gold standard treatment for femoral shaft fractures in HICs, with excellent union rates and limited complications. Choosing the best treatment for femoral shaft fractures should not only consider effectiveness, but also costs. Our results are consistent with what other studies have found regarding IM nailing being more cost-effective than skeletal traction in other LMICs in Africa and Asia [52, 56, 57]. The findings of this study also support the existing body of knowledge that surgery is cost-effective even in resource limited settings [120].

This is the first study that has assessed cost per QALY gained in the treatment of adult femoral shaft fractures using IM nailing and skeletal traction. There is no cost-effectiveness threshold (CET) established for Malawi, i.e. the maximum amount that the government or society would be willing to pay for an intervention, that will result in an incremental health gain [121]. CET helps to determine whether adopting an intervention that gives additional health gains at additional costs represents good value for money. The World Health Organization (WHO), recommends a threshold of one to three times a country's annual gross domestic product (GDP) per capita [122]. However, others have criticized the use of annual GDP per capita as CET because they do not include opportunity costs of funding a particular intervention at the expense of the other [123, 124]. A previous study estimated CET of $61 per DALY averted for Malawi [124]. Woods et al. (2016), estimated the CET for Malawi to be $3 to $116 (1% - 51% GDP per capita) per QALY gained [125]. Since IM nailing is both cost saving and more effective, it is explicitly cost-effective and therefore good value for money. The cost saving of IM nailing compared to skeletal traction could partly be explained by the reduced expenditure associated with reduced hospital stay both from the payer and societal perspectives.

The results of this study highlight the need to consider prioritization of IM nailing as the first-choice treatment for femoral shaft fractures in adults. Prioritizing and increasing access to IM nailing will require improved surgical capacity. Such a change will require a budget impact analysis (BIA), to assess affordability by estimating the total budget required to adopt a new intervention from the payer's perspective [126, 127]. In addition, all relevant benefits associated with choosing IM nailing as first line treatment over skeletal traction should also be evaluated. BIA also takes into consideration the size of the population that will benefit from the new intervention there by addressing equity issues.

The gap between cost-effectiveness and affordability presents a major challenge in a low-income country like Malawi. With a total health expenditure of only $32.26 per capita as of 2017 [128], substantially lower than the SSA average of $83.6 and the global average of $1,061.15, health budgets are not large enough to fund all cost-effective interventions and related expenses. The total health expenditure is also much lower than WHO recommended $86, which is considered the minimum necessary per capita investment to provide basic health services [129]. Even high-value "cost-effective" programs may require more resources than are available in a given budget [127]. This seems to be the case with Malawi. Despite the fact that this study has shown that IM nailing is more cost-effective, there is need for more resources than the health budget can accommodate, making universal access to operative fracture care treatment for all eligible patients improbable in the near future. Malawi's Total Health Expenditure (THE) was 9.65% per GDP as of 2017, lower than 12.49% for HIC [130] and is projected to be almost the same in 2040 [131]. In a setting with such constrained health budgets and rising health care costs, IM nailing has the potential to save costs while at the same time improving the clinical outcomes for femoral shaft fracture patients. Furthermore, the estimated cost of IM nailing in this study included the cost of the SIGN nail implant. Currently SIGN International provides the implants at no cost to hospitals in many LMICs, including Malawi. Thus, in reality the cost of the IM nailing procedure is lower than what has been estimated in this study. This arrangement provides a window of opportunity as the cost savings by the payer can be used to improve other components of surgical capacity.

Some policies have argued that it is more important to achieve equity by providing slightly less effective medical interventions at significantly lower cost, thereby enabling effective treatment for a wider population [132]. Even though skeletal traction treatment is more accessible by the wider population, it is more expensive and less effective with approximately a third of patients having failed treatment. It is therefore counterintuitive to the policy of equity and maximizing populations' health outcomes under a restricted health budget.

There are several factors that play a role in budget allocation, such as political, social or cultural and affordability factors [127]. Hence, cost-effectiveness analysis findings cannot be used as the only determinant to make a decision on resource allocation in health care, but rather as one of the factors in the decision-making process. Nevertheless, we hope that the results of this study will inform policy makers and increase political will, in government, with other stakeholders and development partners, to improve surgical capacity by dedicating resources so that patients with femur shaft fractures in Malawi will be treated with IM nailing, rather than skeletal traction.

5.3 Implications of the study's findings on delivery of fracture care services in Malawi

In Malawi, conservative treatment as a primary option is also used to treat other fractures that are primarily treated with surgery in HICs. The Lancet commission on global surgery estimated that 5 billion people globally have no access to safe and affordable surgical and anesthetic care when needed. Furthermore, in LMICs, 90% cannot access basic surgical care [133]. Surgical capacity is dependent on a balance of several factors grouped in the categories of personnel, infrastructure and equipment (Figure 11).

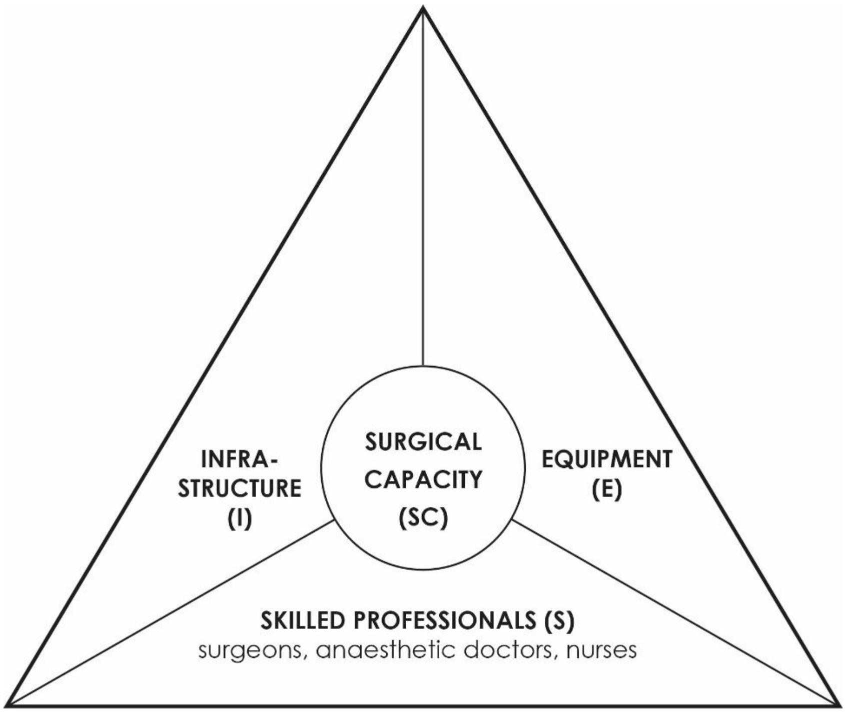

Figure 11: Surgical capacity depends on a balance of several factors. (Diagram: Gemma Teal)

Lack of one or more of these factors will result in limited surgical capacity, hence no single intervention will solve the problem. For instance, training more surgeons without increasing procurement of implants, training more anaesthesia providers, and building more theatres is unlikely to improve access to surgical fracture care. Similarly, improvements in infrastructure, equipment and human resource with no improvements in access to the services, will still result in reduced number of fracture patients being treated by surgery (Figure 12).

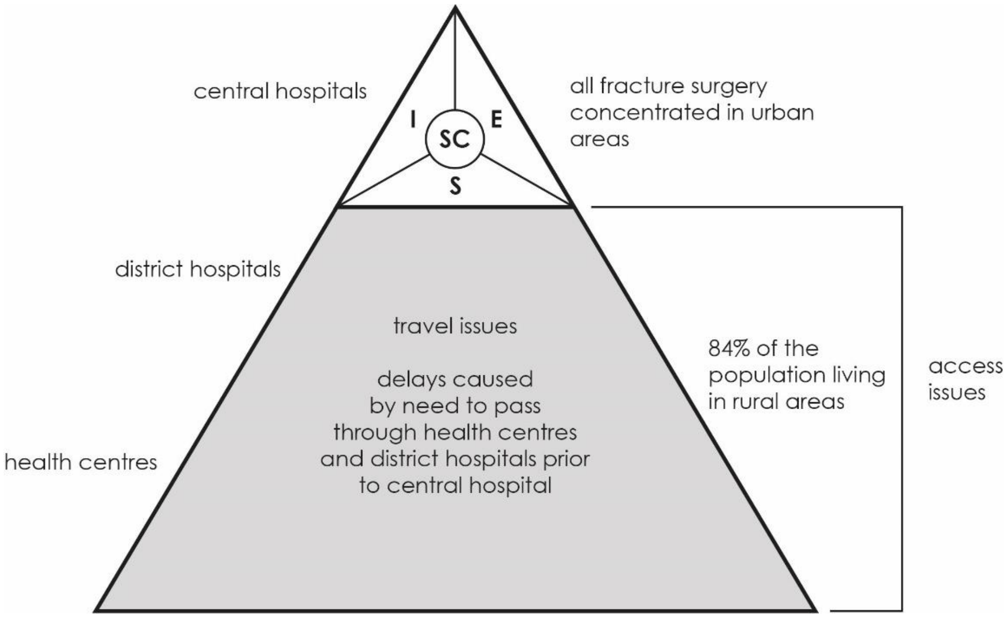

Figure 12: Surgical Capacity and Access to Care, Problems in the Current Health System. I –Infrastructure, E-Equipment, S-Skilled professionals, SC-Surgical capacity. (Diagram: Gemma Teal)

There is need for a multi-initiative approach where several initiatives run at the same time in order to be effective and exert an impact. The Ministry of Health with its stakeholders need to work together in this multi initiative approach to improve access to IM nailing for patients with femoral shaft fractures.

Due to the limited surgical capacity, fracture care services are quite centralized with no fracture care services in primary health facilities and operative care almost exclusively in tertiary care facilities (Figure 13).

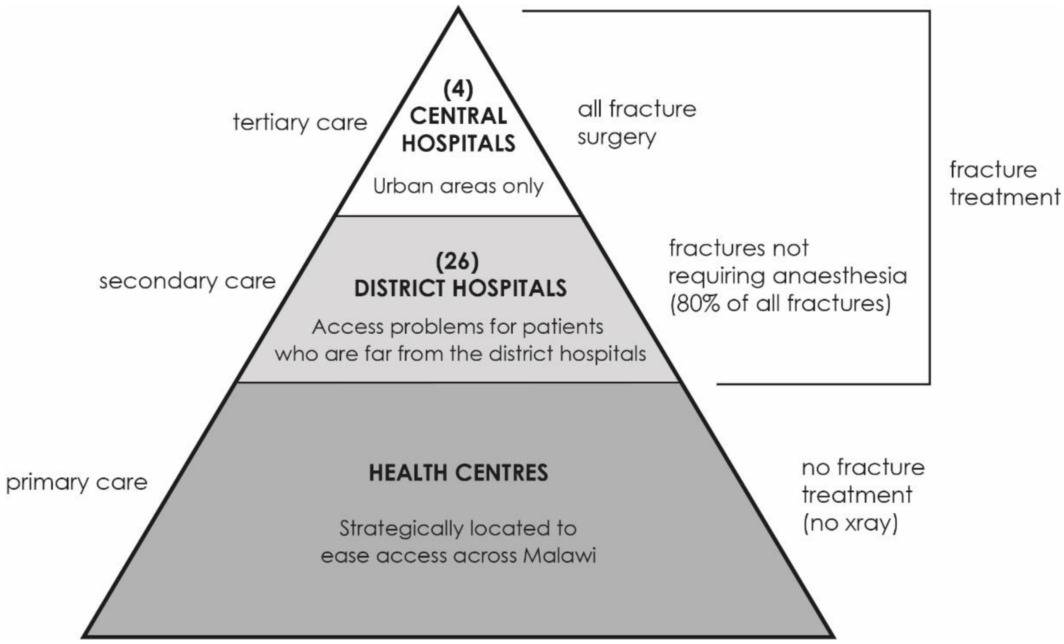

Figure 13: Current health system in Malawi, Centralized fracture treatment (Diagram Gemma Teal)

This creates a problem with access to these services as 84% of the total population in Malawi is rural [84], but operative fracture care is only offered in the urban referral facilities necessitating that patients travel a long distance to access these services. Thus, surgical care of fractures is very hard to reach for at least 84% of the population. In Sub-Saharan Africa, surgical care is not available at an accessible primary care facility for 80% of the population [134].

The key question that needs to be addressed is what is the best way of meeting the needs of our fracture patients and the wider population? The challenge is to find a solution that will ensure delivery of good quality and equitable distribution of fracture care services in Malawi. This calls for balance between two seemingly competing models of fracture care delivery, namely the development of a critical mass of specialists in tertiary facilities and decentralization of fracture care services. Both care delivery models have a role to play and should complement each other for effective and efficient delivery of quality and equitable fracture care in Malawi. Thus, the aim of bringing fracture care services closer to the people where the need is greatest needs to be balanced against the need to develop a critical mass of specialists in central hospitals as centres of excellence for teaching and research.

Development of Critical Mass of Orthopaedic Specialists in Central Hospitals

In capacity development, critical mass usually refers to the number of trained people needed to achieve a particular objective [135]. Developing a critical mass of specialists in central hospitals has several advantages. Firstly, it will ensure sustainable training of orthopaedic specialists and delivering specialist complex fracture surgery. Secondly, it will allow efficient division of labour among the specialists such that there is adequate time to do both clinical and research work. In addition, such a model has the potential of pooling of data, knowledge and ideas from the affiliates [136] resulting in a strong collective voice to influence policy changes. Centres of excellence with a critical mass of expertise delivering comprehensive world class care resulting in the best patient outcomes possible have been reported in HICs. However, such a model may face challenges to deliver both quality and equitable fracture care services in LICs like Malawi. Studies from HICs have shown that an orientation towards a specialist-based system enforces inequity in access to care [137]. Adopting care models which have been shown to be effective in one setting without a clear understanding of the context and health system dynamics can produce unintended consequences [137]. There is therefore need to create an enabling environment for critical mass development to be efficient and effective. Allocation of workforce is one of the issues that needs to be considered in trying to improve fracture care delivery using either model.

There are 14 orthopaedic surgeons in Malawi for a population of 17.5 million representing 0.08 per 100,000 population. High income countries have orthopaedic surgeon’s density ranging from 8-20 per 100,000 population [138]. In order to reach 5 orthopaedic surgeons per 100,000, Malawi will need 875 practicing orthopaedic surgeons. Orthopaedic postgraduate training started in 2003 and as of September 2020, there have been 9 graduates. At this rate it will take 1,552 years to get the number of required surgeons, not considering, retirement, deaths, migration to other countries and other causes of attrition. If we aim to get 5 graduates per year it will take 175 years. Thus, the average number of graduates per year has a bearing on how long it will take to achieve a critical mass of specialists in central hospitals or decentralize services to lower level facilities.

Adequate infrastructure is another issue that needs to be considered, and theatre density is one of the important factors. The functional operating theatre per population was estimated at 0.98 per 100,000 population (0.37 for central hospitals and 0.86 for district hospitals) in Malawi in 2014 [139]. These figures are way below the global average of 6.2 per 100,000 population, and the average of 16.9 per 100,000 for HICs, but close to 1.0 -1.2 per 100,000 population estimates for Sub Saharan Africa [140]. These numbers may have changed due to some improvements in operating theatres infrastructure in the central hospitals, but the situation is likely the same in district hospitals. A pool of specialists in excess of what the available infrastructure is capable of handling will not improve access to surgical care [141]. Thus, some unmet surgical need may be due to too few operating theatres which are unlikely to meet the surgical needs of the population even in the presence of critical mass of specialists.

There is also need to ensure availability of supporting services such as laboratory and radiological investigations and other services befitting a centre of excellence, and accessibility of such services by the rural majority. A LIC like Malawi might need to adapt the critical mass model by identifying the minimum number of specialists necessary and limiting growth centrally beyond what is needed considering the resource constraints [136].

Critical mass development has potential to improve the quality of tertiary care for patients presenting to the tertiary institutions and may establish themselves as centre of excellence for teaching and research. However, it remains to be established whether such a model will improve the outcomes of the majority of patients with fractures who do not have access or have limited access to these centres. A decentralized model for fracture care may actually be more efficient and effective in meeting the needs of the wider population. [142]

Decentralization of Fracture Care Services

Once training institutions are well established to secure continuous education of new specialists, the long-term plan in improving access to both surgical and non-surgical fracture care should include decentralization of these services. Decentralization of care is the process of transferring authority, services, and decision-making power from central governance facilities to lower management levels [143]. Decentralization will allow equitable redistribution of services and improve access for the majority rural population. Such a system will ensure that health care services are closer to the people that may have barriers to access the services otherwise. Decentralization has been shown to improve access to Human Immunodeficiency Virus (HIV) and Tuberculosis (TB) care services by reducing travel time to the facility for rural patients, resulting in improved outcomes and mortality rates [144]. Studies have also shown improved patient level outcomes with decentralization of surgical obstetric care to district hospitals and health centres [144]. Decentralization is likely to improve access to services, but in order to improve clinical outcomes there is need to improve infrastructure, human resources and equipment. A systematic review of decentralization or regionalization of surgical care showed that studies that reported negative results after decentralization of surgical care, had focused on workforce training only and had not included improvement of infrastructure to support surgical procedures and continuous training to maintain surgical skills [144].

Figure 14 illustrates some of the proposed solutions that will ensure decentralization of fracture care, thereby improving access and likely to improve clinical outcomes in the long term.

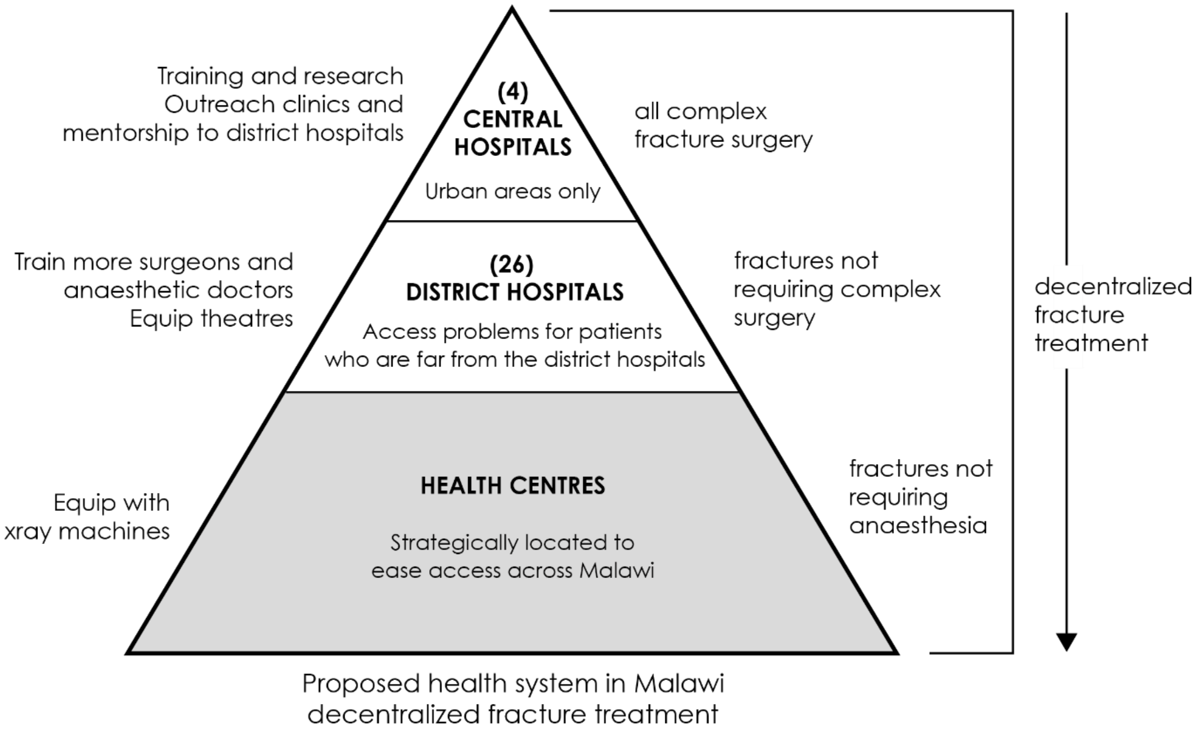

Figure 14: Proposed Decentralized Fracture Treatment in Malawi (Diagram Gemma Teal)

Both health centres and district hospitals serve the rural population which is 84% of the total population. District hospitals are the first level where fracture care is offered. The majority of fractures managed at the district hospitals do not need anaesthesia [88]. There is need for the government to invest in primary care facilities to improve access to fracture care. If the health centres can be improved through provision of x-ray machines and radiographers, basic training of medical assistants on how to diagnose and manage closed undisplaced fractures, and which fractures to refer to district hospitals, then most of the cases managed without need for anaesthesia at the district hospital will be seen in the health centres. The x-ray machines should be custom made to match the needs and constraints of a rural context as recommended by World Health Organization [145]. These modifications include use of rechargeable batteries and solar energy in areas where electricity is limited or not available. Mock et al. (2015), recommend that fractures that do not need anaesthesia should be treated at a primary level facility [146]. Such an initiative will offload the district hospitals, and allow people to access the services nearest to their homes.

Varela et al. (2019), reported transportation barriers to access health care at secondary level facilities in Malawi, with 38.8% of the male and 55.3% of the female head households reporting lack of money to go to the district hospital when a member of the household was sick [147]. There are 413 government health centres in Malawi [85], so such an initiative will require both financial and human resource investments. A situational analysis, economic evaluation and budget impact analysis will establish whether such an initiative will be more cost-effective and affordable than the current care delivery system. In addition, it will provide a roadmap of how to achieve value-based fracture care delivery system with focus on maximizing patient's outcomes and the related costs of achieving the outcomes [106].

In most district hospitals there is one theatre where all surgical procedures are done, and this is therefore not ideal for fracture surgery as combined use with contaminated cases increases risk of fracture infection post-surgery. However, as more and more surgeons are being trained in Malawi, and there is build-up of an adequate critical mass of surgeons at the central hospitals, there will be need to decentralize some of the fracture surgery to district hospitals. This can maximize theatre time for the surgeons, reduce competition for limited resources at the referral centres and potentially reduce the long waiting periods for patients both at the district and central level. Hence the need to improve the theatre infrastructure as well as equipment in these facilities in the long term. In addition, with minor fractures being managed in health centres, the district hospitals will have more ward and clinic space to manage surgical cases.

Iverson et al. proposed three factors that need to be considered in the redistribution of surgical care, namely: acuity, surgical volume and complexity of the condition [144]. Acuity refers to how much care and skills are needed to manage a particular condition. High acuity conditions should not be managed at low-level facilities. Surgical volume refers to how prevalent the condition is, and low prevalence complex conditions are better managed in high level or tertiary facilities. Finally, procedures that will require highly specialized technical skills and resources should only be managed at a tertiary level. Simple fractures that do not need anaesthesia, have low acuity, are highly prevalent and are not complex, and so meet the criteria for decentralization. Some fractures such as supracondylar fractures in children, extraarticular wrist and forearm fractures in adults, ankle fractures, and tibia shaft fractures have relatively low acuity, are quite prevalent, and do not require complex technical skills. These can be done by orthopaedic surgeons in district hospitals if theatre infrastructure and equipment is improved. In addition, there is need to improve living and working conditions for specialists in rural areas so that they are encouraged to work in these facilities. Such an initiative, will make it possible for decentralization of surgical fracture care.

The disparity in the number of surgeons between rural and urban areas in most LICs [148], including Malawi where currently all orthopaedic specialists work in the cities, is often raised as a problem in itself. However, in a country with a poorly developed health system, this is in many cases a necessary step on the way to a fully integrated health system. The situation is often prolonged by the common practice for surgeons in teaching centres to subspecialize in a particular area, narrowing their scope and increasing the perceived size of the needed critical mass centrally. Subspecialties are mainly required at tertiary facilities. In as much as subspecializing is important in raising the quality of care even higher in HICs, general orthopaedic surgeons are more likely needed in a low-income country like Malawi to meet the needs of the general population and address the inequity in access to services, in the long term.

Seventy percent of all services offered at the tertiary facilities in Malawi are for conditions that can be treated at the health centres and district hospitals [85]. Though this is likely to be considerably less for orthopaedic surgery, decentralization of fracture surgery in the long term will offload the tertiary facilities so that they are able to handle mostly the cases that strictly need tertiary care. In addition, access to fracture surgery will improve for the majority rural population. Expanding fracture care services to primary and secondary facilities also has potential to reduce the need for complicated specialist procedures in tertiary facilities done on neglected fractures or complications of conservative treatment. There is also potential to reduce disability that results due to delayed presentation.

The Future of Fracture Care in Malawi

Both critical mass and decentralization models are necessary ingredients for delivery of quality and equitable fracture care in Malawi. Improvement of critical mass without decentralization of fracture care services will result in tertiary centres managing cases that could be managed in lower centres, putting strain on its resources and unable to concentrate on its other mandates of teaching and research. On the other hand, decentralizing fracture care services without improving surgical capacity at the central hospitals will compromise training and quality of care for fractures and other conditions that need tertiary level management.

There is need to redesign fracture care delivery in Malawi to ensure improved outcomes and equity. This will likely require new resources, but also restructuring, redistribution and reallocation of the already available resources. Effective change requires a vision of where we want to go and what we would like to achieve. It will take years to reach the goal, but at least we will be moving in the right direction. The scale up ladder (Figure 15) portrays the proposed steps that need to be taken to reach our goal.

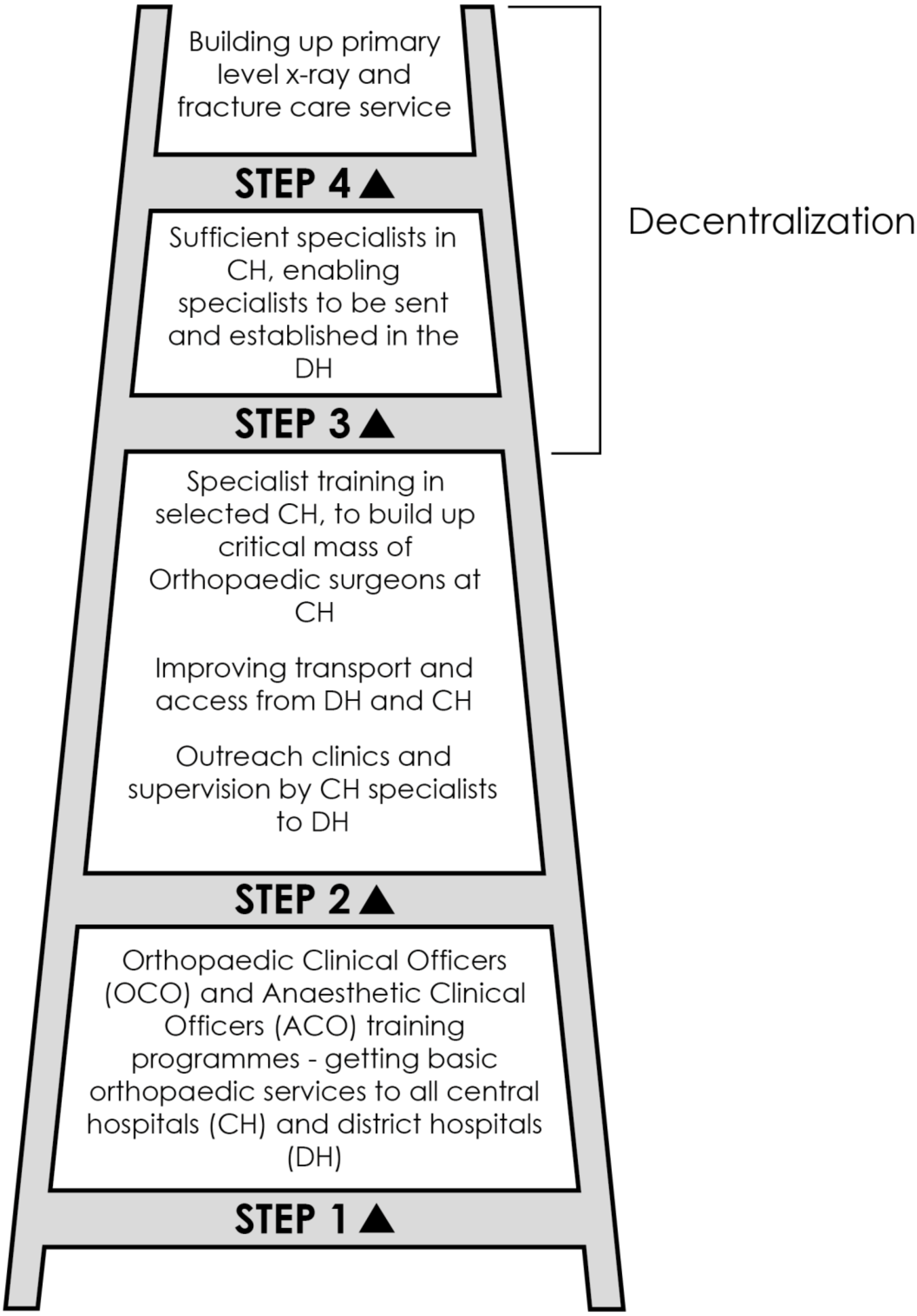

Figure 15: A Scale up Ladder with proposed steps to achieve quality and equitable fracture care delivery in Malawi (Diagram Gemma Teal)

However, establishing a fracture care service that is both high quality and equitable is an enormous task that requires a comprehensive situational analysis of all components of surgical capacity and current care delivery systems. A situation analysis will identify the unmet need, available resources and evidence base to inform decisions regarding either model. An understanding of the situation will help in making realistic and feasible recommendations likely to make each model of care delivery effective and efficient. It is therefore beyond the scope of this thesis to set timelines as to when these models should be implemented and what exact changes need to be made for these models to be effective. Furthermore, these recommended models of fracture care delivery may provide only a partial solution to the current state of care delivery. However, even such partial solutions may be worthwhile if they have the potential of improving quality and making fracture care services equitable.

6. Conclusions

6.1. Paper I and Paper II

Both the Chichewa EQ-5D-3L and the SMFA are valid and reliable tools that are conceptually equivalent to the respective English versions. They were found to be culturally relevant to the Malawian population, such that they can be used to assess quality of life and musculoskeletal function in Chichewa or Chinyanja speaking populations. In addition, results obtained from such studies can be compared with similar studies that used the English versions.

6.2. Paper III

Treatment with IM nailing improved early (≤ 6 months) post-operative quality of life and function and allowed patients to return to work earlier compared to those treated with skeletal traction. Treatment of femoral shaft fractures with skeletal traction in a resource-limited setting may achieve similar outcomes as IM nailing in quality of life and function at one-year post injury if fracture union is achieved. However, approximately one in every three patients treated with skeletal traction failed treatment requiring conversion to surgical treatment with IM nailing.

6.3. Paper IV

IM nailing is both cost saving and more effective as compared to skeletal traction in the treatment of adult femoral shaft fractures in Malawi. Transition to IM nailing when staff numbers and infrastructure allow is likely to be a more efficient use of the limited health care resources. There is need to advocate for improved surgical capacity in the public hospitals in Malawi to ensure universal access to IM nailing of femoral shaft fractures for eligible patients.

7. Future Areas of Research

Situational Analysis of Fracture Care Services in Malawi

Effective planning and implementation of initiatives that will lead to improved fracture care in Malawi requires an understanding of the current situation of the care delivery system in Malawi. There is therefore need for situational analysis studies to understand the burden and epidemiology of fractures in Malawi. To assess the capacity of the health system to deliver adequate fracture care, one option is to use the personnel, infrastructure, procedures, equipment and supplies (PIPES) tool [149]. The PIPES tool has been validated and found to be a useful tool to assess surgical capacity [150, 151]. However, some studies have found the tool's reliability for equipment and supplies to be poor and not very comprehensive when used in isolation [150, 152]. There is therefore need to combine this with other methods to get a complete picture of surgical capacity in Malawi. In addition, a situational analysis needs to assess the performance of the current care delivery system, with all its strengths, weaknesses opportunities and threats, including their root causes and effects [153]. Such a situational analysis will establish an evidence base that will serve as a basis for planning and formulating policies that are likely to improve fracture care in Malawi. There are already some studies that are ongoing to help with understanding of the fracture care situation, but there is need for coordinated efforts with the Ministry of health, academic institutions, and other relevant stakeholders to ensure that the results from such studies will translate into action.

Clinical Outcomes and Quality of Life studies

Fracture care in limited resource settings does not always follow the evidence based recommended guidelines that are used in HICs. Challenging environments can stimulate innovations and new working practices, which in turn may improve quality of service to patients and reduce costs, but there is need to evaluate such working practices to ensure that we are providing the best care possible resulting in best outcomes to the communities that we serve. There is a dearth of clinical outcomes and quality of life studies available to assess the effectiveness of the treatment modalities that are used in our setting and their associated costs. Findings from such studies will determine which treatment modalities represent best value for money and should therefore be prioritised to maximise patient's health. Research of this type will form the essence of value-based fracture care which focuses on improving outcomes of patients relative to costs of achieving the outcome [154]. In addition, measuring and reporting outcomes will help to develop standards or guidelines and implement best practices which will further improve clinical care and outcomes. Thus, we need studies to measure and report outcomes and the associated costs for common fractures such as open tibia, ankle, and forearm fractures, supracondylar humerus fractures in children etc. Using both patient reported outcome measures and clinical assessment in these studies will ensure maximising value for the patient.

Pilot Studies

Fracture care delivery in Malawi is centralised with no provision of fracture care in health centres and operative fracture care only offered in central hospitals. Such a centralised system results in access problems for the rural population which comprises 84% of the total population. Decentralisation of fracture care to health centres and district hospitals is likely to improve access for the rural majority. There is need for a pilot study to assess the feasibility and impact of a proposed decentralised fracture care delivery system in Malawi. The pilot study will identify resources needed, enablers and barriers to successful implementation, and also assess clinical and quality of life outcomes. The evidence generated from the pilot study will inform future developments in achieving the goal of quality and equitable fracture care in Malawi.

Rehabilitation after fracture treatment is important to improve function and minimize disability. Currently femoral shaft fracture patients who have undergone surgery at the central hospital spend at least a week post-surgery to attend physiotherapy before being discharged to their homes. They are then given a follow up date to come back to the central hospital both for clinical review and further physiotherapy. However, most of these patients are referred from a district hospital that is closer to their home than the central hospital. Hence, most have problems with transport to go back to the central hospital, and sustainability of care becomes a problem. Developing post-operative care protocols that will allow clinical review and rehabilitation after surgery in a facility that is as close to home as possible is likely to improve access and sustainability of care. Such protocols may include establishment of short stay admission at the central hospital where they will be operated as soon as possible after admission, and then sent back to the referring district hospital for post-operative rehabilitation and further clinical review if there are no complications. A pilot study to assess the feasibility of such protocols and impact on outcomes will provide evidence to support implementation of the protocols or otherwise.

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9. Papers I-IV

9.1 Paper I

Chokotho L, Mkandawire N, Conway D, Wu H, Shearer D, Hallan G, Gjertsen J, Young S, Lau B. Validation and reliability of the Chichewa translation of the EQ-5D quality of life questionnaire in adults with Orthopaedic injuries in Malawi. Malawi Med J. 2017 June; 29(2):84-88.

Original Research

Validation and reliability of the Chichewa translation of the EQ-5D quality of life questionnaire in adults with orthopaedic injuries in Malawi

Linda Chokotho[1,2], Nyengo Mkandawire[3], Devin Conway[4], Hao-Hua Wu[4], David D. Shearer[4], Geir Hallan[5], Jan-Erik Gjertsen[2,5], Sven Young[5,6], Brian C. Lau[4]

1. Beit CURE International Hospital, Blantyre, Malawi
2. Institute of Clinical Sciences and Centre for International Health, University of Bergen, Bergen, Norway
3. Department of Orthopaedic Surgery, Queen Elizabeth Central Hospital, Blantyre, Malawi
4. Orthopaedic Trauma Institute, Institute for Global Orthopaedics and Traumatology, Department of Orthopaedic Surgery, University of California San Francisco, San Francisco, California, USA
5. Department of Orthopaedic Surgery, Haukeland University Hospital, Bergen, Norway
6. Department of Surgery, Kamuzu Central Hospital, Blantyre, Malawi

Correspondence: Dr Brian C. Lau (blau10@gmail.com)

Abstract

Background

The EQ-5D is a standardised instrument that measures health-related quality-of-life and explores cost-effectiveness of treatments. Malawi is a low-resource country that would benefit from assessment of quality-of-life. Chichewa is the native language of Malawi. The Chichewa version of the EQ-5D-3L developed by EuroQoL group has not been validated with Chichewa speakers. The purpose of this study was to evaluate the clinimetric properties of the Chichewa EQ-5D-3L.

Methods

Patients with orthopaedic conditions were recruited in the outpatient orthopaedic clinics and wards at Queen Elizabeth Central Hospital, Blantyre Malawi. Fifty-three patients with various musculoskeletal problems were administered the Chichewa EQ-5D-3L and World Health Organisation quality of life (WHO-QOL) questionnaires. To assess repeatability, an separate test-retest population of 20 patients were also selected from orthopaedic clinics and wards to fill out the questionnaire twice.

Results

Convergence validity was determined with each of the WHO-QOL domains and the EQ5D Descriptive index and VAS with good to moderate correlation (r = 0.3-0.7). Internal consistency was measured for the Descriptive index and the Cronbach's alpha was 0.7. The ceiling effect for the Descriptive Index and the VAS were 9.4% and 0% respectively. No respondents reached floor effect for the descriptive index or the VAS. The test-retest intraclass correlation coefficient reliability at 14 days was 0.984 for the VAS and 1 for the Descriptive Index with all twenty respondents providing the same responses.

Conclusions

The EuroQoL translated version of the Chichewa EQ-5D-3L was found to demonstrate adequate validity, internal consistency, floor/ceiling effects, and reliability.

Introduction

Quality of life assessment with patient reported outcome measures is a useful addition to measuring functional and clinical outcomes in evaluation of the benefits of health care interventions.[1] In orthopaedics, radiographic and clinical assessment (range of motion, strength, mobility) are often measured by the treating physician which can be prone to bias. Adding patient-reported outcomes may limit the amount of physician bias in assessment of outcomes.

Moreover, "quality of life" is a broad ranging concept affected in a complex way by the person's physical health, psychological state, and level of independence, social relationships, and their relationship to salient features of their culture.[2] As such, quality of life assessment may add another dimension to the conventional outcome measures as it may demonstrate the impact of injury on other areas of life from the patient's perspective.[1]

Quality of life assessment is important for evaluating clinical interventions outcomes. It may also help in resource allocation by prioritising those interventions that result in better quality of life. Priority-setting in health care is more important in limited resource settings like Malawi where demand exceeds supply. Malawi has a population of 15 million and is one of the world's least-developed countries with around 85% of the population living in rural areas.[3] The country has one of the lowest GNI per capita in the world[3] at 250 USD. The majority of health services are offered by Ministry of Health facilities where most public health services are free for patients.[4] The per capital government total expenditure on health is 11.4% of GDP.[4] Given Malawi's limited resources, government provided health care, and high costs of health care, studies evaluating QALY through the EQ-5D is imperative for optimal resource allocation and improvement in patient care.

The EQ-5D-3L is a standardised instrument used to measure health related quality of life. It is used widely in English speaking countries and has been previously evaluated, and its validity and reliability have been studied.[5,6] The EuroQol Group translated the English version of the EQ-5D-3L into Chichewa (Nyanja). However, to our knowledge the clinimetric properties of the Chichewa EQ-5D-3L have not been evaluated. Chichewa is the language of the Chewas, the biggest population group in Malawi, spoken by around two-thirds of the population especially in the populous central and southern regions.[7] Chichewa is also spoken in parts of Zambia and Mozambique.[7] The literacy rate for adults (aged

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≥15 years) in Malawi is 73% with 42% of the population are literate in Chichewa only,[8] hence the need to use a Chichewa version of the EQ-5D when assessing quality of life. This study describes the validation of the EuroQoL Chichewa version of the EQ-5D-3L in Malawi.

Methods

Translation and adaptation

The translation and cultural adaptation of the English version of the EQ-5D-3L into Chichewa (Nyanja) language was commissioned by the EuroQOL group in 2012. The EuroQol group is a network of international multi-disciplinary researchers with members from North America, Europe, Asia, Africa, Australia and New Zealand.[5,9] It is responsible for the development of the EQ-5D, a preference based measure of health status. The translation and cultural adaptation procedure is described elsewhere.[5,9] Permission to use the already translated questionnaire from the EuroQol group was obtained.

Instrument

The EQ-5D-3L is a 2-part questionnaire that assesses quality of life. The first part has five dimensions namely: mobility; self-care; usual activities; pain/discomfort; and anxiety/depression. Each dimension has 3 levels representing no problems; some problems and extreme problems with scores of 1, 2, and 3 representing each level respectively. The respondents are asked to choose one level for each of the 5 dimensions that best describes their own health state on the day of the interview. The second part is a visual analogue scale (VAS) where patients self-rate their health state on a scale of 0 to 100; with 0 and 100 as the worst and best imaginable health states, respectively.

Study setting and population

The Chichewa EQ - 5D-3L was administered to an initial 53 consecutive patients with various musculoskeletal problems presenting at Queen Elizabeth Central Hospital's Orthopaedic wards and outpatients clinic between October 2015 to March 2016. Queen Elizabeth Central Hospital which is located in the city of Blantyre is a tertiary care facility and the main teaching hospital in the country. Orthopaedic outpatients clinics are done once a week where patients with musculoskeletal problems from within Blantyre or referred from any of the 13 districts in the Southern region of the country are treated. Admitted cases on the wards have a similar distribution pattern. A consent form written in Chichewa was given or read aloud to adult patients (≥ 18 years old) in both the clinic and inpatient setting. Patients were made aware of the risks and benefits of participating in the study and that participation was voluntary. Sample size determination was based on guidelines for the process of cross-cultural adaptation of self-report measures.[10] The Chichewa version of the validated World Health Organization Quality of Life (WHO-QOL)[11] questionnaire was also administered to test construct validity. In order to assess repeatability, a separate test-retest population of 20 additional consecutive patients from orthopaedic clinic took the questionnaire twice at an interval of 2 weeks apart. Written informed consent was obtained from all patients who took part in the study. Ethics approval was obtained from College of Medicine Research Ethics Committee (COMREC) and University of California San Francisco Medical Center Institutional Review Board.

Statistical analysis

To aid in analysis, the EQ-5D was separated by its Descriptive Index and the Visual Analog Scale (VAS). The health profiles from the descriptive system were converted to index scores. The index scores were calculated using the index score calculator based on Zimbabwean population – based time trade off (TTO) value set 5 as Malawi population data is not yet available. The possible index scores range from 0.145 to 1.0, where 0 is death and 1 is the best possible health state. The data from these separate subscales was then uploaded to IBM SPSS Statistics version 23 for analysis to determine internal consistency, floor and ceiling effects, and repeatability. Details of each analysis are given below.

Construct validity

Construct validity is utilized to determine that the Chichewa translated EQ5D measures quality of life similarly to a previously validated Chichewa translated measure of general health. To measure this, Pearson correlation was calculated for the EQ-5D descriptive index scores and VAS scores with the WHO-QOL overall health, physical, psychological, social, and environment domain scores. As the R-value approaches 1, this indicates increasing convergence between the two measurement tools. By convention, strong, moderate, weak, and poor correlations were defined as > 0.70, 0.50 to 0.70, 0.30 to 0.50 and < 0.30, respectively.

Internal consistency

Internal consistency is utilized to determine the homogeneity of an individual subscale. Essentially, this value demonstrates that a group of questions is evaluating the same construct.[12] To measure this, Cronbach's alpha was calculated for the Descriptive Index using the initial population. Since EQ-VAS is only a single construct, rather than multiple questions, internal consistency cannot be measured. A Cronbach's alpha greater than 0.70 is accepted as being significant.[12]

Floor and ceiling effects

Floor and ceiling effects occur when a large percentage of survey respondents score the lowest or highest possible score respectively. When present, this causes a potential question about the survey's ability to capture extreme data, as well as difficulty in distinguishing among respondents who achieved maximum or minimum scores.[12] To determine if these effects were present, the percentage of patients who achieved the best scores and those who achieved the worst scores were determined for each subscale using the initial population. Floor or ceiling effects were considered to be present if 15% of respondents or greater reported either the worse or best possible scores, respectively.[12]

Repeatability

To assess repeatability, questionnaires were analysed to determine their agreement—the extent to which scores from different time points resemble each other—and reliability, which measures how easily patients can be distinguished from each other on repeated testing.[12] For this section of analysis, the test-retest population was utilized. The EQ-VAS scores were assessed separately from the Descriptive Index. To assess agreement, the mean difference of the sums between time points was calculated, along with their respective 95% confidence intervals (CI). Scores were considered to be statistically similar if the confidence interval contained zero. Reliability was evaluated by determining the Pearson's correlation coefficient and the intraclass correlation coefficient (ICC) between sums (of index scores) at the two time points. The ICCs were determined using the two-way random effects model with agreement type, along with

Table 1: Patient demographics

	Initial sample (N = 53)	Test-retest sample (N = 20)
Mean age (standard deviation)	36.5 (14.6)	43.4 (17.2)
Gender, n (%)		
Male	28 (52.8)	18 (90)
Female	25 (47.2)	2 (10)
Education Level, n (%)		
Did not attend	0 (0)	2 (10)
Primary	13 (24.5)	9 (45)
Secondary	9 (17)	6 (30)
Tertiary	4 (7.5)	3 (15)
Unknown	27 (50.9)	0 (0)
Injury, n (%)		
Femur fracture	11 (20.8)	7 (35)
Tibia/fibula fracture	12 (22.6)	5 (25)
Radius/ulna fracture	6 (11.3)	1 (5)
Back pain	5 (9.4)	0
Ankle fracture	4 (7.4)	0
Joint dislocation	5 (9.4)	0
Other	10 (18.9)	7 (35)

their corresponding 95% confidence interval. A significant correlation was demonstrated by an ICC value of 0.70 or higher.[12]

Results

All surveys were completed by all respondents. All questions of the EQ-5D and WHO-QOL were answered by all patients.

Demographics

Demographic characteristics of the initial cohort and the reliability cohort are presented in Table 1. The mean age for the initial population was 36.5 years. There were more males (52.8%) than females in the initial population; more than half had unknown education indicating that they had attended but not completed primary school.

Validity

The Pearson's correlation between the Descriptive Index and VAS of the EQ-5D and the WHO-QOL overall health, physical, psychological, social, and environment domains demonstrated a good to moderate correlation (Table 2).

Internal consistency

The Cronbach's alpha for the Descriptive Index of the EQ-5D was 0.70 (Table 3).

Floor and ceiling effects

The Descriptive Index of the EQ-5D had 9.4% (5/53) respondents who scored the best possible functioning score. No patient reported the best possible score in the VAS. No respondents scored the worse functioning score on any of the indices (Table 3).

Repeatability

All data for repeatability is listed in Table 3. For the EQ-VAS, the mean difference in scores was 1.0 (range -0.44- 2.44). The Pearson's coefficient was 0.986 and the ICC was 0.984 (CI: 0.961, 0.994). All twenty respondents in the test-retest population gave the same responses for the Descriptive Index of the EQ-5D at both baseline and follow-up. Thus, the mean difference between the two time points was 0, and the Pearson's coefficient and ICC were both 1.

Discussion

This is the first study to evaluate the clinimetric properties of translated Chichewa version of the EQ-5D. This study represents only the second time the EQ5D has been validated in an African language.[13] Jelsma & Chivaura translated and validated the EQ-5D in Shona, an important language in Zimbabwe, and found that Zimbabweans valued health states differently from previous European study populations. The results of this study have demonstrated that the translated Chichewa questionnaire is a reliable and valid tool that can be used to assess quality of life in Chichewa speaking patients with musculoskeletal problems.

The questionnaire was tested across all education levels from those with limited formal education to completion of college with full education. The fact that despite the wide range of education, all respondents were able to answer all the questions highlights the acceptability and comprehensibility of the questionnaire.

The Descriptive index and VAS from the EQ-5D-3L had a good to moderate correlation with the previously validated WHO-QOL overall domain. This demonstrates that the Chichewa version of the EQ-5D-3L appropriately measures quality of life.

The internal consistency had a value of Cronbach's Alpha of 0.70 demonstrating that the questions in the translated

Table 2: Construct validity of the EQ-5D quality of life questionnaire with the WHOQoL-BREF questionnaire (Pearson Correlation between EQ5D with WHOQoL-BREF)

	WHOQoL- BREF: Domains				
EQ-5D	General Health	Physical	Psychological	Social	Environment
Descriptive Index (R)	0.57 (P < 0.01)	0.42 (P < 0.01)	0.46 (P = 0.023)	0.43 (P = 0.035)	0.63 (P = 0.019)
EQ-VAS (R)	0.49 (P = 0.026)	0.31 (P = 0.183)	0.39 (P = 0.042)	0.34 (P = 0.145)	0.52 (P = 0.022)

Table 3: Questionnaire internal consistency, floor and ceiling effect, and repeatability

	EQ5D	
Subscales	**Descriptive index**	**Visual analog scale (VAS)**
Internal consistency		
Cronbach's alpha	0.70	-
Floor and ceiling effect, n (%)		
Floor effect	0/53 (0)	0/53 (0)
Ceiling effect	5/53 (9.4)	0/53 (0)
Repeatability*		
Baseline average (SD)	0.307 (0.23)	44 (17.6)
Follow-up mean (SD)	0.307 (0.23)	45 (18.2)
Mean difference (95% CI)	0	1.0 (–0.44 to 2.44)
Pearson's coefficient	1	0.980
ICC (95% CI)	1	0.984 (0.961 to 0.994)

Table 3 shows the results of statistical analysis of each subscale in the two questionnaires, consisting of internal consistency, floor/ceiling effects, and repeatability.
*For repeatability, the units for baseline and follow-up averages are different for each subscale. The Descriptive Index is recorded as the average of all patients' converted health index scores. The VAS is reported as the average of the individual VAS scores.

SD = standard deviation; CI = confidence interval; ICC = interclass correlation coefficient

questionnaire were measuring Quality of Life. The Descriptive Index had a ceiling effect of 9.4% which was well within the acceptable range of 15%. One explanation for the ceiling effects can be the possibility that there was a proportion of patients who had successful treatment and were just coming to the clinic for regular follow up accordingly but did not have any limitation in function and hence scored best possible scores. Additionally, no respondents had floor effects in the Descriptive Index or either floor or ceiling effects with VAS. These values are similar to other translated versions of the EQ-5D.[14–19]

Test-retest reliability was examined in this study with a time interval of 2 weeks in between responses. There is no recommended time interval for questionnaire administration for test-retest reliability for quality of life questionnaires. Marx et. al.[20] found that there was no statistically significant differences in test-retest reliability of health status instruments between the time intervals of 2 days or 2 weeks among orthopaedic patients with knee disorders. Nevertheless there is need to have adequate time in between interviews to minimise the possibility of recall bias and the time interval should not be too long to allow for change in disease status. The responses between the two time intervals in our study were likely to be stable as the 2-week period was sufficient to minimise recall bias and also not long enough to have significant change in disease status.

All answers on the descriptive index of the EQ-5D were the same over the 2-week interval. The VAS score also demonstrated excellent repeatability with a Pearson's Coefficient of 0.986 and ICC of 0.984. The excellent repeatability highlights that questions were interpreted similarly by readers at two different time points.

One of the limitations of this study was that the study population included only patients with orthopaedic injuries. This limits its generalizability to other medical conditions. Another limitation is that we did not record the economic status of respondents, as it was difficult to estimate monthly income for the majority of patients with informal employment or small scale businesses. This information may offer insight to the responses and comprehension of the EQ-5D questionnaire. Education level, however, which was recorded may serve as a proxy for economic status. In the test-retest population, there was a disproportionate amount of males (18) to females (2) which may affect its generalisability. The index scores used in this study were for the Zimbabwean population because there are no index scores for Malawi. Although Zimbabwe is a low income country in sub Saharan Africa like Malawi, it has one of the highest literacy rates in Africa at 86.5% compared to Malawi at 65.8% (REF-UNESCO). The level of understanding therefore may be different and as such the scores may not be truly representative of the Malawi population. Future studies should aim to develop index scores for the Malawi population.

Notwithstanding the limitations, this study provides evidence that the translated Chichewa version of the EQ-5D is valid and reliable for future use within Malawi to measure Quality of Life in patients with musculoskeletal problems. It is hoped that subsequent evaluations of health states, treatment interventions, and wider public policy interventions will benefit from its use.

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Competing interests

All authors declare that they have no competing interests related to this work.

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9.2 Paper II

Chokotho L, Lau B, Conway D, Wu H, Shearer D,Mkandawire N,Hallan G, Gjertsen J, Young S**.** Validation of the Chichewa Short Musculoskeletal Function Assessment (SMFA) questionnaire. Malawi Medical Journal. 2019;31(1):65-70.

ORIGINAL RESEARCH

Validation of Chichewa Short Musculoskeletal Function Assessment (SMFA) questionnaire: A cross-sectional study

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Correspondence:
linda.chokotho@gmail.com

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Linda Chokotho[1,2], Brian C. Lau[3,4], Devin Conway[3], Hao-Hua Wu[3], David Shearer[3], Geir Hallan[5], Jan-Erik Gjertsen[5], Nyengo Mkandawire[6,7], Sven Young[5,8]

1. Beit Cure International Hospital, Blantyre Malawi.
2. University of Bergen, Institute of Clinical Sciences and Centre for International Health, Bergen, Norway.
3. The Institute for Global Orthopaedics and Traumatology, Orthopaedic Trauma Institute, University of California San Francisco Medical Center
4. Duke University Medical Center
5. Department of Orthopaedic Surgery, Haukeland University Hospital, Bergen, Norway. Department of Clinical Sciences, University of Bergen, Bergen, Norway.
6. University of Malawi, College of Medicine. School of Medicine

Abstract

Background
The Short Musculoskeletal Function Assessment (SMFA) tool measures function and quality of life in patients with musculoskeletal conditions.
Objective
This study aimed to translate and adapt culturally the SMFA into *Chichewa,* and assess its clinimetric properties.
Methods
The translated *Chichewa* version was administered to 53 patients with musculoskeletal disorders. To assess repeatability, an additional 20 patients answered the questionnaire twice over a time interval of two weeks. Internal consistency, floor and ceiling effects, and repeatability were tested; construct validity was assessed with the World Health Organization Quality of Life Assessment tool (WHOQOL-BREF).
Results
There was good internal consistency for both Dysfunction and Bothersome indices (Cronbach's alpha 0.90) and good construct validity between both indices with the WHOQOL-BREF. Pearson's correlation coefficient and intraclass correlation coefficient (ICC) for repeatability for the Dysfunction Index were 0.941 and 0.922 (95% CI: 0.772, 0.971) respectively, and 0.877 and 0.851 (95% CI: 0.629, 0.941) for the Bothersome Index respectively.
Conclusion
The translated *Chichewa* SMFA is a valid tool for populations that speak the *Chichewa* language.

Keywords: Short Musculoskeletal Function Assessment Questionnaire, SMFA, *Chichewa*, clinimetric measures, quality of life

Introduction

Trauma and musculoskeletal impairment (TMSI) conditions are the most common cause of severe long-term pain and physical disability worldwide [1]. TMSI conditions vary in clinical presentation and include both acute and chronic disorders. Examples include low back pain, different types of arthritis, and musculoskeletal injuries such as fractures and sprains.

In the 2010 World Health Organization Global Burden of Disease (WHO-GBD) study, musculoskeletal disorders accounted for 21.3% of Years Lived with Disability (YLDs) globally[2]. Low back pain (LBP) was the leading cause of YLDs, whereas neck pain was the fourth cause [2]. Although most musculoskeletal disorders do not directly lead to mortality, they limit individuals' activities and capacity to live independent lives. Hence, their impact on quality of life is significant, leading to loss of productivity for the individuals and society. The World Health Organisation has recognized the significant contribution of musculoskeletal problems towards the total burden of disease as can be seen by their endorsement of the Bone and Joint Decade from 2000-2010 [3]. Most musculoskeletal impairment (MSI) conditions are associated with increasing age and lifestyle. The increasing number of older people globally [4], the epidemiological shift of disease pathology and the escalating burden of trauma in low- and middle- income countries mean that these conditions will increase, and so will their resulting burden in these countries. Malawi has a population of approximately 18 million with 83% of the population living in rural areas [5]. The country has one of the lowest Gross National Income (GNI) per capita in the world at 320 USD [6]. In 2009 injuries were responsible for 5.1% of all Disability

Adjusted Life Years (DALYs) in Malawi [7]. The common musculoskeletal disorders endure for long periods, even if their limit on function is less than some other diseases. As a result, musculoskeletal disorders ranked as the third leading cause of years lived with disability (YLD) in Malawi in 2016, with 909 YLD per 100,000 [8]. This was in contrast to other non-communicable diseases with 1714 YLD per 100,000 and mental disorders, with 1555 YLD per 100,000. In 1990, musculoskeletal disorders had ranked fifth, when nutritional deficiencies (1167 YLD) and malaria/neglected tropical diseases (985 YLD) were more prominent[8]. In 2016, musculoskeletal disorders ranked thirteenth as a cause of DALYs (929 DALYs per 100,000) [8].

There is need to understand the effect of TMSI on the quality of life in developing countries such as Malawi which are experiencing an increase in trauma and musculoskeletal impairment. A standardized simple assessment of the function of people with musculoskeletal disorders could help to determine the impact of the disease on the individual's daily life. Results from musculoskeletal function assessment over the course of a disease will also help to optimize interventions to improve function or prevent progression of the disease and long-term disability. The Short Musculoskeletal Function Assessment (SMFA) is a tool designed to measure function in patients with a broad range of musculoskeletal disorders and may be used for assessment of the health status of the patient or impact of treatment [9]. It is widely used in English-speaking countries. However, it is now recognized that if questionnaires are to be used across cultures, they must not only be translated well but must also be adapted for a particular culture to maintain content validity of the instrument [10]. Thus, there are several non-English versions of the SMFA that have been cross-culturally adapted, and their validity and reliability have been studied, proving to be consistent across gender and age categories [11-14]. However, to our knowledge, there is no*Chichewa* version of the SMFA adapted for the Malawian community. *Chichewa* is the language of the Chewas, the biggest population group in Malawi, and is spoken by around two-thirds of the population especially in the populous central and southern regions and is also spoken in parts of Zambia and Mozambique [15]. The literacy rate for adults (aged ≥15 years) in Malawi is 64% with 42% of the population being literate in *Chichewa* only [5], hence the need to use a *Chichewa* version of the SMFA when assessing musculoskeletal function status. This paper describes the validation of the SMFA *Chichewa* version in Malawi.

Methods

This study was done in two stages. Firstly, the English version of the SMFA questionnaire was translated into *Chichewa*. Secondly, the clinimetric properties of the translated version were assessed. The World Health Organization Quality of Life (WHOQOL) assessment tool was used to assess the construct validity of the *Chichewa* SMFA. The WHOQOL-BREF was the only quality of life assessment tool that was previously translated and validated in *Chichewa* [16]. Written informed consent was obtained from all patients who took part in the study. Ethics approval was obtained from the College of Medicine Research Ethics Committee (COMREC) and the University of California San Francisco Medical Center Institutional Review Board.

Description of the tools

The SMFA is a 46-item self-reported functional status questionnaire, which has two parts: the Dysfunction and Bothersome indices [9]. The Dysfunction Index consists of 34 questions that assess the functional status of the patients, whereas the Bothersome Index has 12 questions that allow patients to evaluate how bothered they are by their functional problems. The Dysfunction Index questions are grouped into four categories: daily activities, emotional status, hand and arm function, and mobility. The Bothersome Index questions assess how much one is bothered in areas of recreation or leisure, work, sleep and rest. All items are rated on a 5-point scale with a score of 1 indicating no problem, or not at all bothered, and a score of 5 indicating unable to do something or extremely bothered. The total scores for each sub scale are then standardized using the formula: *(Actual raw score – lowest possible score / possible raw score range) x 100*. The standardized scores for each subscale or index range from 0 to 100 with higher scores indicating poor function.

Translation Process

The translation process followed a standardized procedure[10]. Firstly two bilingual translators with *Chichewa* as their mother tongue translated the English questionnaire independently into *Chichewa*. Differences from these two translations were resolved by consensus between the translators, and one *Chichewa* questionnaire was accepted. Secondly, the accepted *Chichewa* version was translated back into English by another set of two independent translators, with no prior knowledge of the contents of the SMFA questionnaire. These back-translated forms were compared with the original form to ensure that they had the same content. A committee then reviewed the translated questionnaire to ensure that the wording was clear, that there were no vague sentences, the words meant the same, and that they had experiential equivalence. Experiential equivalence means that activities of daily living in the translated version of the questionnaire reflected activities of daily living in Malawian culture. The committee consisted of three orthopaedic surgeons, two research assistants, and two lay people from the community. The translated questionnaire was then pre-tested on a purposive sample of 20 non-study participants with different musculoskeletal problems before administering them to the study population, as recommended by Beaton et.al. [10]. The aim of pre-testing was to explore how the participants interpreted the items on the questionnaires and whether they understood the meaning of the questionnaire items but also to probe the meaning of their responses. Only a few minor corrections on some words were made after the pre-testing.

Study setting and participants

The final translated *Chichewa* version of the SMFA and the WHOQOL-BREF were administered to 53 participants to assess the clinimetric properties of the translated version of the SMFA. Another sample of 20 participants separate from the initial population answered the questionnaire twice at an interval of 2 weeks apart to test for repeatability. The respondents were consecutive patients with either traumatic or non-traumatic musculoskeletal problems presenting at Queen Elizabeth Central Hospital's orthopaedic wards or outpatients clinic, from October 2015 to March 2016. Queen Elizabeth Central Hospital, which is located in the city of Blantyre, is a tertiary care facility and the main teaching hospital in the country. Orthopaedic patients come from within Blantyre or are referred from any of the 13 districts in the southern region of the country. Outpatient clinics are done once a week. Sample size determination was based on guidelines for the process of cross-cultural adaptation of self-report measures[10].

Statistical analysis

The initial population of 53 respondents completed 99.9% of all SMFA and WHOQOL-BREF questions, while the test-retest population of 20 respondents answered 97.9% of questions. Given their small number, unanswered questions were disregarded in statistical analysis. To aid in the investigation, the SMFA was categorized into its two documented subscales: the Dysfunction Index and the Bothersome Index, consisting of 34 and 12 questions respectively. Each response was scored and raw scores for each patient's Dysfunction Index were calculated by summing up scores for questions 1 to34. Raw scores for each patient's Bothersome Index were calculated by summing up scores for questions 35 to 46. The data from these separate subscales were analyzed using IBM SPSS Statistics version 23 to determine validity, internal consistency, floor/ceiling effects, and repeatability.

Construct validity

Construct validity was utilized to determine that the *Chichewa* translated SFMA measured quality of life similarly to a previously validated *Chichewa* translated measure of general health. To measure this, Pearson correlation was calculated for the Dysfunction Index and Bothersome Index with the WHO-QOL domain scores for overall health, physical, psychological, social, and environment. The WHOQOL-BREF is a 26-item shorter version of the WHOQOL-100, and is divided into four domains namely: physical, psychological, social and environmental[17]. The closer the R-value is to 1 indicates increasing convergence between the two measurement tools. By convention, strong, good, moderate, and weak correlations were defined as >0.70, 0.50-0.70, 0.30-0.50 and <0.30, respectively.

Internal consistency

Internal consistency is utilized to determine the homogeneity of an individual subscale. Essentially, this value demonstrates that a group of questions is evaluating the same construct [18]. To measure this, Cronbach's alpha was calculated for each subscale. A Cronbach's alpha >0.70 was accepted as being significant [18].

Floor/ceiling effects

To determine if floor and ceiling effects were present, the percentage of patients who achieved the best scores and those who achieved the worst scores for both indexes were determined for each subscale using the initial population. Floor or ceiling effects were considered to be present if 15% of respondents or greater reported either the worse or best possible scores, respectively [18].

Repeatability

To assess repeatability, questionnaires were analyzed to determine their agreement—the extent to which scores from different time points resemble each other—and reliability, which measures how easily patients can be distinguished from each other on repeated testing. For these analyses, the test-retest population was utilized. The sum of the scores for the SMFA subscales was determined at each of the two time points. To assess agreement, the mean difference of the sums between time points was calculated, along with their respective 95% confidence intervals (CI). Scores were considered to be statistically similar if the confidence interval contained zero. Reliability was evaluated by determining the Pearson's correlation coefficient and the intraclass correlation coefficient (ICC) between sums (or index scores) at the two time points. The ICCs were determined using the two-way random effects model with agreement type, along with their corresponding 95% confidence interval. A significant correlation was demonstrated by an ICC value of 0.70 or higher [18].

Results

Demographics

In the initial population, 53 patients were included and 20 patients were included in the test-retest population. The mean age was 36.5 years in the initial population and 43.4 years in the test-retest population. Of respondents in the test-retest population, 18 (90%) were males. All patients in the test-retest population had fractures whereas 62.1% of the initial population had fractures. Demographic details for both populations are shown in Table 1.

Table 1: Patient demographics

	Initial Population (N=53)	Test-Retest Population (N=20)
Average Age (SD)	36.5 (14.6)	43.4 (17.2)
Gender: N (%)		
Male	28 (52.8)	18 (90)
Female	25 (47.2)	2 (10)
Education Level: N (%)		
Did not attend	0 (0)	2 (10)
Primary	13 (24.5)	9 (45)
Secondary	9 (17)	6 (30)
College/University	4 (7.5)	3 (15)
Not disclosed	27 (50.9)	0 (0)
Injury: N (%)		
Femur fracture	11 (20.8)	7 (35)
Tibia/Fibula fracture	12 (22.6)	5 (25)
Radius/Ulna Fracture	6 (11.3)	1 (5)
Back Pain	5 (9.4)	0
Ankle fracture	4 (7.4)	0
Joint Dislocation	5* (9.4)	0
Other	10# (18.9)	7^ (35)

*=Joint dislocation includes: 2 hip, 2 elbow, and 1 ankle dislocations.
#=Other includes: stiff knee, joint pain, shoulder pain, clavicle swelling, knee fracture, bilateral leg swelling, thumb fracture, lower extremity amputation, painful fore-

arm, and bilateral lower extremity tendon injury.
^=Other includes: pelvic fracture, amputated hand, maimed lower extremity, gunshot wound to femur, bilateral lower extremity fractures, chronic osteomyelitis, and a review of previous femur operation.

The majority of patients found the questions in *Chichewa* clear and easy to understand. Question 15 regarding how difficult it is for one to drive did not apply to the majority (75%) of respondents, as they do not drive cars. Question 2 regarding how difficult it is to open medicine bottles or jars was adapted because, in Malawi, medicines are dispensed in packets rather than bottles or jars. Accordingly, the respondents were asked to say how difficult it is for them to open other small bottles or jars.

Internal consistency
Cronbach's alpha was 0.90 for both the Dysfunction and Bothersome indices (Table 2).

Floor/ceiling effects
The Bothersome Index of the SMFA had 9.4% (5/53) respondents reporting the best possible functioning score. No patient reported the best possible score in the Dysfunction Index. No respondents reported the worse functioning score on any of the indices (see Table 2).

Table 2: Questionnaire internal consistency, floor/ceiling effect, repeatability

	SMFA	
Subscales	Dysfunction Index	Bothersome Index
Internal Consistency		
Cronbach's Alpha	0.90	0.90
Floor/Ceiling Effect: N (%)		
Floor Effect	0/53 (0)	0/53 (0)
Ceiling Effect	0/53 (0)	5/53 (9.4)
Repeatability*		
Baseline Average (SD)	94.7 (17.3)	35.1 (5.9)
Follow-up Average (SD)	91.0 (18.0)	33.7 (5.4)
Mean Difference (95% CI)	-3.65 (-3.65, -0.65)	-1.45 (-2.78, -0.12)
Pearson's Coefficient	0.941	0.877
ICC (95% CI)	0.922 (0.772, 0.971)	0.851 (0.629, 0.941)

*For repeatability, the units for baseline and follow-up averages are different for each subscale. For the two indices of the SMFA, the average is the average sum of

each patient's responses to all questions in that subscale.

Construct validity
There was moderate to good correlation between the Dysfunction and Bothersome indexes of the SMFA and each of the WHOQOL-BREF domains (Table 3).

Table 3: Construct validity SFMA with WHOQOL-BREF

	WHOQOL-BREF: Domains				
SFMA	General Health	Physical	Psychological	Social	Environment
Dysfunction Index (R)	-0.61 (p=0.0002)	-0.43 (p=0.043)	-0.39 (p=0.0684)	-0.43 (p=0.0474)	-0.57 (p=0.0272)
Bothersome Index (R)	-0.51 (p=0.0256)	-0.39 (p=0.0412)	-0.42 (p=0.0433)	-0.34 (p=0.0754)	-0.48 (p=0.0392)

Repeatability
All data for repeatability is listed in Table 2. The Dysfunction Index of the SMFA had a mean difference of -3.65 (95% CI: -6.65, -0.65), while the Bothersome Index had a mean difference of -1.45 (95% CI: -2.78, -0.12). The Pearson's correlation coefficient and ICCs for Dysfunction Index were 0.941 and 0.922 (95% CI: 0.772, 0.971) respectively. For the Bothersome Index, Pearson's correlation coefficient was 0.877 and the ICC was 0.851 (95% CI: 0.629, 0.941).

Discussion
The findings in this study demonstrated sufficient validity, repeatability and internal consistency indicating that the *Chichewa* version of the SMFA is a valid and reliable tool that can be used to assess function in patients with musculoskeletal conditions. Translation and cross cultural adaptation of assessment tools is important to ensure validity.

The good internal consistency of the *Chichewa* SMFA with a Cronbach's alpha of 0.90 for both the Dysfunction and the Bothersome Indexes demonstrates that the *Chichewa* questions were evaluating the same construct, thus each category in the translated version maintained its homogeneity. Our findings are comparable to those found in the initial validation of the SMFA where the Cronbach's alpha was 0.95 and 0.92 at baseline for Dysfunction and Bothersome Index respectively [9]. The internal consistency results from the Dutch, Brazilian, Swedish and Chinese SMFA validation studies [11-14] also compare satisfactorily with our results.

There were no floor effects for both indices and only a small ceiling effect for the Bothersome Index. The proportion of ceiling effects in our study is less than what was found in the Dutch validation study[12] where the Bothersome Index had ceiling effects of 14.2%. Swiontkowski et al. reported no floor effects and less than 5% ceiling effects in the initial validation study [9]. Although the ceiling effects in our study were higher than in the study by Swiontkowski et al., they are still lower than the accepted limit of 15%. One explanation for the ceiling effects can be the possibility that a proportion of patients had successful treatment and were just coming to the clinic for regular follow up, without having any limitation in function and hence scored best possible scores. Duration from time of injury or onset of symptoms was not recorded in this study and therefore further analysis to substantiate this hypothesis could not be done.

There was good correlation between the SFMA scores and the *Chichewa* version of WHOQOL-BREF general health scores. This finding highlights that there was a degree of external consistency of the *Chichewa* SFMA to measure overall general health. There was also moderate correlation between the SFMA and the WHO-QOL environment subsection. Of note, however, there was borderline correlation between the dysfunctional index of the SMFA and the psychological-domain of the WHOQOL-BREF at 0.39 and Bothersome Index and physical and social domains was 0.39 and 0.34 respectively. These findings suggest that the *Chichewa* SFMA cannot be used to measure specific domains of psychological, social, and physical domains. Future studies using the *Chichewa* version SFMA should be cautious in attempting to associate findings beyond the general overall health of subjects, specifically to the psychological or social domains. The *Chichewa* SFMA should be used with other validated measures to make inferences on these domains.

The test-retest reliability of the *Chichewa* SFMA between baseline and 2 weeks later was high with Pearson's correlation >0.88 and intraclass coefficients >0.85. These results are comparable with the findings in the study by Swiontkowski et al. [9].

This is the first study to evaluate the clinimetric properties of a translated *Chichewa* version of the SMFA. This study has several strengths. Firstly, although our sample size was small, our findings were comparable with other validation studies and showed that the *Chichewa* version of the SMFA is a valid tool that can be used to assess musculoskeletal function in patients with similar conditions as our study population. Secondly, the test-retest respondents answered the questions two weeks apart. Marx et al.[19] found no statistically significant differences in test-retest reliability of health status instruments between the time intervals of 2 days or 2 weeks among orthopaedic patients with knee disorders. The time interval in our study was adequate to minimize the possibility of recall bias and not too long to allow for significant change in disease status; so the responses were likely to be stable.

The study had some limitations. The majority of participants in both populations were treated for fractures, most of which were lower limb fractures. This dominance of fractures may limit the generalizability of the findings to other non-traumatic musculoskeletal conditions. Additional studies with wider variation of musculoskeletal disorders should be performed to examine the generalizability of our results. Another limitation is that there was uneven distribution of gender in the test-retest population which may have affected the results as some studies have suggested that gender may have a significant impact on both general and health related quality of life [20, 21]. Presence of comorbidities was not assessed in this study. Consequently, dysfunction may have been caused by other comorbidities rather than musculoskeletal conditions. Data on comorbidities would also have helped assess divergent validity.

Conclusion

In conclusion, our findings have shown that our *Chichewa* version of the SMFA is a valid and reliable tool that can be used to assess musculoskeletal function in populations who speak the *Chichewa* language.

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Conflict of interest

All authors declare that they have no conflict of interest.

Ethical approval

This article does not cite any animal-based studies. All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards. The study was approved by the College of Medicine Research Ethics Committee (COMREC).

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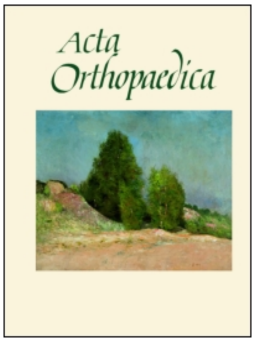
9.3 Paper III

Chokotho L, Wu H, Shearer D, Lau B, Mkandawire N, Gjertsen J, Hallan G, Young S**.**
Outcome at 1 year in patients with femoral shaft fractures treated with intramedullary nailing or skeletal traction in a low-income country: a prospective observational study of 187 patients in Malawi. *Acta Orthop. 2020 Jul 23:1-8.*



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Outcome at 1 year in patients with femoral shaft fractures treated with intramedullary nailing or skeletal traction in a low-income country: a prospective observational study of 187 patients in Malawi

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Outcome at 1 year in patients with femoral shaft fractures treated with intramedullary nailing or skeletal traction in a low-income country: a prospective observational study of 187 patients in Malawi

Linda CHOKOTHO [1,2], Hao-Hua WU [3], David SHEARER [3], Brian C LAU [4], Nyengo MKANDAWIRE [1,6], Jan-Erik GJERTSEN [2,5], Geir HALLAN [2,5], and Sven YOUNG [5,7]

[1] Department of Surgery, College of Medicine, University of Malawi; [2] Department of Clinical Medicine, University of Bergen, Bergen, Norway; [3] Institute for Global Orthopedics and Traumatology, Orthopedic Trauma Institute, University of California San Francisco, San Francisco, CA, USA; [4] Department of Orthopedic Surgery, Duke University Medical Centre, Durham, NC, USA; [5] Department of Orthopedic Surgery, Haukeland University Hospital, Bergen, Norway; [6] School of Medicine, Flinders University, Adelaide, Australia; [7] Department of Surgery, Kamuzu Central Hospital, Lilongwe, Malawi
Correspondence: lindachokotho@gmail.com
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Background and purpose — Intramedullary nailing (IMN) is underutilized in low-income countries (LICs) where skeletal traction (ST) remains the standard of care for femoral shaft fractures. This prospective study compared patient-reported quality of life and functional status after femoral shaft fractures treated with IMN or ST in Malawi.

Patients and methods — Adult patients with femoral shaft fractures managed by IMN or ST were enrolled prospectively from 6 hospitals. Quality of life and functional status were assessed using EQ-5D-3L, and the Short Musculoskeletal Function Assessment (SMFA) respectively. Patients were followed up at 6 weeks, 3, 6, and 12 months post-injury.

Results — Of 248 patients enrolled (85 IMN, 163 ST), 187 (75%) completed 1-year follow-up (55 IMN, 132 ST). 1 of 55 IMN cases had nonunion compared with 40 of 132 ST cases that failed treatment and converted to IMN ($p < 0.001$). Quality of life and SMFA Functional Index Scores were better for IMN than ST at 6 weeks, 3 and 6 months, but not at 1 year. At 6 months, 24 of 51 patients in the ST group had returned to work, compared with 26 of 37 in the IMN group ($p = 0.02$).

Interpretation — Treatment with IMN improved early quality of life and function and allowed patients to return to work earlier compared with treatment with ST. Approximately one-third of patients treated with ST failed treatment and were converted to IMN.

The gold standard treatment for femoral shaft fractures is intramedullary nailing (IMN), with low complication rates ranging from 1.2% to 5% for postoperative infection (Brumback et al. 2006, Young et al. 2013a, Salawu et al. 2017) and high union rates ranging from 72% to 100% (Ricci et al. 2001, El Moumni et al. 2009, Young et al. 2013b). However, nonoperative treatment using skeletal traction (ST) for at least 6 weeks remains the mainstay treatment for these fractures in low-resource settings (Hollis et al. 2015, Kramer et al. 2016). Nonoperative treatment is associated with increased risk of both medical and surgical complications, reported as high as 55% in some studies (Bucholz and Jones 1991, Doorgakant and Mkandawire 2012, Kramer et al. 2016, Parkes et al. 2017).

In Malawi, femoral shaft fractures are most commonly treated by ST. IMN, when performed, is done using the SIGN IM nail, which is donated by SIGN Fracture Care International (Richland, WA, USA) (Shah et al. 2004). Most studies comparing IMN with ST in LICs used conventional measures such as fracture union, complications, and range of motion (Swai 2005, Kamau et al. 2014, Parkes et al. 2017). No prior study has measured quality of life or function using a validated patient-reported outcome instrument to compare ST and IMN in any context.

This study compared the quality of life and functional status of patients with femoral shaft fractures treated with either ST or IMN in Malawi.

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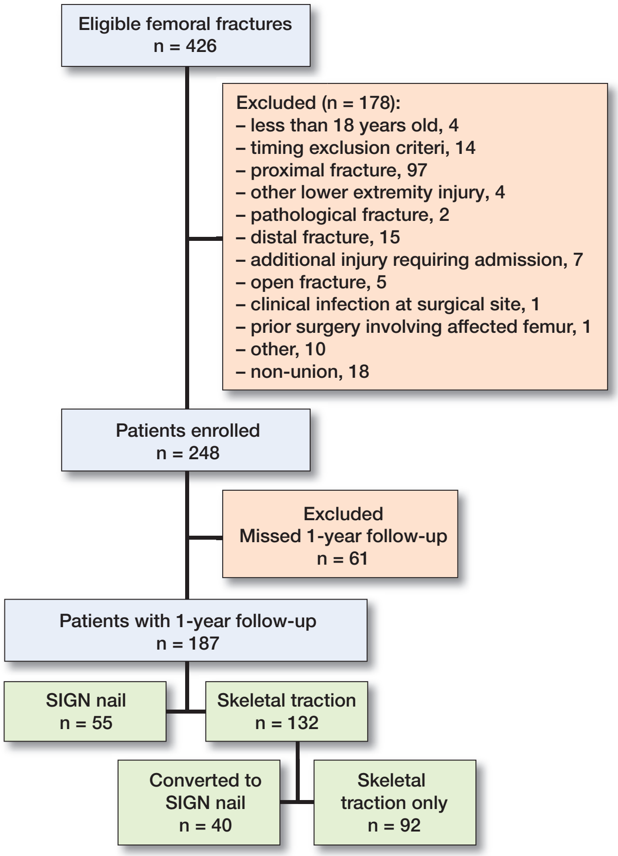

Figure 1. Flow chart showing eligibility, exclusion, enrolment and loss to follow-up of patients.

Patients and methods

Study setting and patient enrolment

This is a prospective multicenter observational study where adult patients aged 18 years and older, with isolated unilateral femoral shaft fractures (AO/OTA class 32) in 6 hospitals in Malawi, were enrolled from March 2016 to July 2018. Patients with associated major injuries, pathological or open fractures, infection at the surgical site, or prior surgery involving the affected femur were excluded (Figure 1).

The type of treatment (ST or IMN) was determined by the treating orthopedic clinical officer (OCOs) or surgeon. OCOs are non-physician clinicians trained to provide nonoperative care for orthopedic conditions and emergency orthopedic surgery for selected cases, such as acute infections and open fractures (Mkandawire et al. 2008).

The patients were recruited from Queen Elizabeth Central Hospital (QECH), Kamuzu Central Hospital (KCH), Beit Cure International Hospital (BCIH), and 3 district hospitals: Chiradzulu, Thyolo, and Chikwawa. In both QECH and KCH, patients with femoral shaft fractures were treated with ST or IMN based on the treating clinician's assessment, which was based largely on surgical capacity of the hospital at that time. In the district hospitals all patients were treated by ST. IMN patients who met the inclusion criteria were recruited into the study if they had surgery within 6 weeks from the time of injury. ST patients either continued with skeletal traction until clinical and radiological signs of fracture union were present or were offered IMN if, in the opinion of the treating clinician, union was unlikely without further intervention. The diagnosis of delayed union was made by the treating clinician, if at 6 weeks or more post-injury there was still tenderness and mobility at the fracture site, and no radiological evidence of callus formation. Non-union was defined as no evidence of fracture healing both clinically and radiologically after at least 3 months on ST or 6 months after IMN. Consequently, the ST group had 2 subgroups: those who started with skeletal traction but later converted to IMN because of either delayed union or nonunion and those who had skeletal traction as definitive treatment until union. A sample size of 110 patients in each group was initially calculated using OpenEpi software (www.openepi.com) (Sullivan et al. 2009) at 95% confidence interval and 80% power using the minimal clinically important difference (MCID) (Jaeschke et al. 1989) of 0.1 between the 2 groups for the EQ-5D, with a standard deviation of 0.12 (Luo et al. 2010, Ibrahim et al. 2018) and a more conservative standard deviation of 0.2 was used for the ST group. The calculation was adjusted to account for 20% loss to follow-up. However, at the 1-year interim analysis there were 65 patients in the IMN group and 120 patients in the ST group. A new sample size was calculated with an allocation ratio of 2:1, resulting in a required sample size of 80 cases in the IMN group and 160 patients in the ST group.

Treatment

The SIGN nail was used in all IMN patients. This is a solid locking IM nail that can be inserted without need for a fracture table or intraoperative fluoroscopy. At KCH and QECH, the SIGN nail was inserted using open reduction on a standard operating table. At BCIH, fluoroscopy guidance was used.

All ST patients had straight leg extension skeletal traction with a Steinmann pin inserted into the proximal tibia under local anesthesia, using an aseptic technique. A stirrup, rope and weights assembly was hung over a bar, pulley, or directly over the end of the bed. Counter-traction and anti-rotating mechanisms were used at the treating clinician's discretion. Pin site care was performed daily by the patients' guardians.

All patients received physiotherapy by either the hospitals' physiotherapists or rehabilitation technician.

Outcomes

The primary outcomes were quality of life determined by European Quality of Life 5-Dimensions Survey (EQ-5D-3L) index score (Brooks and Group 1996) and the Short Musculoskeletal Functional Assessment (SMFA) Function and Bothersome index scores (Swiontkowski et al. 2005). Both tools have been translated to Chichewa and validated in Malawi (Chokotho et al. 2017, 2019). Both tools were administered verbally by the research assistants who recorded the responses on Microsoft surface computers.

Index utility scores for the EQ-5D-3L were generated using the value set for the Zimbabwean population (Jelsma et al. 2003).

At each follow-up, patients were asked if they had returned to their pre-injury work, whether employed or otherwise. No specification was made as to whether the patients did not return to work because of the injury or because they were laid off due to injury-related absenteeism.

Follow-up

Follow-up assessments were performed 6 weeks, 3 months, 6 months, and 1 year after injury. If patients missed scheduled appointments, a telephone interview to answer the EQ-5D-3L and SMFA questionnaires was undertaken.

Patients who failed to come for an appointment and were not reached by phone were assessed by research assistants in their homes. Patients who could not be contacted by telephone and could not be found in person were regarded as lost to follow-up.

Statistics

Data were collected using RedCap electronic data capture tools hosted at the University of California San Francisco (UCSF) (Harris et al. 2009). Data were analyzed using Stata version 10.0 (StataCorp, College Station, TX, USA). Unadjusted analysis was done between IMN and ST groups using Satterthwaite's t-test for means with unequal variances. Subgroup analysis was also done between the IMN group and successful ST patients. Potential confounders associated (not necessarily causally related) with the outcome were first identified in a univariate regression analysis. Marital status, mechanism of injury, and education level were identified as significantly associated with both the EQ-5D and SMFA scores. The potential confounders and other independent variables were then added in a generalized linear regression model using the forward stepwise regression approach to come up with a final model. Comparison of categorical data was done using a chi-square test, or Fisher's exact test when any expected cell frequency was less than 5. Listwise deletion of missing data was used in unadjusted and adjusted regression analysis. Findings were considered statistically significant if the p-value was less than 0.05, thus "significant" results refers to statistical significance. Clinical significance is presented using MCID. Estimates were presented with their 95% confidence intervals (CI).

Ethics, funding, and potential conflicts of interest

The study was approved by the College of Medicine Research Ethics Committee, in Malawi, and the University of Bergen and University of California San Francisco Institutional Review Boards. Written informed consent was obtained from all patients in the study. The study was funded by the Institute of Global Orthopedics and Traumatology (IGOT), University of California San Francisco, James O. Johnston Research Grant, and a PhD grant through the Norhed Project, financed by Norad. Author DS is a non-paid member of the Board of Directors for SIGN Fracture Care International. The rest of the authors declare no conflict of interest.

Results

There were 426 eligible cases, of which 248 were enrolled in the study. 1-year follow up was achieved in 187 cases (75%) (Figure 1). 55 and 132 cases were treated with IMN and ST respectively.

Baseline demographic and injury details

The mean age of patients was 38 (SD 13) years in the IMN group and 40 (SD 16) years in the ST group (Table 1). In both groups the majority of patients were male. The most common cause of injury was road traffic injury followed by falls. More people in the ST group had primary school as their highest level of education, whereas there were more people with post-secondary education in the IMN group ($p < 0.001$). Most fractures were AO/OTA type 32A, but there were more type 32B in the IMN group than in the ST group, $p = 0.02$ (Table 1).

Treatment

The mean waiting time from injury to definitive treatment was 13 (SD 12) days for the IMN group and 4.4 (SD 5) days for the ST group, $p < 0.001$ (Table 1). 1 patient in the IMN group had a nonunion and was treated with an exchange nail, whereas 40 patients (30%) in the ST group had either nonunion or delayed union and subsequently converted to IMN during the course of the study ($p < 0.001$). Details on duration from time of injury to conversion were available for 20 patients out of 40, with a median of 63 days and a range of 50 to 252 days.

Quality of life

IMN versus all ST patients

The unadjusted mean EQ-5D index scores were higher in the IMN group than ST group at 6 weeks ($p = 0.03$) and 3 months ($p = 0.03$) after injury (Figure 2) but not at 6 months and 1 year. The mean EQ-5D index scores were lower at 1-year post injury compared with baseline, ($p < 0.001$). Patients in the IMN group reported significantly better quality of life than those in the ST group at 6 weeks, 3 months, and 6 months after the injury, with an adjusted mean difference of –0.14 (CI –0.27 to –0.02); –0.07 (CI –0.14 to –0.0001); –0.08 (CI –0.15 to –0.01) respectively. The mean difference was greater than MCID at 6 weeks and equal to MCID at 3 months and 6 months (Table 3).

Table 1. Baseline details

Variable	IM nailing n = 55	All skeletal traction n = 132	p	Convert n = 40	Successful traction only n = 92
Age, mean (SD)	38 (13)	40 (16)	0.3	37 (14)	41 (17)
median	37	37			
IQR	28–45	26–48			
Sex, n (%)			0.7		
Female	12	22 (17)		6	16
Male	42	107 (81)		33	74
Missing	1	3 (2)		1	2
Marital status			0.8		
Single	16	39 (30)		10	29
Married	36	79 (60)		26	53
Divorced/separated	1	5 (3.8)		2	3
Widow/widower	2	7 (5)		1	6
Missing	0	2 (2)		1	1
Education			< 0.001		
Primary	13	76 (58)		16	60
Secondary	18	40 (30)		18	22
Post-secondary	22	12 (9)		5	7
Missing	0	4 (3)		1	3
Mechanism of injury			0.4		
Fall	13	45 (34)		12	33
RTI	37	68 (52)		24	44
Other	4	16 (12)		2	14
Missing	1	3 (2)		2	1
Smoking			0.3		
No	52	112 (85)		33	79
Yes	2	13 (10)		4	9
Missing	1	7 (5)		3	4
OTA classification			0.02		
A (simple)	37	97 (74)		31	66
B (wedge)	13	15 (11)		5	10
C (complex)	4	5 (4)		1	4
Missing	1	15 (11)		3	12
OTA 32A subclass			0.06		
Oblique	10	11 (8)		4	7
Spiral	6	16 (12)		7	9
Transverse	18	67 (51)		20	47
Missing	21	38 (29)		9	29
Location			0.4		
Distal zone	3	16 (12)		6	10
Middle zone	35	82 (62)		27	55
Subtrochanteric	9	14 (11)		3	11
Missing	8	20 (15)		4	16
Side of injury			0.7		
Right	29	70 (53)		22	48
Left	23	53 (40)		14	39
Missing	3	9 (7)		4	5
Duration before treatment			< 0.001		
mean (SD)	13 (12)	4.4 (5)		6 (6)	5 (12)
median	10	3		3	3
IQR	3–18	1–6		1–8	1–5

Successful skeletal traction versus IMN

There were no significant differences in the unadjusted and adjusted mean EQ-5D index scores between patients who were treated successfully with ST (without converting to IMN) and those patients who were treated primarily with IMN (Tables 2 and 3). However, the adjusted mean difference in index scores was similar to MCID at the 6 weeks (–0.09, CI –0.2 to 0.06) and 3 months intervals (–0.07, CI –0.2 to 0.03) (Table 3).

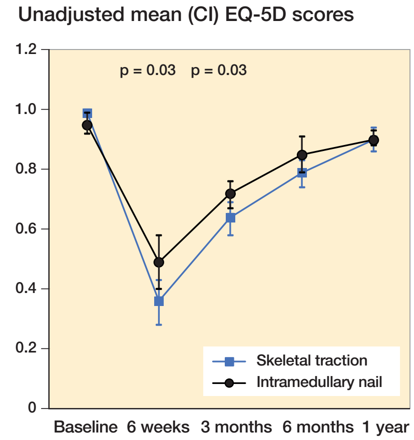

Figure 2. Unadjusted mean EQ-5D scores for IM nailing vs. skeletal traction.

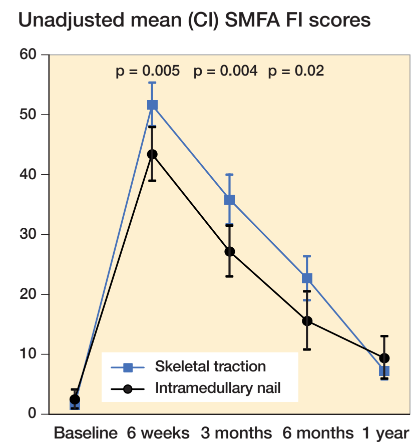

Figure 3. Unadjusted mean SMFA Functional Index scores for IM nailing vs. skeletal traction.

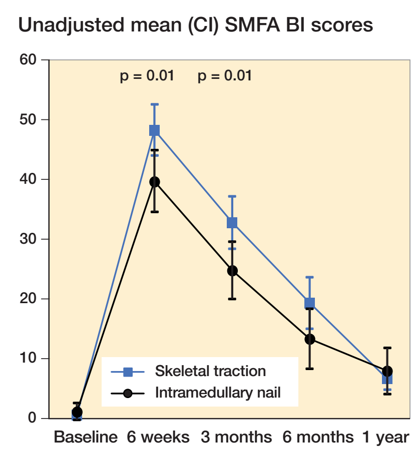

Figure 4. Unadjusted mean SMFA Bothersome Index for IM nailing vs. skeletal traction.

Functional status

IMN versus all ST patients

Both unadjusted and adjusted analyses showed significantly lower mean SMFA functional index scores at 6 weeks, and 3 and 6 months post-injury in the IMN group, indicating better function compared with the ST group (Figure 3 and Table 3).

Table 2. Unadjusted results for sub-group analysis. Values are mean (CI)

Variable	Pre-injury/baseline	6 weeks	3 months	6 months	1 year
EQ-5D					
Successful ST	0.99 (0.98–1)	0.40 (0.31–0.49)	0.64 (0.50–0.73)	0.80 (0.74–0.86)	0.91 (0.88–0.93)
IMN	0.95 (0.92–0.99)	0.50 (0.42–0.59)	0.72 (0.68–0.77)	0.85 (0.78–0.91)	0.91 (0.87–0.95)
SMFA FI					
Successful ST	1.5 (1.0–2.0)	52 (48–57) [a]	36 (29–42) [a]	23 (18–28) [a]	6.7 (4.9– 8.5)
IMN	2.5 (0.8–4.1)	43 (38–47)	27 (23–31)	16 (11–20)	9.3 (5.7–13)
SMFA BI					
Successful ST	0	48 (43–54) [a]	30 (24–37)	18 (13–23)	6.3 (4.1–8.4)
IMN	1 (–0.4 to 2)	39 (34–44)	24 (19–29)	13 (7.9–18)	7.6 (3.6–12)

[a] statistically significant ($p < 0.05$)
SMFA FI, SMFA Function Index. SMFA BI, SMFA Bothersome Index

Table 3. Adjusted results

Variable	Pre-injury/baseline coefficient (CI)	6 weeks coefficient (CI)	3 months coefficient (CI)	6 months coefficient (CI)	1 year coefficient (CI)
ST vs. IMN					
EQ5D score	0.03 (–0.004 to 0.1)	–0.14 (–0.27 to –0.02)	–0.07 (–0.14 to –0.0001)	–0.08 (–0.15 to –0.01)	0.001 (–0.05 to 0.05)
p-value	0.1	0.03	0.05	0.04	1
SMFA FI	–1.0 (–2.5 to 0.6)	8.7 (2.6 to 15)	8.4 (2.6 to 14)	7.9 (1.7 to 14)	–2. (–5.8 to 1.7)
p-value	0.2	0.01	0.01	0.01	0.3
SMFA BI	–0.5 (–1.9 to 0.9)	9.2 (2.4 to 16)	7.7 (1.2 to 14)	6.7 (–0.3 to 14)	–1.2 (–5.4 to 2.9)
p-value	0.5	0.01	0.02	0.1	0.6
IMN vs. successful ST					
EQ5D score	0.03 (–0.002 to 0.1)	–0.09 (–0.2 to 0.06)	–0.07(–0.2 to 0.03)	–0.05 (–0.14 to 0.03)	–0.0001 (–0.05 to 0.05)
p-value	0.1	0.2	0.2	0.2	1
SMFA FI	–1.1 (–2.6 to 0.5)	8.5 (1.8 to 15)	7.6 (0.4 to 15)	7.2 (0.4 to 14)	–2.4 (–6.3 to 1.5)
p-value	0.2	0.01	0.04	0.04	0.2
SMFA BI	–0.9 (–2.2 to 0.4)	8.8 (0.9 to 17)	5.5 (–2.5 to 14)	4.1(–3.6 to 12)	–1.2 (–5.6 to 3.1)
p-value	0.2	0.03	0.2	0.3	0.6

Further, the unadjusted mean SMFA Bothersome index was significantly lower in the IMN group compared with the ST group at 6 weeks and 3 months post-injury, indicating that patients in the IMN group were less bothered by their condition (Figure 4). Adjusted analysis showed a similar trend with mean difference in the SMFA Bothersome index of 9.2 (CI 2.4–16) at 6 weeks and 7.7 (CI 1.2–14) at 3 months (Table 3).

Successful skeletal traction vs. IMN

The mean SMFA functional index scores were significantly lower in the IMN group compared to the successful ST group at 6 weeks, and 3 and 6 months post-injury for both unadjusted (Table 2) and adjusted analysis (8.5, CI 1.8–15; 7.6, CI 0.4–15; 7.2, CI 0.4–14), (Table 3).

The unadjusted and adjusted mean SMFA Bothersome index scores were significantly lower in the IMN group compared with the successful ST group at 6 weeks (Tables 2 and 3).

Return to work

88 of 103 cases followed up at 6 months responded to the question of whether they had returned to work. No reasons were specified for non-response to this question in the remaining 15 cases (9 in the IM group and 6 in the ST group). 24 of 51cases in the ST group had returned to work compared with 26 of 37 in the IMN group ($p = 0.02$). There were no significant differences in proportions of patients who had returned to work at the other follow-up time points.

Discussion

This study found improved quality of life and function up to 6 months post-injury for IMN compared with ST in patients treated for femoral shaft fractures in Malawi. Almost one-third of patients treated with ST failed treatment and were ultimately converted to IMN due to delayed union or nonunion, typically between 6 and 12 weeks after initiating traction. Nonetheless, patients achieving union with skeletal traction had equivalent outcomes to those treated with early IMN at 1 year.

As far as we know, this is the first study comparing quality of life and functional status in femoral shaft fracture patients treated with ST or IMN. Haug et al. (2017) looked at quality of life in femoral shaft fracture patients treated with skeletal traction and found that patients had both physical and psychological pain as well as emotional distress due to prolonged hospitalization and the associated negative economic impact on their families. Tay et al. (2014) found that patients with long bone diaphyseal fractures treated surgically still had residual physical impairment and pain in the first year post-injury, which was worse among those with delayed union and nonunion even after treatment. Ibrahim et al. (2018) also found that EQ-5D scores did not return to the pre-injury level after operative treatment of femoral shaft fractures, a finding that was also replicated in our study. These studies support the concept that long bone fractures affect long-term quality of life and functional status even after operative treatment.

Patients treated with skeletal traction are normally admitted to hospital for at least 6 weeks, which is likely to have substantial financial implications for the patients, their guardians, and the health service providers. In our study, less than half of the ST patients had returned to work at 6 months after the injury compared with approximately three-quarters in the IMN group. The direct and indirect costs associated with skeletal traction may be more than the cost of intramedullary nailing. A cost-effectiveness study of the 2 treatment modalities is needed to give a complete picture of the impact of the treatment modalities and the findings could assist in better priority setting and resource allocation.

One-third of the ST patients were converted to IMN due to either delayed union or nonunion. These findings highlight the unmet need for operative fracture treatment in Malawi, where patients are offered operative treatment mostly after failure of primary nonoperative treatment, despite clear evidence in the literature that operative treatment is superior (Brumback et al. 2006, Kamau et al. 2014, Chagomerana et al. 2017). Femoral shaft nonunion is incapacitating and its impact on health-related quality of life is comparable to severe hip osteoarthritis and worse than medical conditions such as myocardial infarction and congestive cardiac failure (Brinker et al. 2017). In addition, nonunion surgery is more complex than acute fracture surgery and has an increased risk of infection and other complications (Mahomed 2008, Young et al. 2013b), and also has the potential to use more resources. Efforts should therefore be made to improve surgical services and avert the problem of converting to IMN after failed skeletal traction.

Conducting clinical research in low-resource settings presents many challenges, and our study has several limitations. First, the IMN group was not homogeneous. The delay from time of injury to treatment ranged from 1 day to 6 weeks, signifying the challenges faced by orthopedic surgeons in Malawi to provide operative fracture care in a setting where theatre time is limited, and the few available specialists are overwhelmed by the large burden of fractures needing surgery. This baseline discrepancy may have contributed to suboptimal quality of life and function in the IMN group, as early operative stabilization of these fractures is associated with fewer complications and better outcomes in the short term (Mahomed 2008, El-Menyar et al. 2018). Lack of homogeneity also limits its external validity. Another limitation is that there was a high rate of conversion from ST to IMN due to either delayed union or nonunion. This occurred after at least 6 weeks on skeletal traction, and as a result there was no bias at 6 weeks. However, the remaining time points were likely biased towards the null hypothesis of no difference between groups because those patients who failed traction would have experienced a poor outcome had they continued with ST for the entire follow-up period. Details on post-treatment physiotherapy, which plays a crucial role in improving function after injury (Paterno and Archdeacon 2009), were not collected. However, patients in both groups were provided with standard rehabilitation by either the hospitals' physiotherapists or rehabilitation technicians. Thus it is unlikely that post-treatment rehabilitation affected the functional outcome in 1 group more than the other. We also did not collect detailed information on comorbidities. However, as the mean age in both groups was less than 40 years it is unlikely that there were patients with substantial comorbidities. Loss to follow-up at the different time intervals may have reduced the power of the study to detect a statistically significant difference. Nonetheless, the differences were significant at early time points, and the mean difference found at 1 year was far below the MCID for the EQ-5D. Loss to follow-up also causes uncertainty with regard to the true effect of the treatment modalities, due to unknown outcomes of those who missed follow-up. However, Young et al. (2013b) found that the majority of the femoral shaft fracture patients in Malawi who did not return to hospital for follow-up were doing well. Another limitation was that there was no standard definition of delayed union and nonunion in the study's facilities. As most patients routinely have only one radiographic view, either anteroposterior (AP) or lateral, it was not possible to use standard scoring systems such as the RUST Score (Whelan et al. 2010) or the criteria used by Tsang et al. (2016). Finally, because patients' assignment to the 2 study groups was not randomized, there is a potential for confounding due to unmeasured baseline characteristics. Further, regression models may not adequately control for confounding (Shrier and Platt 2008). However, since only confounders measured at baseline were included, we argue that none of these can be colliders in the analysis. Nevertheless, this prospective observational study is the first to compare the quality of life and functional status of femoral shaft fractures treated with either an intramedullary nail or skeletal traction in a LIC.

In conclusion, this study found that treatment with IMN improved early (≤ 6 months) postoperative quality of life and function and allowed patients to return to work earlier compared with those treated with ST. Treatment of femoral shaft fractures with ST in a resource-limited setting may achieve similar outcomes to IMN in quality of life and function at 1-year post-injury if fracture union is achieved. However, approximately 1 in every 3 patients treated with straight-leg

ST failed treatment, requiring conversion to surgical treatment. There is a need for a cost-effectiveness study comparing these 2 treatment modalities to gain a broader picture of the impact of treatment for femoral shaft fractures in low-resource settings.

LC designed the concept of study, supervised and monitored data collection, analyzed the data, and drafted the manuscript. BL provided input on the concept of the study, supervised and monitored data collection, and helped with database design and critical revision of the manuscript. HHW set up the database, and supervised and monitored data collection, and critical revision of the manuscript. DS provided input on the concept of the study, monitored data collection, and undertook critical revision of the manuscript. NM, JEG, GH, and SY provided input on the concept of the study, and undertook critical revision of the manuscript.

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9.4 Paper IV (Manuscript)

Chokotho L, Donnelley C, Young S, Lau BC, Wu H, Mkandawire N, Gjertsen JE, Hallan G, Shearer D. Cost Utility Analysis of Intramedullary Nailing and Skeletal Traction Treatment for Patients with Femoral Shaft Fractures in Malawi.
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Cost Utility Analysis of Intramedullary Nailing and Skeletal Traction Treatment for Patients with Femoral Shaft Fractures in Malawi

Linda CHOKOTHO[1,2], Claire A. DONNELLEY[3], Sven YOUNG[1,4,5], Brian C. LAU[6], Hao-Hua WU[3], Nyengo MKANDAWIRE[1,7], Jan-Erik GJERTSEN[2,4], Geir HALLAN[2,4], David SHEARER[3]

1. Department of Surgery, College of Medicine, University of Malawi
2. Department of Clinical Medicine, University of Bergen, Bergen, Norway
3. The Institute for Global Orthopaedics and Traumatology, Orthopaedic Trauma Institute, University of California San Francisco, San Francisco, CA, USA
4. Department of Orthopaedic Surgery, Haukeland University Hospital, Bergen, Norway
5. Department of Surgery, Kamuzu Central Hospital, Lilongwe, Malawi.
6. Department of Orthopaedic Surgery, Duke University Medical Centre
7. School of Medicine, Flinders University, Adelaide, Australia

Corresponding Author: Linda Chokotho, Department of Surgery, College of Medicine, University of Malawi, Private Bag 360, Blantyre, Malawi.

Phone: +265881668152

Email: lindachokotho@gmail.com

Abstract

Background: In Malawi, skeletal traction (ST) is still used in the treatment of femoral shaft fractures. Previous studies have found that intramedullary nailing (IMN) has improved outcomes and is less expensive than ST. However, no cost- effectiveness analyses have compared IMN and ST in Malawi. We report the results of a cost-utility analysis (CUA) comparing treatment using either IMN or ST.

Methods: A CUA used a decision tree model from government health care payer and societal perspectives with 1-year time horizon. EQ-5D-3L utility scores and probabilities were obtained from a prospective observational study. Quality Adjusted Life Years (QALYs) were calculated from utility scores using the area under the curve method. Direct treatment costs were obtained from a prospective costing study. Indirect costs included patient lost productivity, patient transportation, meal, and childcare costs associated with hospital stay and follow-up visits. Multiple sensitivity analyses assessed model uncertainty.

Results: Total treatment costs were higher for ST ($1,348.81) compared to IMN ($1,121.97). QALYs were lower for ST than IMN, 0.71 (95% Confidence Interval (CI): 0.66 – 0.76) and 0.77 (CI: 0.71-0.82) respectively. Based on lower cost and higher utility, IMN was the dominant strategy. IMN remained dominant in 93.8% of simulations. IMN was less cost-effective than ST at a total procedure cost exceeding $880 from the payer perspective, or $1,035 from the societal perspective.

Interpretation: IMN was cost saving and more effective than ST in the treatment of adult femoral shaft fractures in Malawi, and may be an efficient use of limited health care resources.

Introduction

The incidence of femoral shaft fractures in low- and middle-income countries (LMICs) is estimated to range from 15.7 to 45.5 per 100,000 people per year (Agarwal-Harding et al. 2015). In Malawi, a recent study estimated the prevalence of femoral shaft fractures at 1.38 per 100,000 people and incidence of 26.5 per 100,000 people per year (Agarwal-Harding et al. 2020), translating into approximately 4,700 fractures annually. A femoral shaft fracture can result in significant physical disability if not treated properly. Thus, the goal of treatment for these fractures is to achieve stability at the fracture site, thereby promoting union and painless weight bearing, and allowing early patient rehabilitation. Treatment with intramedullary nailing (IMN) achieves this goal earlier and more consistently than skeletal traction (ST), and has become the gold standard for managing these fractures in high-income countries. In Malawi however, treatment using ST, requiring patient immobilization in bed for at least 6-weeks, remains the mainstay treatment.

Femoral shaft fractures do not only affect physical function, but also patient's social and psychological well-being (Haug et al. 2017, Kohler et al. 2017). Accordingly, better treatment of these fractures should improve quality of life by improving not only physical function but also social and psychological functions. A Quality Adjusted Life Year (QALY), is an appropriate measure of outcome as it includes both quantity and quality of life (Stothers 2006). Studies from Malawi and elsewhere, have found that treatment with IMN is less costly compared to ST (Gosselin et al. 2009, Opondo et al 2013, Kamau et al. 2014, Diab et al 2019). However, these studies did not assess the effectiveness of these two treatment modalities using a generic outcome measure such as the QALY. As such it remains unclear which modality represents a better use of limited health care resources in terms of costs and QALYs gained. Malawi is a low-income country in Southern Africa with a gross domestic product (GDP) per capita of only 380 US Dollars ($) (World Bank 2019a). In a resource-limited setting like Malawi, appropriate resource allocation to ensure optimization of the health-care budget is a priority. Cost-effectiveness analyses of health care interventions can provide the necessary evidence needed to change clinical practice, funding, and policies for the better.

The aim of our study was to evaluate the cost-effectiveness of IMN versus ST in the treatment of femoral shaft fractures in Malawi using QALYs as a measure of effectiveness, to determine which treatment modality best represents efficient use of health-care resources from government healthcare payer and societal perspectives.

Methods

Design and Setting

This study is a cost-utility analysis (CUA) comparing IMN to ST for treatment of adult femoral shaft fractures in Malawi. This was a planned analysis using data from a previously published prospective observational study that compared quality of life (QOL) and function for adults with closed femoral shaft fractures treated with IMN or ST in Malawi (Chokotho et al. 2020). Adult patients were recruited from six hospitals in Malawi: Queen Elizabeth Central Hospital (QECH), Kamuzu Central Hospital, Beit Cure International Hospital, and Chiradzulu, Thyolo and Chikwawa district hospitals. Patients not eligible for inclusion were excluded using the following criteria: (1) age less than 18, (2) polytraumatized, defined as any additional injury requiring admission on its own merits, (3) pathological fractures, (4) open fractures, (5) clinical evidence of infection at the surgical site before or during surgery, and (6) prior surgery involving the affected femur. Study participants were treated using ST or IMN at the discretion of the treating surgeon or orthopaedic clinical officer (OCO). OCOs are non-physician clinicians trained to provide non-operative care for orthopaedic conditions and emergency orthopaedic surgery for selected cases, such as acute infections and open fractures (Mkandawire et al. 2008). Follow-up assessments were performed at 6 weeks, 3 months, 6 months, and 1 year after the injury.

Treatment Technique

The SIGN nail (Zirkle and Shahab 2016) was used in all IMN patients. This is a solid locking IM nail that can be inserted without the need for a fracture table or intraoperative fluoroscopy. The SIGN nail was inserted antegrade using open reduction, with the patient in the lateral position on a standard operating table.

All ST patients had straight leg extension skeletal traction with a Steinmann pin inserted into the proximal tibia under local anaesthesia, using aseptic technique and a stirrup to connect the rope that was used to position the weights. The weights were positioned either using a bar, pulleys or by placing the rope directly over the end of the bed, depending on the type of bed and equipment available at the hospital.

Effectiveness Data

The effectiveness of each treatment strategy was measured using quality-adjusted life years (QALYs) based on the EQ-5D-3L (Rabin and Charro 2001). At each follow up time, research assistants administered the EQ-5D-3L questionnaire to the study participants. The EQ-5D-3L is a tool used to measure health-related quality of life (HRQoL) that has been translated to Chichewa and validated for use in Malawian orthopaedic patients (Chokotho et al. 2017). Utility scores were calculated using EQ-5D-3L responses based on data from the Zimbabwean population value set (Jelsma et al 2003). QALYs were calculated from the utility scores using the area under the curve method (Billingham et al. 1999). There was no measurable difference between groups in EQ-5D-3L index score at 1 year after treatment, hence a 1-year time horizon was used.

Costing Data

Direct medical and overhead costs and indirect patient costs were estimated. Direct costs were estimated using time and motion analysis, and included procedure personnel and supplies, ward personnel, medications and investigations, surgical implants, and instruments. Overhead costs included food, building maintenance, renovation, cleaning and sanitation, beddings, stationery, uniforms, protective wear, and staff training. The direct medical and overhead cost data were collected on a subset of patients in the main clinical study at one of the six sites (QECH) (Diab et al 2019). Hourly salaries for personnel were calculated by dividing mean annual salary by the product of 9-hour days which is the average working hours for public hospitals in Malawi, and 251 working days per year. Further details on how the direct costs were calculated have been published earlier (Diab et al. 2019). All costs were presented in 2017 USD ($). Outpatient costs included clinic personnel, physiotherapy, and X-ray costs. Indirect costs included patient lost productivity, and patient transportation, meal, and childcare costs associated with hospital stay and follow-up visits. Costs associated with lost productivity were calculated for patients who reported either formal or informal employment prior to injury. Employment was scored as a binary value at each follow-up time point. Using midpoints between follow-up visits before and after the follow-up time point, overall loss productivity was weighted by the sum of weeks of reported unemployment, with a maximum of 52 weeks. The costs associated with productivity loss were calculated using a standardized wage for Malawi, adjusted using purchasing power parity to USD (World Bank 2019b). Patients were interviewed to estimate transportation, meal, and childcare costs. Resource utilization for each treatment group is shown in Table 1.

Decision Tree Model

A simple decision tree model (Figure 1) was constructed to compare the two treatments using TreeAge Pro 2020 (Pro 2019). In the ST treatment strategy, there were two potential outcomes: (1) successful traction, or (2) failure of treatment with conversion to IMN. Successful traction was defined as complete fracture union after treatment with ST. Failure of ST treatment was defined as either delayed union or non-union of the fracture requiring conversion to IMN. Patients treated in the IMN group had two potential outcomes: (1) successful IMN, or (2) failure of treatment with reoperation. The diagnosis of delayed union was made by the treating clinician if at 6 weeks or more post-injury, there was still tenderness and mobility at the fracture site and no radiological evidence of callus formation. Non-union was defined as no evidence of fracture healing both clinically and radiologically after at least 3 months on ST or 6 months after IMN.

The primary outcome of the analysis was the Incremental Cost-effectiveness Ratio (ICER), which was calculated by dividing the difference in cost by the difference in utility between the two treatment groups. The inputs for the model are shown in Table 2. There was no difference in EQ-5D-3L index scores at 1 year in the primary study, hence a 1-year time horizon was used. 3% discounting was applied. Both payer and societal perspectives were considered in the base case.

Sensitivity Analysis

Both deterministic and probabilistic sensitivity analyses were done to assess which parameters are most important for the ICER and the uncertainty of the input parameters on the ICER. A tornado diagram was used to perform multiple one-way sensitivity analyses assessing the relative influence of each model input on the ICER across a range of plausible input values based on the upper and lower limits of 95% confidence intervals (CIs). One-way sensitivity analyses were presented independently where appropriate. A multivariate probabilistic sensitivity analysis (PSA) was performed by performing 10,000 iterations of the model with a unique value for each input drawn from a probability distribution. The distributions used and standard errors are shown in Table 2. In general, costs were represented using a gamma distribution (range 0 to ∞) while probabilities and utilities were represented with a beta distribution (range 0 to 1). The results of the PSA are presented as an ICER scatter plot, which visually demonstrates the outcome of each iteration of the PSA as a point on the cost-effectiveness plane.

Ethics, funding and potential conflicts of interest

The study was approved by the College of Medicine Research Ethics Committee, in Malawi, and the Western Norway Regional Research Committee and University of California San Francisco Institutional Review Boards. Written informed consent was obtained from all patients in the study. The study was funded by the James O. Johnston Research Grant, a PhD grant through the Norhed Project, financed by Norad and Institute of Global Orthopedics and Traumatology (IGOT), University of California San Francisco. Author DS is a non-paid member of the Board of Directors for SIGN Fracture Care International. The rest of the authors declare no conflict of interest.

Results

Data from 187 patients who completed one year follow up were used to estimate utilities and probabilities, including 55 cases treated with a SIGN intramedullary nail (IMN) and 132 cases treated with ST. The overall total QALYs at 1 year were higher after IMN compared to ST (Table 3).

Data on a subset of 65 patients treated at QECH (38 IMN, 27 ST) were used to estimate direct costs. The total direct cost of treatment was higher in the ST group compared to IMN

(Table 3). The total societal cost was higher for ST ($1,543 (CI: $1,149 – $1,625)) than IMN (1,139 (CI: $1,080 - $1,210)). Based on higher costs from both payer and societal perspectives, and lower utility with ST, IMN was the dominant strategy.

Sensitivity Analysis

The Tornado diagram (Figure 2) shows that the ICER was most sensitive to effectiveness of successful IMN, followed by effectiveness of successful traction. No change in the range of values for any of the variables resulted in IMN being less cost-effective than ST.

Figures 3 and 4 show the one-way sensitivity analysis varying the total cost of IMN on ICER from the payer and societal perspectives respectively. IMN was dominant (more effective, less costly) up to a total procedure cost of $880 from the payer perspective or $1,035 from the societal perspective. Focusing specifically on the cost of the intramedullary implant, surgery was cost saving up to a nail cost of $472 from the payer perspective or $691 from a societal perspective.

Probabilistic Sensitivity Analysis

The ICER scatter plot (Figure 5) shows that IMN was cost saving and more effective (dominant) in 93.8% of simulations.

Discussion

This study found that treatment of adult femoral shaft fractures with IMN was more cost-effective than with ST in Malawi. Sensitivity analyses showed more than 90% certainty that this conclusion is true, and will remain true for IMN procedural costs of less than $880 and $1,035 from the payer and societal perspectives, respectively. Although there were no significant differences in effectiveness between treatment modalities at one year, there were small but significant differences at the other time intervals (Chokotho et al. 2020). The cost of IMN was lower and utility higher compared to ST; IMN is therefore the dominant approach from both societal and payer perspectives.

The finding of lower cost of IMN compared to ST has been reported by previous studies. Gosselin et al. (2009), found lower costs for IMN compared to ST even accounting for re-nailing costs following infection or non-union. Gosselin also reported significantly better union rates with IMN than ST. Similarly, both Opondo et al. (2013) and Kamau et al. (2014) found IMN to be less costly with better healing and functional outcomes than ST among patients with femoral shaft fractures in Kenya. However, the time horizon in these studies ranged from 12-16 weeks limiting the assessment of non-union. Further, there was no measure of patient-reported outcomes or preference-weighted instruments, such as the EQ-5D, and cost was only measured from the payer perspective.

Patients treated with ST in Malawi are normally admitted in hospital for at least 6 weeks whereas those treated with IMN have an average length of stay of 17 days (Diab et al. 2019). In Malawi, patients do not pay service fees in public hospitals, therefore prolonged hospital stay is likely to have cost implications from the governmental payer perspective. A treatment method like IMN, which is both cost-saving and more effective, is certainly worth prioritizing to optimise the limited health budget.

Prolonged hospital stay is also likely to have significant financial implications for the patients and their guardians, who usually accompany patients in the hospital during the entire admission period. Due to the lack of nursing staff in Malawi, it is customary for these guardians, who are typically family members, to serve as the primary caregiver for patients during their hospitalization, with both patients and caregivers incurring significant indirect costs of lost-productivity, and hospital-related expenses. This is the first study that has evaluated the cost-effectiveness of femoral shaft fracture treatment with IMN and ST from the societal perspective. Haug et al. (2017) found that patients treated with skeletal traction complained that prolonged hospitalisation caused significant financial strain because patients and their families were unable to engage in income generating activities. In addition, they found that there was increased out of pocket expenditure while in hospital. Survival mechanisms to keep up with the increased expenditure included selling their property and borrowing money, sometimes with high interest rates [Damme et al. 2004, Kohler et al. 2017). Therefore, if hospital stays can be reduced through IMN, this treatment has cost-saving potential from both the governmental payer and societal perspective.

SIGN Fracture Care International currently donates intramedullary nails free of charge to many hospitals in LMICs, including Malawi. This fact increases the potential cost saving beyond this study's estimates, since our analysis included the cost of the IM nail. Cost-effective interventions are, however, not always affordable and accessible, and such is the case for Malawi where provision of operative fracture treatment is not universal in public hospitals. Future studies should include budget impact analyses assessing the affordability of adopting a new intervention from the payer's perspective (Sullivan et al. 2014), thereby evaluating the opportunity costs and relevant benefits associated with choosing IM nailing as first line treatment over ST.

The present study had several limitations. Firstly, since it was not a randomised study, there were likely unmeasured confounding variables. Secondly, loss to follow up at the different time points could lead to selection bias thereby affecting the findings of the study. However, there was no differential loss to follow up as the proportions in both groups were similar. The results in our model were validated by univariate sensitivity analysis and Monte Carlo simulation and both analyses showed that IMN was the cost-effective treatment approach. Thirdly, the time horizon of 1 year used in this study may have been too short. As such we may have missed long term QALY gains. However, there were no significant differences in effectiveness between the two treatment groups at 1 year, likely because those who failed ST treatment, and were likely to have a poor outcome if left untreated, were switched to treatment with IMN. Conversely, in a setting where IMN is not offered, ST is likely to result in substantial loss of QALYs. Another limitation is that the decision tree in our analysis did not include all possible pathways or complications that represent the course of outcomes after treatment. Only delayed union and non-union were considered because cost data for other complications was not available. The majority of patients in this study were recruited from government run hospitals, and so the findings may not be applicable to patients treated in private care facilities. However, ST treatment is not routinely offered in private hospitals where all patients are treated with IMN and the majority of the population in Malawi does not have medical insurance and therefore uses public hospitals where services are free at point of care. Thus, the findings of this study are applicable to the majority of health facilities in the country.

Despite its limitations, the present study has shown that IMN is more effective and costs less than ST, and therefore scale-up of IMN may be an efficient use of limited health care resources in low income countries. The findings of this study are relevant to health care policy makers and other stakeholders to justify and advocate for improved surgical capacity so that patients with femur shaft fractures are treated with intramedullary nailing rather than skeletal traction.

Table 1. Resource utilization for each treatment group including both direct and indirect costs excluding the cost of failed traction or surgery requiring reoperation.

			IMN	ST
Direct costs				
	Inpatient			
		Ward personnel	$263.75	$445.45
		Overhead	$116.15	$196.16
		Surgical implants	$135.50	$0.00
		Investigations	$38.47	$28.48
		Procedure personnel	$23.65	$2.72
		Procedure supplies	$8.51	$3.60
		Instruments	$8.73	$0.18
		Medications	$2.23	$1.60
		Total	$596.97	$678.20
	Outpatient			
		Clinic personnel	$1.02	$0.78
		Physiotherapy personnel	$2.62	$1.21
		X-ray	$40.90	$28.63
		Total	$44.54	$30.62
	Total Direct Costs		$641.51	$708.82
Indirect costs				
		Lost Productivity	$453.60	$610.20
		Transportation	$3.98	$4.01
		Meals	$3.38	$0.67
		Childcare costs	$19.50	$25.12
	Total Indirect Costs		$480.46	$639.99
Total Costs (Direct + Indirect Costs)			$1,121.97	$1,348.81

Table 2. Inputs for the Decision Tree Model

	Mean	SE	95% CI Lower	95% CI Upper	Distribution Type	Reference
Costs						
IMN						
Direct Inpatient Cost	597	27.4	543	651	Gamma	[Diab et al. 2019]
Direct Outpatient Cost	45	-	-	-	-	[Chokotho et al. 2020]
Cost of Reoperation	900	-	600	1200	Uniform	Estimate*
Indirect Cost (Societal)	480	-	-	-	-	[Chokotho et al. 2020]
ST						
Direct Inpatient Cost	678	27.7	624	732	Gamma	[Diab et al. 2019]
Direct Outpatient Cost	31	-	-	-	-	[Chokotho et al. 2020]
Cost of IMN after Failed ST	649	43.8	563	735	Gamma	[Diab et al. 2019]
Indirect Cost (Societal)	640	-	-	-	-	[Chokotho et al. 2020]
Utilities						
IMN						
Utility Successful IMN	0.77	0.03	0.72	0.83	Beta	[Chokotho et al. 2020]
Utility After Reoperation	0.71	0.05	0.61	0.81	Beta	[Eliezer et al. 2017]
ST						
Utility Successful ST	0.72	0.03	0.66	0.79	Beta	[Chokotho et al. 2020]
Utility Failed ST	0.69	0.04	0.61	0.76	Beta	[Chokotho et al. 2020]
Probabilities						
IMN						
Probability Reoperation	1.8%	0.02	0.0%	5.3%	Beta	[Chokotho et al. 2020]
ST						
Probability Failed ST	30.0%	0.04	22.2%	37.8 %	Beta	[Chokotho et al. 2020]

*Assumed reoperation cost 1- to 2-fold higher than index surgery

Table 3. Output from decision tree model including incremental cost and effectiveness.

		95% CI*				95% CI*	
Strategy	**Utility**	**Lower**	**Upper**			**Lower**	**Upper**
Skeletal traction	0.71	0.66	0.76				
				Cost (Payer)	$903	$828	$986
				Cost (Societal)	$1,543	$1,469	$1,625
Early IMN	0.77	0.71	0.82				
				Cost (Payer)	$659	$599	$729
				Cost (Societal)	$1,139	$1,080	$1,210

Incremental Utility		**Incremental Cost**	
	0.06	Payer	-$244.00
		Societal	-$404.00

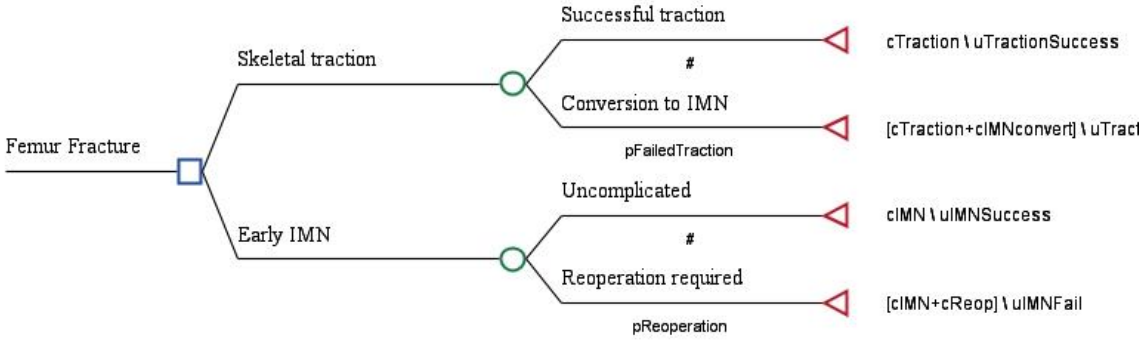

Figure 1: Decision Tree Model of Possible Outcomes after ST and IMN Treatment of Femoral Shaft Fractures. The costs and effectiveness of each pathway are presented at the end of each potential pathway

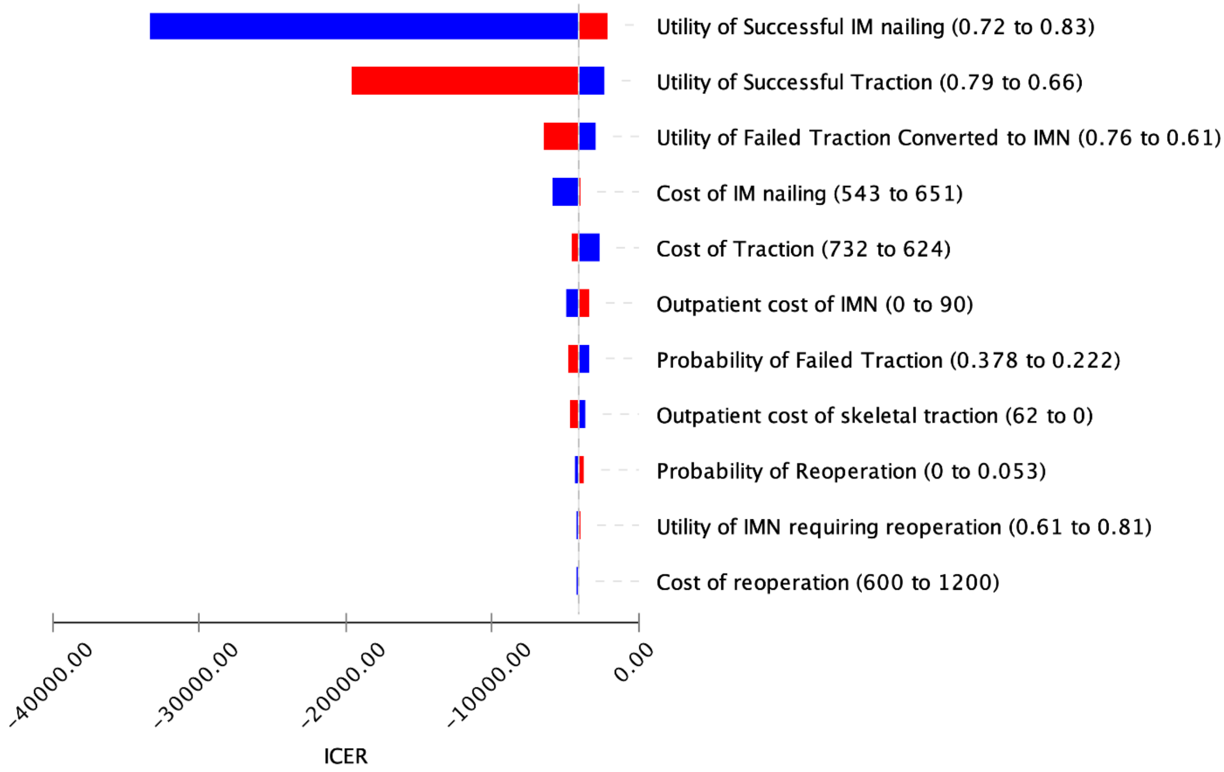

Figure 2: Tornado diagram demonstrating influence of each variable on the ICER across a plausible range of inputs based on the upper and lower bound of 95% confidence interval. The dotted line represents ICER per QALY gained for the base case.

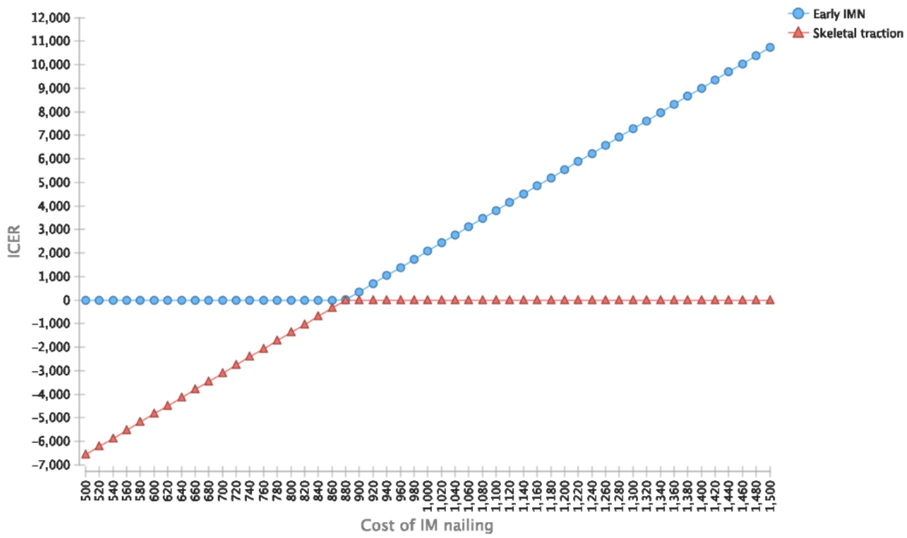

Figure 3: A one-way sensitivity analysis on the payer total cost of early intramedullary nailing and ICER

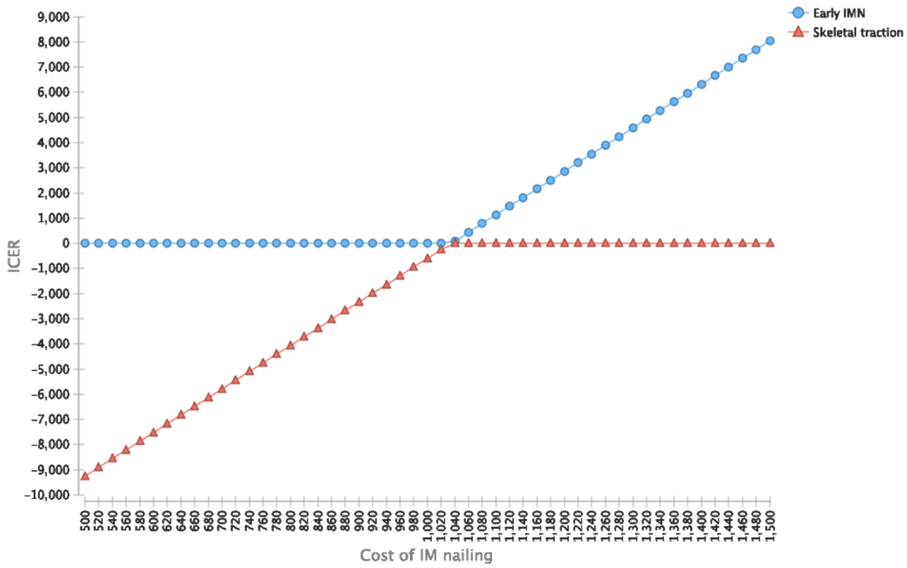

Figure 4: A one-way sensitivity analysis on the societal total cost of early intramedullary nailing and ICER

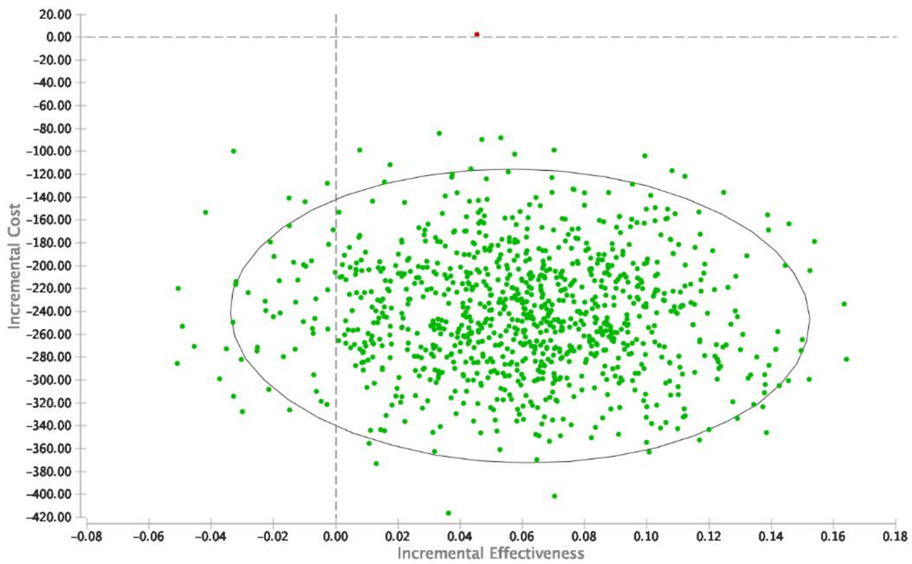

Figure 5: ICER Scatter Plot demonstrating output from the probabilistic sensitivity analysis.

Author contributions

LC, designed the concept of study, analysed the data and drafted the manuscript.

CD, analysed the data and critical revision of the manuscript

SY, provided input on the concept of the study, critical revision of the manuscript

HHW, critical revision of the manuscript

BCL, provided input on the concept of the study, critical revision of the manuscript

NM, provided input on the concept of the study, critical revision of the manuscript

JEG, provided input on the concept of the study, critical revision of the manuscript

GH, provided input on the concept of the study, critical revision of the manuscript.

DS, provided input on the concept of the study, analysed the data, critical revision of the manuscript

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10. Appendices

10.1. EQ-5D (Chichewa and English)

Mafunso a za Umoyo

Chinyanja (Chichewa) cha ku Malawi

(Nyanja (Chichewa) version for Malawi)

Chongani mu bokosi limodzi mu gulu lililonse pansipa, chonde sonyezani mfundo zimene zikufotokoza bwino za umoyo wanu lero.

Mayendedwe

Ndilibe vuto lina lililonse poyenda ❑

Ndimakhala ndi mavuto ena poyenda ❑

Ndimangobindikira pa kama ❑

Kudzisamalira ndekha *(mwachitsanzo kusamba ndi kudziveka ndekha)*

Ndilibe vuto podzisamalira ndekha ❑

Ndimakhala ndi mavuto ena posamba kapena podziveka ndekha ❑

Ndimalephera kusamba kapena kudziveka ndekha ❑

Zochitika za tsiku ndi tsiku *(monga kugwira ntchito, kuwerenga, ntchito za pakhomo, za m'banja kapena kuchita zimene zimandisangalatsa)*

Ndilibe mavuto ali onse pogwira ntchito zanga za nthawi zonse ❑

Ndimakhala ndi mavuto ena pogwira ntchito zanga za nthawi zonse ❑

Ndimalephera kugwira ntchito zanga za nthawi zonse ❑

Ululu/Kuphwanya m'thupi kosowetsa mtendere

Ndilibe ululu kapena sindikumva kuphwanya m'thupi ❑

Ndimakhala ndi ululu kapena kumva kuphwanya m'thupi mwapakatikati ❑

Ndimakhala ndi ululu kapena kumva kuphwanya m'thupi kwambiri ❑

Nkhawa/Khumudwa (Osasangalala)

Sindikuda nkhawa kapena kukhumudwa ❑

Ndimakhala oda nkhawa kapena okhumudwa mwapakatikati ❑

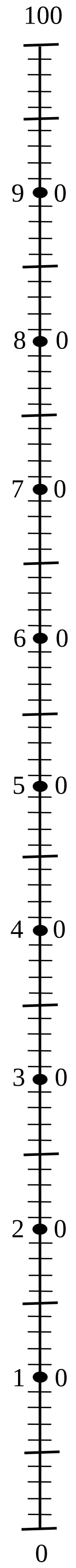
Ndimakhala oda nkhawa kapena okhumudwa kwambiri ❑

Kuti tithandize anthu kunena za umoyo wawo, tajambula mlingo woyesera (chofanana ndi choyesera kuzizira/kutentha kwa m’thupi) womwe umoyo wabwino wayerekezedwa ndi chizindikiro cha 100 ndipo umoyo woipa wayerekezedwa ndi chizindikiro cha 0.

Tikufuna mutisonyeze pa mlingowu mmene umoyo wanu ulili lero kuti uli bwino kapena suli bwino mmene inu mukuganizira. Lembani mzere kuchokera pa bokosi pansipa kupita pa mlingo woyesera umene ukufotokoza za ubwino kapena kuipa kwa mmene umoyo wanu ulili lero.

Mmene umoyo wanu ulili lero

Kuyerekezedwa kuti umoyo uli bwino kwambiri



Kuyerekezedwa kuti umoyo si uli bwino

Health Questionnaire

English version for the UK (validated for Ireland)

By placing a tick in one box in each group below, please indicate which statements best describe your own health state today.

Mobility

I have no problems in walking about ❑

I have some problems in walking about ❑

I am confined to bed ❑

Self-Care

I have no problems with self-care ❑

I have some problems washing or dressing myself ❑

I am unable to wash or dress myself ❑

Usual Activities (*e.g. work, study, housework, family or leisure activities)*

I have no problems with performing my usual activities ❑

I have some problems with performing my usual activities ❑

I am unable to perform my usual activities ❑

Pain/Discomfort

I have no pain or discomfort ❑

I have moderate pain or discomfort ❑

I have extreme pain or discomfort ❑

Anxiety/Depression

I am not anxious or depressed ❑

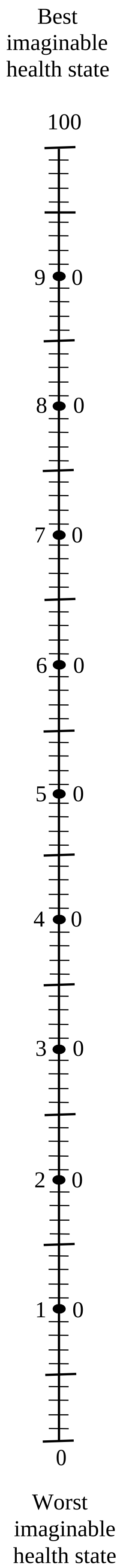
I am moderately anxious or depressed ❑

I am extremely anxious or depressed ❑

To help people say how good or bad a health state is, we have drawn a scale (rather like a thermometer) on which the best state you can imagine is marked 100 and the worst state you can imagine is marked 0.

We would like you to indicate on this scale how good or bad your own health is today, in your opinion. Please do this by drawing a line from the box below to whichever point on the scale indicates how good or bad your health state is today.

Your own health state today



10.2. SMFA (Chichewa and English)

KUFUFUZA KAGWIRIDWE NTCHITO KA MINOFU NDI MAFUPA (SHORT MUSCULOSKELETAL FUNCTION ASSESSMENT)

Malangizo

Tili ndichidwi kuti tidziwe mmene mukuthera kukhala ndi nthenda yopweteka, yotupitsa ndi youmitsa malo omwe mafupa amakumana mthupi mwanu (arthritis), kapena kuvulala kwanu, musabata lino. Tikufuna tidziwe vuto lina lililonse lomwe mukukumana nalo mukagwiridwe ka ntchito zanu za tsiku ndi tsiku lomwe labwera chifukwa cha matenda a arthritis kapena kuvalala.

Chonde yankhani funso lililonse pochonga mukabokosi malingana ndi chisankho chomwe mwasankha chomwe chikufotokozera bwino za inu.

Mafunso awa, afunsa muyezo wa zovuta zomwe mwawona kapena mwakumana nazo sabata lino pogwira ntchito zanu za tsiku ndi tsiku, omwe abwera chifukwa cha kuvulala kwanu kapena chifukwa cha matenda wopweteketsa, wotupitsa ndi woumitsa malo okumana mafupa mthupi lanu (arthritis)

	Palibe vuto	Pali vuto pang'ono	Pali vuto lochulukirapo	Pali vuto lalikulu ndithu	Sindingathe
1. Kodi ndikovuta bwanji kwa inu kuti mukhale pampando kapena muimirire kuchoka pampando wam'musi?					
2. Kodi ndikovuta bwanji kuti inu mutsekule mabotolo kapena Mikebe ya mankhwala kapena mabotolo ena?					
3. Kodi ndikovuta bwanji kuti mukwere masitepe?					
4. Ndikovuta bwanji kuti inu mugule zinthu musitolo?					
5. Ndikovuta bwanji kuti inu mukunge chibakela					
6. Ndikobvuta bwanji kuti mulowe kapena mutuluke mubafa losambilamo kapena malo wosambira?					
7. Kodi ndikovuta bwanji kuti mukagona pansi tulo tibwere?					
8. Kodi ndikovuta bwanji kuti muwerame kapena kugwada pansi?					
9. Kodi ndikovuta bwanji kuti mumange mabatani,zip, lamba kapena zomangira malaya zina?					
10. Ndikovuta bwanji kuti inu muwenge dzikhadabo dzanu?					
11.Kodi ndikovuta bwanji kuti mudziveke zovala?					

12. *Kodi ndikovuta bwanji kuti muyende?*

13. *Kodi kumakhala kobvuta bwanji kuti muyambenso kuyenda mutatha kukhala pansi kapena kugona kwathawi yayitali?*

14. Kodi n*dikovuta bwanji kuti mutuluke panja muyende nokha?*

15. Ndikovuta bwanji kuti muyendetse galimoto, ngati mumatha kale kuyendatsa galimotolo?

16. Kodi ndikovuta bwanji kuti mudzisamalire mukachoka ku chimbudzi

17. Kodi ndikovuta bwanji kugwiritsa ntchito zotsegulira dzitseko; mwachitsanzo zitseko za mnyumba kapena chotsitsila mawindo a galimoto?

18. *Ndikovuta bwanji kwa inu kuti mulembe kapena kutayipa?*

19. *Kodi* ndikobvuta bwanji kuti mutembenuke mutaima malo amodzi?

20. Kodi ndikovuta bwanji kuti mupange masewera wolimbitsa thupi monga kutchova njinga, kuthamanga kapenanso kuyenda ndawala?

21. Kodi ndikovuta bwanji kuti muchite zinthu zina zokonda zanu, munthawi yongokhala ngati kusema, zakudimba, kusewela ziganda (ma kadi) kapenanso kukayenda ndi anzanu?

22. *Kodi mukuvutika bwanji, pankhani yogonana?*

23. Kodi ndikovuta bwanji kuti mugwire ntchito zopepuka Za mnyumba kapena panja, ngati kukuntha fumbi, kutsuka mbale kapena kuthilira mbeu?

24. Kodi ndikovuta bwanji kuti mugwire ntchito zolimba zamnyumba kapena panja, ngati kukolopa kapene kuzira pansi, kapena kutchetcha?

25. Kodi ndikovuta bwanji kwa inu mugwire ntchito zanu zozolowereka, monga ntchito yolipidwa, yapakhomo kapena yongothandiza?

Mafunso otsatilawa, akufunsa kuwirikiza kwa mavuto omwe mwakumana nawo sabata limeneli chifukwa cha kuvulala kwanu kapena cha matenda wopweteketsa, wotupitsa ndi woumitsa malo okumana mafupa mthupi lanu (arthritis)

	Palibe	Nthawi pang'ono	Nthawi zina	Nthawi zambiri	Nthawi zonse
26. Kodi mumatsimphina mowirikiza bwanji?					
27. Kodi ndimowirikiza bwanji pomwe mumapewa kugwiritsa ntchito manja, miyendo kapena msana owawa?					
28. Ndimowilikiza bwanji pomwe mwendo wanu umakanika kuongoka Kapena umagujuka					
29. Ndimowirikiza bwanji pomwe mumakhala ndi vuto Kuti mukhale ndi chidwi kapena kuika mtima pa chinthu Chimene mukuchita.					
30. Kodi ndimowirikiza bwanji pomwe mukagwira ntchito kwambiri lero kumakhudza kagwiridwe ka ntchito zanu tsiku lotsatilalo?					
31. Kodi ndimowirikiza bwanji pomwe mumakwiyira iwo womwe akuzungulirani, mwachitsanzo, kuyankhula mosaganizira munthu, kupereka mayankho wokhadzula kapena kutsutsa mulimonse?					

32. Kodi mumatopa mowirikiza bwanji?	☐	☐	☐	☐	☐
33. Kodi n*dimowirikiza bwanji pomwe mumamva kuti simungathe Kuchita kanthu (ngati ndinu munthu wolumala)*	☐	☐	☐	☐	☐
34. Kodi ndimowilikiza *bwanji pomwe mumakhala wokwiya kapena kukhumudwa chifukwa cha kuvulala kwanu kapena cha matenda wopweteketsa, wotupitsa ndi woumitsa malo okumana mafupa mthupi lanu (arthritis)*	☐	☐	☐	☐	☐

Mafunso otsatilawa, akufunsa kuti ndinu okhudzidwa bwanji ndi mavuto womwe muli nawo sabata lino chifukwa cha kuvulala kwanu kapena chifukwa cha matenda wopweteketsa, wotupitsa ndi woumitsa malo okumana mafupa mthupi lanu (arthritis)

	Sizindikhudza konse	Zimandikhudza pang'ono	Zimandikhudza Mochulukirapo	Zimandikhudza kwambiri	Zimandikhudza koopsya
35. Kodi ndinu wokhudzidwa bwanji ndi vuto logwiritsa ntchito manja, mikono kapena miyendo yanu?	☐	☐	☐	☐	☐
36. Kodi ndinu wokhudzidwa bwanji ndi vuto logwiritsa ntchito nsana wanu?	☐	☐	☐	☐	☐
37. Kodi n*dinu wokhudzidwa bwanji ndivuto logwira ntchito zapakhomo lanu?*	☐	☐	☐	☐	☐
38. Kodi ndinu wokhudzidwa bwanji ndimavuto apogona ndi kupumula?	☐	☐	☐	☐	☐

39. *Kodi ndinu wokhudzidwa bwanji ndimavuto aposamba, kugwiritsa ntchito chimbudzi ndi zina zokhudzana ndichisamaliro cha inu eni?*

40. *Kodi ndinu wokhudzidwa bwanji ndi mavuto amene amakhalapo pamene mukupanga masewero odzisangalatsa?*

41. *Kodi ndinu wokhudzidwa bwanji ndi mavuto amene amakhalapo ndi anzanu, abale ndi anthu ena wofunika pamoyo wanu?*

42. Kodi ndinu wokhudzidwa motani ndi mavuto amene amakhalapo, kukhala ndi chidwi pa zochitika kapena kukumbukira zinthu?

43. *Kodi ndinu wokhudzidwa motani ndimavuto amene amakhalapo povomereza kapena kuzolowera za kuvulala kwanu kapena nthenda yopweteketsa, yotupitsa ndi youmitsa malo okumana mafupa mthupi lanu (arthritis)*

44. *Kodi ndinu okhudzidwa bwanji ndi mavuto amene amakhalapo pogwira ntchito yanu yozolowereka?*

45. *Kodi ndinu okhudzidwa bwanji ndimavuto omwe amakhalapo chifukwa chakumva kuti mukudalira anthu ena?*

46. *Kodi ndinu okhudzidwa bwanji ndimavuto akuuma ziwalo ndi ululu?*

Short Musculoskeletal Function Assessment

Instructions: We are interested in finding out how you are managing with your injury or arthritis this week. We would like to know about any problems you may be having with your daily activities because of your injury or arthritis. Please answer each question by putting a check in the box corresponding to the choice that best describes you.

These questions are about how much difficulty you may be having this week with your daily activities because of your injury o arthritis.

		Not at all Difficult A	A Little Difficult B	Moderately Difficult C	Very Difficult D	Unable to do E
1.	How difficult is it for you to get in or out of a low chair?	☐	☐	☐	☐	☐
2.	How difficult is it for you to open medicine bottles or jars?	☐	☐	☐	☐	☐
3.	How difficult is it for you to shop for groceries or other things?	☐	☐	☐	☐	☐
4.	How difficult is it for you to climb stairs?	☐	☐	☐	☐	☐
5.	How difficult is it for you to make a tight fist?	☐	☐	☐	☐	☐
6.	How difficult is it for you to get in or out of the bathtub or shower?	☐	☐	☐	☐	☐
7.	How difficult is it for you to get comfortable to sleep?	☐	☐	☐	☐	☐
8.	How difficult is it for you to bend or kneel down?	☐	☐	☐	☐	☐
9.	How difficult is it for you to use buttons, snaps, hooks, or zippers?	☐	☐	☐	☐	☐
10.	How difficult is it for you to cut your own fingernails?	☐	☐	☐	☐	☐
11.	How difficult is it for you to dress yourself?	☐	☐	☐	☐	☐
12.	How difficult is it for you to walk?	☐	☐	☐	☐	☐
13.	How difficult is it for you to get moving after you have been sitting or lying down?	☐	☐	☐	☐	☐
14.	How difficult is it for you to go out by yourself?	☐	☐	☐	☐	☐
15.	How difficult is it for you to drive?	☐	☐	☐	☐	☐
16.	How difficult is it for you to clean yourself after going to the bathroom?	☐	☐	☐	☐	☐
17.	How difficult is it for you to turn knobs or levers (for example, to open doors or to roll down car windows)?	☐	☐	☐	☐	☐
18.	How difficult is it for to write or type?	☐	☐	☐	☐	☐
19.	How difficult is it for you to pivot?	☐	☐	☐	☐	☐
20.	How difficult is it for you to do your usual physical recreational activities, such as bicycling, jogging, or walking?	☐	☐	☐	☐	☐
21.	How difficult is it for you to do your usual leisure activities, such as hobbies, crafts, gardening, card-playing, or going out with friends?	☐	☐	☐	☐	☐
22.	How much difficulty are you having with sexual activity?	☐	☐	☐	☐	☐
23.	How difficult is it for you to do light housework or yard work, such as dusting, washing dishes, or watering plants?	☐	☐	☐	☐	☐
24.	How difficult is it for you to do heavy housework or yard work, such as washing floors, vacuuming, or mowing lawns?	☐	☐	☐	☐	☐
25.	How difficult is it for you to do your usual work, such as a paid job, housework, or volunteer activities?	☐	☐	☐	☐	☐

These next questions ask how often you are experiencing problems this week because of your injury or arthritis.

	None of the Time A	A Little of the Time B	Some of the Time C	Most of the Time D	All of the Time E
26. How often do you walk with a limp?	☐	☐	☐	☐	☐
27. How often do you avoid using your painful limb(s) or back?	☐	☐	☐	☐	☐
28. How often does your leg lock or give way?	☐	☐	☐	☐	☐
29. How often do you have problems with concentrating?	☐	☐	☐	☐	☐
30. How often does doing too much in one way affect what you do the next day?	☐	☐	☐	☐	☐
31. How often do you act irritable toward those around you(for example, snap at people, give sharp answers, or criticize easily)?	☐	☐	☐	☐	☐
32. How often are you tired?	☐	☐	☐	☐	☐
33. How often do you feel disabled?	☐	☐	☐	☐	☐
34. How often do you feel angry or frustrated that you have this injury or arthritis?	☐	☐	☐	☐	☐

These questions are about how much you are bothered by problems you are having this week because of your injury or arthri

	Not at All Bothered A	A Little Bothered B	Moderately Bothered C	Very Bothered D	Extremely Bothered E
35. How much are you bothered by problems using your hands, arms, or legs?	☐	☐	☐	☐	☐
36. How much are you bothered by problems with your back?	☐	☐	☐	☐	☐
37. How much are you bothered by problems doing work around your home?	☐	☐	☐	☐	☐
38. How much are you bothered by problems with bathing, dressing, toileting, or other personal care?	☐	☐	☐	☐	☐
39. How much are you bothered by problems with sleep and rest?	☐	☐	☐	☐	☐
40. How much are you bothered by problems with leisure or recreational activities?	☐	☐	☐	☐	☐
41. How much are you bothered by problems with your friends, family, or other important people in your life?	☐	☐	☐	☐	☐
42. How much are you bothered by problems with thinking, concentrating, or remembering?	☐	☐	☐	☐	☐
43. How much are you bothered by problems adjusting or coping with your injury or arthritis?	☐	☐	☐	☐	☐
44. How much are you bothered by problems doing your usual work?	☐	☐	☐	☐	☐
45. How much are you bothered with feeling dependent on others?	☐	☐	☐	☐	☐
46. How much are you bothered with stiffness and pain?	☐	☐	☐	☐	☐

Name: ___________________________ Date: __________________________

10.3. WHOQOL-BREF (Chichewa and English)

The WHOQoL-BREF I.D. number ☐☐☐☐

Tikudziweni

Musanayambe, tikadakonda mutayankha mafunso pang'ono okhudzana ndi inu: pozunguliza yankho lolondola kapena polemba yankholo m'mizere yotsatilayi.

Kodi ndinu amuna kapena akazi? Amuna Akazi

Kodi tsiku lanu lakubadwa ndiliti? _______/______/________
Tsiku Mwezi Chaka

Kodi munafika pati ndi maphunziro anu?

- sindinapitepo ku sukulu
- pulayimale sukulu
- sekondale sukulu
- maphunziro opitilira sekondale sukulu

Kodi muli pabanja?

- sindinakwatirepo
- okwatira
- timakhala limodzi koma tilibe setifiketi ya kutchalitchi kapena kwa DC
- tinasiyana koma banja silinathe
- banja linatha
- namfedwa

Kodi panopa mukudwala?

- eya
- ayi

Ngati muli ndi vuto la umoyo mukuganiza kuti ndichani? ____

Malangizo

Mafunso otsatilawa akufuna kudziwa za zomwe mukumvera zokhudzana ndi kupambana kwa moyo wanu, umoyo kapena zinthu zina zokhudza moyo wanu. **Chonde yankhani mafunso** onse. Ngati mukukayikira yankho limene mukufuna mupereke, chonde sankhani lomwe likuwoneka ngati lokhonza. Nthawi zambiri yankholi limakhala lomwe munaliganizila poyamba.

Chonde kumbukirani mulingo omwe mumadziyika, ziyembekezo zanu, zomwe zimakusanagalatsani, ndi nkhawa zanu. Tikufunsani kuti muganizire za moyo wanu **m'sabata ziwiri zapitazi**. Mwachitsanzo, poganizira masabata awiri apitawa, mukhonza kufunsidwa:

	Kodi mumalandira chinthandizo choyenera chimene mumafuna kuchokera kwa anthu ena?	Ayi 1	Pang'ono 2	Pakatikati 3	Kwambiri 4	Chonse 5

Muzungulize nambala yomwe ikulongosola bwino kuchuluka kwa chithandizo chomwe munalandira kuchokera kwa anthu ena m'sabata ziwiri zapitazi. Choncho munakazungi nambala 4 ngati munalandira chithandizo kwambiri kuchokera kwa anzanu ena motere.

	Kodi mumalandira chinthandizo choyenerera chimene mumafuna kuchokera kwa anthu ena?	Ayi 1	Pang'ono 2	Pakatikati 3	Kwambiri 4	Chonse 5

Munakazunguliza nambala 1 ngati simunalandire chithandizo chilichonse chomwe munafuna kuchokera kwa anthu ena m'sabata ziwiri zapitazi. Chonde werengani funso lililonse, ganizilani za malingaliro anu ndipo zungulizani namabala pa mulingo omwe yankho lolondola kwa inuyo layikidwa pa funso lililonse.

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		Sulibwino kwambiri	Sulibwino	Uli pakatikati	Ulibwino	Ulibwino kwambiri
1 (G1)	Mukaziona, moyo wanu ndiwapambana bwanji?	1	2	3	4	5

		Osakhutitsidwa kwambiri	Osakhutitsidwa	Pakatikati	Okhutitsidwa	Okhutitsdwa kwambiri
2 (G4)	Kodi ndinu okhutira bwanji ndi umoyo wanu?	1	2	3	4	5

Mafunso otsatilawa akufunsa za mulingo wa zina zomwe mwakumana nazo m'sabata ziwiri zapitazi.

		Palibe/ayi	Pang'ono	Pakatikati	Kwambiri	Kwambiri zedi
3 (F1.4)	Mukuona ngati kuwawa kwa mthupi kwanu kwakulepheretsani bwanji kuchita zomwe mumafuna kuchita?	1	2	3	4	5
4 (11.3)	Kodi mumafuna chithandizo cha chipatala chochuluka bwanji kuti muchite zofunika kuchita tsiku ndi tsiku?	1	2	3	4	5
5 (F4.1)	Kodi mumasangalala kwambiri bwanji ndi moyo?	1	2	3	4	5
6 (F24.2)	Kodi mukuganiza kuti moyo wanu ndi watanthauzo motani?	1	2	3	4	5

		Ayi/Palibe	Pang'ono	Pakatikati	Kwambiri	Kwambiri zedi
7 (F5.3)	M'makhala ndi chidwi (chomvetsera) choyenera bwanji pakuchita zinthu?	1	2	3	4	5
8	Kodi mumaona kuti ndinu	1	2	3	4	5

		Ayi/Palibe	Pang’ono	Pakatikati	Kwambiri	Kwambiri zedi
(F16.1)	otetezedwa bwanji pa moyo wanu wa tsiku ndi tsiku?					
9 (F22.1)	Kodi malo amene mumapezeka kapena kukhala kawirikawiri ndi abwino bwanji ku umoyo wanu?	1	2	3	4	5

Mafunso otsatilawa akufuna kudziwa kuti mwakwanitsa bwanji komanso munatha bwanji kuchita zina ndi zina m’sabata ziwiri zapitazi.

		Tilibe/Ayi	Pang’ono	Pakatikati	Kwambiri	Kwambiri zedi
10 (F2.1)	Kodi muli ndi mphamvu zokwanira zochitila zinthu tsiku ndi tsiku?	1	2	3	4	5
11 (F7.1)	Kodi mutha kuvomereza m’mene maonekedwe anu alili?	1	2	3	4	5
12 F(18.1)	Kodi mumakhala ndi ndalama zokwanira kuti mukwanitse zofunikira?	1	2	3	4	5
13 (F20.1)	Kodi muli ndi mwayi otani wotha kupeza zinthu zokuphunzitsani zimene mumafuna pa moyo wanu	1	2	3	4	5
14 (F21.1)	Kodi muli ndi mwayi wotani wochita zinthu za nsangulutso?	1	2	3	4	5
27	Kodi mumakhala ndi chakudya chokwanira kudyetsa banja lanu?	1	2	3	4	5

		Ndikovuta kwambiri	ndikovuta	pakatikati	Ndikophweka	Ndikophweka kwambiri
15 (F9.1)	Kodi ndikophweka bwanji kwa inuyo kutha kuyendayenda?	1	2	3	4	5

Mafunso otsatiliwa akufuna kudziwa m’mene mwamvera ubwino kapena m’mene mwakhutitsidwira ndizochitika zosiyanasiyana za moyo wanu m’sabata ziwiri zapitazi

		Osakhutitsi -dwa kwambiri	Osakhutit -sidwa	Pakatikati	Okhutitsidwa	Okhutitsidwa kwambiri
16 (F3.3)	Kodi ndinu okhutitsidwa bwanji ndi tulo timene mumapeza mukagona?	1	2	3	4	5
17 F(10.3)	Ndinu okhutitsidwa bwanji ndi m’mene mungakwanilitsire kugwira ntchito zanu za tsiku ndi tsiku?	1	2	3	4	5
18 (F12.4)	Kodi mumakhutitsidwa bwanji ndi m’mene mumangakwanilitsire kugwira ntchito?	1	2	3	4	5

		Osakhutitsi -dwa kwambiri	Osakhutit -sidwa	Pakatikati	Okhutitsidwa	Okhutitsidwa kwambiri
19 (F6.3)	Kodi ndinu okhutitsidwa bwanji ndinu mwini?	1	2	3	4	5
20 (F13.3)	Ndinu okhutitsidwa bwanji ndi m'mene ubale wanu ulili ndi anthu ena?	1	2	3	4	5
21 (F15.3)	Ndinu okhutitsidwa bwanji ndi moyo wanu ogonana ndi achikondi anu?	1	2	3	4	5
22 (F14.4)	Ndinu okhutitsidwa bwanji ndi chithandizo chomwe mumalandira kuchokera kwa anzanu?	1	2	3	4	5
23 (F17.3)	Ndinu okhutitsidwa bwanji ndi m'mene malo anu mumakhala alili?	1	2	3	4	5
24 (F19.3)	Muli okhutira bwanji ndi kupezeka kwa chithandizo cha za umoyo?	1	2	3	4	5
25 (F23.3)	Muli okhutitsidwa bwanji ndi zokhudza ndi mayendedwe (tharasipoti)?	1	2	3	4	5

Funso lotsatilalri likukhudzana ndi m'mene mwamvera kapena kudutsana ndi zinthu zina kawirikawiri bwanji m'sabata ziwiri zapitazi.

		Sizinachiti-kepo	Mwapatali-patali	Kawirikawiri	Kawirikawiri kwambiri	Nthawi zonse
26 (F8.1)	Kodi ndi kawirikawiri bwanji pomwe mumakhala osakondwa monga kukhala a chisoni, otaya mtima, odandauladandaula, kapena okhumudwa?	1	2	3	4	5

Kodi alipo anakuthandizani kuyankha mafunsowa?

____

Zinakutengerani nthawi yayitali bwanji kuti mumalize kuyankha mafunsowa?

____

Kodi muli ndi ndemanga iliyonse yokhudzana ndi mafunsowa?

____

____

____

Zikomo kwambiri pakutenga mbali kwanu

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The following questions ask how you feel about your quality of life, health, or other areas of your life. I will read out each question to you, along with the response options. **Please choose the answer that appears most appropriate.** If you are unsure about which response to give to a question, the first response you think of is often the best one.

Please keep in mind your standards, hopes, pleasures and concerns. We ask that you think about your life **in the last four weeks.**

		Very poor	Poor	Neither poor nor good	Good	Very good
1.	How would you rate your quality of life?	1	2	3	4	5

		Very dissatisfied	Dissatisfied	Neither satisfied nor dissatisfied	Satisfied	Very satisfied
2.	How satisfied are you with your health?	1	2	3	4	5

The following questions ask about **how much** you have experienced certain things in the last four weeks.

		Not at all	A little	A moderate amount	Very much	An extreme amount
3.	To what extent do you feel that physical pain prevents you from doing what you need to do?	5	4	3	2	1
4.	How much do you need any medical treatment to function in your daily life?	5	4	3	2	1
5.	How much do you enjoy life?	1	2	3	4	5
6.	To what extent do you feel your life to be meaningful?	1	2	3	4	5

		Not at all	A little	A moderate amount	Very much	Extremely
7.	How well are you able to concentrate?	1	2	3	4	5
8.	How safe do you feel in your daily life?	1	2	3	4	5
9.	How healthy is your physical environment?	1	2	3	4	5

The following questions ask about how completely you experience or were able to do certain things in the last four weeks.

		Not at all	A little	Moderately	Mostly	Completely
10.	Do you have enough energy for everyday life?	1	2	3	4	5
11.	Are you able to accept your bodily appearance?	1	2	3	4	5
12.	Have you enough money to meet your needs?	1	2	3	4	5
13.	How available to you is the information that you need in your day-to-day life?	1	2	3	4	5
14.	To what extent do you have the opportunity for leisure activities?	1	2	3	4	5

		Very poor	Poor	Neither poor nor good	Good	Very good
15.	How well are you able to get around?	1	2	3	4	5

		Very dissatisfied	Dissatisfied	Neither satisfied nor dissatisfied	Satisfied	Very satisfied
16.	How satisfied are you with your sleep?	1	2	3	4	5
17.	How satisfied are you with your ability to perform your daily living activities?	1	2	3	4	5
18.	How satisfied are you with your capacity for work?	1	2	3	4	5
19.	How satisfied are you with yourself?	1	2	3	4	5

20.	How satisfied are you with your personal relationships?	1	2	3	4	5
21.	How satisfied are you with your sex life?	1	2	3	4	5
22.	How satisfied are you with the support you get from your friends?	1	2	3	4	5
23.	How satisfied are you with the conditions of your living place?	1	2	3	4	5
24.	How satisfied are you with your access to health services?	1	2	3	4	5
25.	How satisfied are you with your transport?	1	2	3	4	5

The following question refers to how often you have felt or experienced certain things in the last four weeks.

		Never	Seldom	Quite often	Very often	Always
26.	How often do you have negative feelings such as blue mood, despair, anxiety, depression?	5	4	3	2	1

Do you have any comments about the assessment?

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[The following table should be completed after the interview is finished]

		Equations for computing domain scores	Raw score	Transformed scores	
				4-20	0-100
27.	**Domain 1**	(6-Q3) + (6-Q4) + Q10 + Q15 + Q16 + Q17 + Q18 ☐ + ☐ + ☐ + ☐ + ☐ + ☐ + ☐	a. =	b:	c:
28.	**Domain 2**	Q5 + Q6 + Q7 + Q11 + Q19 + (6-Q26) ☐ + ☐ + ☐ + ☐ + ☐ + ☐	a. =	b:	c:
29.	**Domain 3**	Q20 + Q21 + Q22 ☐ + ☐ + ☐	a. =	b:	c:
30.	**Domain 4**	Q8 + Q9 + Q12 + Q13 + Q14 + Q23 + Q24 + Q25 ☐ + ☐ + ☐ + ☐ + ☐ + ☐ + ☐ + ☐	a. =	b:	c: