

Femur Bone Fracture Treatment in Addis Ababa, Ethiopia:  
A Cost-effectiveness Analysis

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## Abstract

**Introduction:** Surgically treatable conditions represent about 11 % of the world's Disability Adjusted Life Years (DALYs) lost. Cost-effectiveness analyses for trauma show that surgical interventions are more cost effective as compared to non-surgical interventions. The objective of this study is to do a health economic evaluation of orthopedic treatment of femur bone fracture by comparing traction and Intramedullary Nail (IMN) for patients treated at a tertiary and general hospitals in Addis Ababa, Ethiopia.

**Method:** Direct out of pocket expenditures that were included are cost of hospitals bed day, drugs, investigations and physiotherapy. Patients' medical record was used to extract the type and number of investigations ordered and medications given. Expenditures were estimated by multiplying the number of investigations and medicines reported by each patient by their prices as given by the price-list of service fees set by the hospitals. The unit cost of health worker per treated patient was calculated by multiplying the time spent to treat a patient by salary rate per hour of health professionals. Patients were interviewed about their functional status using a structured questionnaire. Their health status was then used to select disability weights as given by the Global Burden of Disease Study, and further used to estimate health outcomes as Health Adjusted Life Years (HALY). A societal cost perspective has been used, and health benefits were calculated over a lifetime.

**Results:** The direct out of pocket expenditure for the traction treatment group was 6,262 USD (132,754 ETB). Cost per patient is 250 USD (5,310 ETB). Provider costs for the traction treatment group was 1,562 USD (33,114 ETB) and total cost was 7824 USD (165,869 ETB). The direct out of pocket expenditure for the IMN treatment group was 4,849 USD (102,804 ETB). Cost per patient was 194 USD (4,112 ETB). Provider costs for the IMN treatment group was 6,112 USD (129,574 ETB) and total costs was 10,961 USD (232,373 ETB).

The net discounted HALY gained in the traction treatment group was 16.2 and the net discounted HALY gained in the IMN group was 33.6. The average cost-effectiveness ratio (ACER) for the traction group was 483 USD/HALY gained and for the IMN treatment group it was 326

USD/HALY gained. Therefore the incremental cost of going from traction to IMN treatment group was 3,137 USD and the incremental health gain was 17 HALYs. The incremental cost-effectiveness ratio was 180 USD per HALY gained.

**Conclusion:** This study has shown that IMN is more cost effective than traction for the treatment of femur bone fracture treatment.

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## Acronym

ACER – Average Cost-Effectiveness Ratio

CEA – Cost-Effectiveness Analysis

DALY – Disability Adjusted Life Years

ETB – Ethiopian Birr

GBD – Global Burden of Disease

HALY – Health Adjusted Life Year

HIC – High Income Countries

IM- Intra Medullary

ICER – Incremental Cost-effectiveness Ratio

LMIC – Low and Middle Income Countries

MSK – Musculoskeletal



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# 1.INTRODUCTION

## 1.1 Background

Conditions that are treated primarily or frequently by surgery constitute a significant portion of the global burden of disease. The significant avertable burden from surgical conditions is directly related to the low capacity for surgical care in many low and middle income countries LMIC(1). Surgically treatable conditions represent about 11 % of the world's Disability Adjusted Life Years (DALYs) lost, which is about equivalent to the number of DALYs contributed by HIV/AIDS, malaria and tuberculosis combined (2).

LMIC experience more than 91% (5.3 million) of injury-related deaths in the world according to a study by Sharma et al (3). Injuries often result in long-term disability. For every person who dies from injury, many more are injured, with temporary or permanent disability (4).

Ethiopia, is one of the most populous nations in the Sub Saharan African continent. The population was estimated to be 96.96 million in 2014 with life expectancy of 63 years at time of birth (5). The burden of injury is high in Ethiopia. For instance in the 2013 – 2014 Ethiopian Fiscal Year trauma including fracture of the extremities was the fourth leading cause of admission in Ethiopian hospitals (6). Road traffic accident is the cause of such injuries in most cases (7-9).

A three year retrospective study on orthopedic and major limb trauma in Tikur Anbessa Specialized Hospital showed that 49.7% of all patients admitted at the orthopedic ward had upper limb injury and 43.5% had lower limb injury. The leg (below knee) was the most common limb site injured (22.2%) (10). A similar study done in Dilchora Referral hospital, located in Eastern Part of Ethiopia also showed that patients with long bone injury of the lower extremity constituted up to 73 % of all patients admitted to orthopedic ward (11). The femur is the largest bone of the body and principal weight bearing bone of the lower extremity that is commonly injured following lower extremity trauma (12).

A study done in Ghana has shown that the prevalence of long term injury related disability was 0.83% (95% CI: 0.67%, 1.00%) in the population surveyed and 78% of such disabilities were due to extremity injuries (13). Most fractures result in a temporary loss of function for the patient and also a loss of work time for the parents, children or other careers of the injured person (11).

## 1.2 Statement of the Problem

There are different treatment options for fractures. In general, fractures are managed by closed or open reduction depending on the type and severity of the fracture. Closed reduction include casting and traction and those under open reduction include external and internal fixation. (4)

Traction refers to the set of mechanisms for straightening broken bones or relieving pressure on the spine and skeletal system. There are two types of traction, skin traction and skeletal traction. Skeletal traction is applied to the affected structure by a metal pin or wire inserted into the structure and attached to traction ropes. Skeletal traction is often used when continuous traction is desired to immobilize, position and align a fractured bone properly during the healing process(14). Skin traction is a traction on an extremity by means of adhesive tape or other types of strapping applied to the limb having the same objective as stated for skeletal traction.

Internal fixation involves the implementation of implants to guide the healing process of a bone, as well as the open reduction of the bone itself. Fixation of tibia, femur and humerus are made with screws and/or plates or intramedullary bone nails to enable or facilitate healing(14).

In Ethiopia patients with femoral fracture are in most cases treated with either skeletal or skin traction (8, 11, 15).The duration of hospital stay for patients managed with this treatment option usually takes a number of weeks (7, 12, 15). Despite long hospital stays, results are good for most of the fracture patients treated by conservative management (11). Some studies have shown that for femur fracture, skeletal traction remain to be safe, effective and cheap in a setting like Ethiopia (7).

However, as a result of long hospital stays, new patients with similar injuries that require admission are denied care due to constrained capacity(16). A study at a tertiary level hospital in

Ethiopia has shown that 69% of emergency patients requiring urgent admission had in practice been referred to other hospitals (10). Furthermore, delayed mobilization and long hospital stays can have a significant economic impact on patients, their families and more broadly on the hospital and health care system (15).

Surgical treatment for fracture of hip, femur and tibia have been found to be superior over conservative management in high income countries (HIC). However, to this day, most of these fractures are treated conservatively with cast or traction in LMICs (8). It has been a long standing dogma that surgery for musculoskeletal (MSK) injuries would be too expensive in LMIC (17).

## 2. OBJECTIVES

### General Objective

- Perform a health economic evaluation of orthopedic treatment of femur bone fracture by comparing traction and Intramedullary Nail (IMN) for patients treated at a tertiary and general hospitals in Addis Ababa.

### Specific Objective

- Determine the cost for femur bone fracture treatment by traction for patients treated in Addis Ababa Burn Emergency Medicine and Trauma Hospital (AaBET) and Menelik Hospital in April and May, 2016.
- Determine the cost for femur bone fracture treatment by IMN
- Calculate the Health-Adjusted Life Years (HALYs) gained for patients with femur fracture treated by traction
- Calculate the HALYs gained for patients with femur fracture treated by IMN
- Determine the cost per HALY averted for femur bone fracture treatment by traction and IMN treatment.

### 3. Literature Review

There have been different perspectives and recommendations with regards to management of femoral shaft fractures in resource poor settings. On one hand there is a group of clinical practitioners who argue that conservative management remains the best and very often the only option for femoral bone fracture. One reason is that the surgical environment is unreliable and this could increase the risk of surgical complications(7). However, studies done in LMIC on the risk of infection after IMN have shown that the infection rate was acceptable and that IM nailing is a safe procedure in these settings (18, 19). A systematic review by Kramer et al has shown that the use of traction in treating femoral shaft fractures is associated with a high incidence of complications and prolonged course of treatment (15).

The other argument against surgical treatment is that surgical treatment in resource limited countries is relatively more costly than traction (7). However, selected surgical interventions for trauma have proven cost effective in these settings and innovative low cost programs and interventions have improved trauma care outcomes at individual hospitals (17).

A health economic evaluation done by Gosselin et al of Surgical Trauma Centers in Nigeria and Haiti estimated the cost to be \$172 and \$223 per Disability-Adjusted Life Year (DALY) averted, which was in line with other reported Cost-Effectiveness Analyses (CEAs) of surgical and nonsurgical activities in similar contexts (20). Similarly in Cambodia, a study comparing the first 50 patients who received IMN for their femur fractures to the last 50 patients who were treated by traction showed that surgery had better clinical outcomes and was more cost effective than traction (US \$888 verses US \$1,107 per DALY averted, respectively) (21). In Kenya , a study done at level 5 hospital found that better clinical outcome was attained at a lower cost with surgery compared to Perkins traction in the management of adult femoral shaft fractures. Majority of the patients (55.1 %) who underwent surgery attained normal mobility without any support compared to 29.1 % in the group managed by traction (OR 3.8 and p 0.004). The average cost of treatment for patients who underwent surgery was 112 USD compared to those managed conservatively 156 USD (12).

Patients managed with skeletal or skin traction have longer hospital stays. The systematic review by Kramer et al showed that mean length of hospital stay for patients with femoral fracture treated with skeletal traction was 55.4 days (15). Long hospital stays will lead patients to incur more cost. This can be either direct medical cost or indirect cost associated with productivity loss. Patients treated with intramedullary nail have short duration of hospital stay and thus have less private expenditure (12).

#### 4. Justification and Significance of the Study

The prevalence of injuries and fracture of extremities is increasing in Ethiopia. Despite the argument that surgical care for trauma patients is very expensive in resource limited countries like Ethiopia, there are a number of reasons to consider surgery to be one of the best treatment options. The first being that IMN has shown to be cost effective to similar settings like Ethiopia. This is so because patients that receive conservative treatment (traction) are forced to stay in hospitals for a long period of time, which cause additional costs to the patients (i.e. hospital bed and food expenditures) (20). Long hospital stays is likely to cause substantial productivity losses both for the patient as well as attendants. Moreover, traction patients are bed blockers. Other patients who could have used the same bed will be forced to wait or go elsewhere when a traction patient blocks the bed for a long time. This may be inefficient use of limited resources, including specialists. On the other hand, patients treated surgically will be discharged earlier and may have less productive loss and block less hospital beds.

In a country where a significant proportion of the population live on manual work like agriculture, injury to upper and lower limb results in significant negative impact on productivity loss. Thus, it is worth to investigate if surgery is more cost-effective than traction for treatment of femur fractures in Ethiopia. To the best of the investigators' knowledge, no cost-effectiveness analysis of surgical treatment of femur fracture has been done in Ethiopia. Therefore by identifying this gap, this study is set out to explore cost effective options for femur fracture treatment in Ethiopia.

## 5. Methods

### 5.1 Study Area

The study has been conducted in Menelik and Addis Ababa Burn Emergency Medicine and Trauma Hospital (AaBET). These hospitals are among the 11 government hospitals in Addis Ababa.

Menelik hospital is among the early established hospitals in Addis Ababa. According to the 2016 Health Service Directory of Ministry of Health, it has a total of 203 beds. It gives a total of 10 in-patient specialty services including Orthopedics. The orthopedics out patient service works four days in a week.

AaBET is one of the semi-independent institutions under St Paul's Hospital Millennium Medical College. AaBET provides comprehensive emergency care in emergency medicine, critical care, orthopedics, neurosurgery and forensic medical service.

### 5.2 Study Period

The data has been collected from October 2016 to January 2017.

### 5.3 Data Collection

Four nurses who have experience working in hospital have been recruited to do the data collection. Data collectors retrieved price of drugs, physiotherapy, laboratory and imaging from the hospitals' pharmacy, rehabilitation, laboratory and imaging units respectively. Salary of health professionals working in orthopedics ward have been retrieved from human resource office. Cost pertaining to medical equipment and supplies have been retrieved from pharmacy units.

Disability status of patients was assessed using a questionnaire that was developed based on GBD 2013 description of health states. The questionnaire asks the functional status including walking, running and lifting heavy things. Data from patient records including type of investigations and drugs ordered were retrieved using a check list (See Annex 6).

## 5.4 Source and study Population

### 5.4.1 Source Population

- All patients admitted to tertiary level and general hospitals in Addis Ababa for femoral bone fracture treatment.

### 5.4.2 Study Population

- All patients admitted to Menelik and AaBET hospitals for femoral bone fracture during the data collection period.

## 5.5 Inclusion and Exclusion Criteria

### 5.5.1 Inclusion Criteria

- Patients 18 years and above with closed fracture of femur bone.

### 5.5.2 Exclusion Criteria

- Patients diagnosed to have pathological fractures based on history and radiological findings.
- Patients with compound fracture of the femur bone
- Patients presented with poly-trauma

## 5.6 Sampling procedure

All patients who were treated either with IMN or skeletal traction for femur fracture in the months of April and May, 2016 in Menelik and AaBET hospital and who fulfilled the inclusion criteria were included as study participants.

In AaBET hospital, data collectors went to orthopedics out-patient clinic. After getting written consent, they interviewed patients with femur fracture who were on follow up. Similarly, data collectors went to Menelik hospital and interviewed 11 patients at follow up clinic but could not get other patients who fulfilled inclusion criteria. To identify further patients for inclusion, addresses of 14 patients was retrieved from the log book and from the record room. A call was made and consent was obtained. A data collector and the primary investigator went to their home and made the interview.



## 5.7 Socio - demographics

A total of 50 patients were interviewed. The mean age of patients in the traction treatment group is 35 with 95 % CI of (30.5, 40.2) and that in IMN group is 31 with 95 CI of (27.2, 35.37).

Table 1 : Socio- demographics of study participants

	Total	Traction	IMN
<b>Sex</b>			
Female	n = 19	14 (56%)	5 (20%)
Male	n = 31	11 (44%)	20 (80%)
<b>Marital Status</b>			
Single	n = 21	8 (32 %)	13 (52 %)
Married	n = 29	17 (68 %)	12 (48 %)
Divorced	n = 0	0 (0%)	0 (0%)
Widowed	n = 0	0 (0%)	0 (0 %)
<b>Place of Residence</b>			
Addis Ababa	n = 26	18 (72%)	8 (32 %)
Outside Addis Ababa	n = 24	7 (28%)	17 (68%)
<b>Education</b>			
Higher Education	n = 6	5 (20 %)	1 (4%)
Secondary Education	n = 12	4 (16 %)	8 (32%)
Primary Education	n = 24	10 (40%)	14 (56%)
Literate	n = 7	5 (20%)	2 (8 %)
Illiterate	n = 1	1(4%)	0 (0%)
<b>Occupation</b>			
Employed at Gov/Priv Institution	n = 25	15 (60%)	11 (44%)
Self Employed	n = 12	4 (16 %)	7 (28 %)
Farmer	n = 7	3 (12%)	4 (16%)

Student	n = 3	0	3 (12 %)
Did not have Job	n = 3	3 (12 %)	0

### 5.8 Study Perspective, discounting and currency

The chosen study perspective is a societal perspective. All costs are included regardless of who pays them. Resources used or created by health interventions are valued as benefits foregone because society could not use the resources in their next best use (22). A discount rate of 3 percent has been used for measure of health outcome. Discount rate has not been used for cost as the cost that was taken is incurred in the same time period.

The costs and effects have been analyzed using Excel 2013. The currency Ethiopian Birr (ETB) has been used and then converted to USD according to the average exchange rate during the study period. 1 USD was on average 21.2 ETB between October 2014 and October 2016.

### 5.9 Comparators

The major treatment options are conservative management versus surgical management for fracture of the femur. From the conservative management, skeletal traction was selected because it is the most common conservative management option for fracture admitted patients. From surgery, IMN was selected because this treatment modality is often chosen in other countries, but not regarded as cost-effective in Ethiopia.

### 5.10 Estimation of Health Outcomes

Health-Adjusted Life Years (HALY) has been used as the measure of health outcome. The disability weight for the functional status of patients was based on the 2013 Global Burden of Disease study. According to the study, musculoskeletal problems has been classified as mild, moderate and severe with disability weight of 0.023, 0.079 and 0.165 respectively (see Annex 1).

The questionnaire for the assessment of disability weight for femur fracture treatment was developed based on GBD 2013 descriptions of health states for musculoskeletal problems. For each question three alternative answers are provided (i.e occurs sometimes, occurs often, occurs almost every time). The aim was to classify patients as with mild, moderate and severe health

states. It is assumed that patients who have mild pain will ‘sometimes’ have pain. Patients who have moderate pain have pain that ‘occurs often’ and patients who have severe pain have pain which ‘occurs almost every time’.

For each alternative, a score is given. (i.e. ‘sometimes’- 0, ‘occurs often’ – 1, ‘occurs almost every time’ – 2.). Then at the end, for patients in which the sum was between 0 to 3, they have been categorized as having mild musculoskeletal problem, for patients having a score between 4 up to 9, they have been categorized as having moderate musculoskeletal problem and for patients for which the score was between 10 to 16, they have been categorized as having severe musculoskeletal problem.

Once patients have been categorized using the scoring system specified above, a life table with GBD 2013 data on age specific mortality rates and health state valuations adjusted by the empirical disability weights reported by patients was used to calculate HALYs for each patient. A mean age of 33 was used for both groups to avoid a bias in different starting ages. Then the HALY gained for each of the two treatment groups was estimated.

In order to understand the health gain from the two treatment groups better, a comparative group was assumed to exist for which no intervention was made. Since there has not been any studies done on the disability status of untreated patients (to the best of the investigator’s knowledge), an assumption was made that all patients who did not get a treatment would have the same disability weight as patients who were categorized as having severe musculoskeletal problem. Discounted values of HALY were used for both treated and untreated groups. Then the net discounted HALY gained for the traction and the IMN group was calculated by subtracting the HALY gained of the untreated group from HALY gained in the treated group.

The definition given for the different status of musculoskeletal problems in GBD 2013 are as follows:

Mild Musculoskeletal problem – when the patient has pain on the leg which causes some difficulty in running, walking long distance and getting up and down.

Moderate musculoskeletal problem – when the patient has moderate pain in the leg which makes the person limp and cause some difficulty in walking, standing, lifting and carrying heavy things, getting up and down and sleeping.

Severe musculoskeletal problem – when the patient has severe pain in the leg which makes the person limp and cause a lot of difficulty in walking, standing, lifting and carrying heavy things, getting up and down and sleeping.

## 5.11 Estimation of resources and cost

### 5.11.1 Provider Cost

Salary of health professionals and cost of equipment that was used separately by the two treatment groups were taken as provider cost. However fixed costs like land and infrastructure were not taken because these utilities are being utilized by both treatment groups equally.

#### *5.11.1.1 Salary of health professionals*

The first step in estimating the salary of health professionals was to calculate the time spent for treating each patient at emergency outpatient unit, ward and OR by different type of health professionals. This was then multiplied by the salary per hour rate of the health professionals to get the total salary cost the hospital will incur to treat a single patient.

Uniform hospital duration was taken for patients in the two groups to make the process of calculating salary cost convenient. This was done by taking the mean hospital stay i.e 53.04 days  $\approx$  8 weeks for patients in traction treatment group and 36.28 days  $\approx$  5 weeks for patients in IMN treatment group. Thus, for a patient in the traction treatment group the salary cost of health professionals is 40 USD (845 ETB) and for a patient in IMN group it is 32 USD (679 ETB).

#### *5.11.1.2 Equipment*

The cost of Intramedullary nail and consumables need for procedures was included as part of the provider cost. Currently intramedullary nails are being provided by SIGN Fracture Care International which donates Intramedullary nails for low and middle income countries. The cost for a single SIGN nail is estimated to be 150 USD (3450 USD). And the hospitals cover the cost for some of the consumables needed for the procedure.

### 5.11.2 Direct out of pocket expenditure

In this study, the direct out of pocket expenditure that were included are the cost of hospitals bed day, drugs, investigations and physiotherapy. Data retrieved from patients' medical record has been used to know the type and number of investigations ordered as well as the medications given during admission and follow up.

#### *5.11.2.1 Drug Cost*

The retail price per tablet/capsule/bottle was retrieved from the hospitals' pharmacy units. For each drug average cost was made from the two hospitals price list. This was multiplied by the number of frequency (number in a day and total number of days) the patient has taken the drug to get the total cost that the patient has incurred for medication. (See annex 2.1)

#### *5.11.2.2 Hospital bed day, Imaging and Laboratory*

The two hospitals have a price list for imaging, laboratory and hospital bed. Similar to drug cost average price-lists are available for these service fees. These were used to calculate the cost for each patient based on the type and number of investigations ordered and based on the total number of days the patient has been admitted (See annex 2.2 and 2.3).

#### *5.11.2.3 Physiotherapy*

Uniform follow up period has been taken to calculate service fee for physiotherapy. Based on expert opinion, the average duration of follow up for femur fracture patients being treated by traction is 3 months and that for IMN group is 2 months.

The average service fee for physiotherapy in the two hospitals is 16 Birr/session. A patient is appointed 3 times per week which will be a total of 36 visit for patients in traction treatment group and 24 times for patients in the IMN treatment group. This will then give 27 USD (576 ETB) for traction group and 18 USD (384 ETB) for IMN group.

### 5.12 Data Quality Assurance

To ensure quality of data, data collectors was given one day orientation on how to fill the structured questionnaire. During the data collection period, the principal investigator had a session with the data collectors. During the sessions, thorough checking of the filled questionnaire has been done.

### 5.13 Analysis

A decision tree model in Excel was used to calculate cost-effectiveness. The structure of the model is represented in Figure 1. For each patient, the cost of hospital bed day, card (registration payment), drug, physiotherapy, x ray, food, laboratory and attendant was arranged in a row on Excel 2013. The sum of each of the listed items was calculated to get the total cost a single patient has incurred for admission and follow up. Then these sub totals were summed up to get the total patient cost for the treatment group. Mean, SD, and 95 % CI were calculated to get the cost incurred in USD per patient. A life table with GBD 2013 data on age specific mortality rates and health state valuations adjusted by the empirical disability weights reported by patients was used to calculate HALYs for each patient. A mean age of 33 was used for both groups to avoid bias in different starting ages. Then the HALY gained for each of the two treatment groups was estimated ( See Figure 1 and more below).

The cost of an intervention was divided to effectiveness to get the cost in USD per HALY. The incremental cost-effectiveness ratio was calculated as:

$$= \text{Cost}_{\text{IMN}} - \text{Cost}_{\text{traction}} / \text{HALY}_{\text{IMN}} - \text{HALY}_{\text{traction}}$$

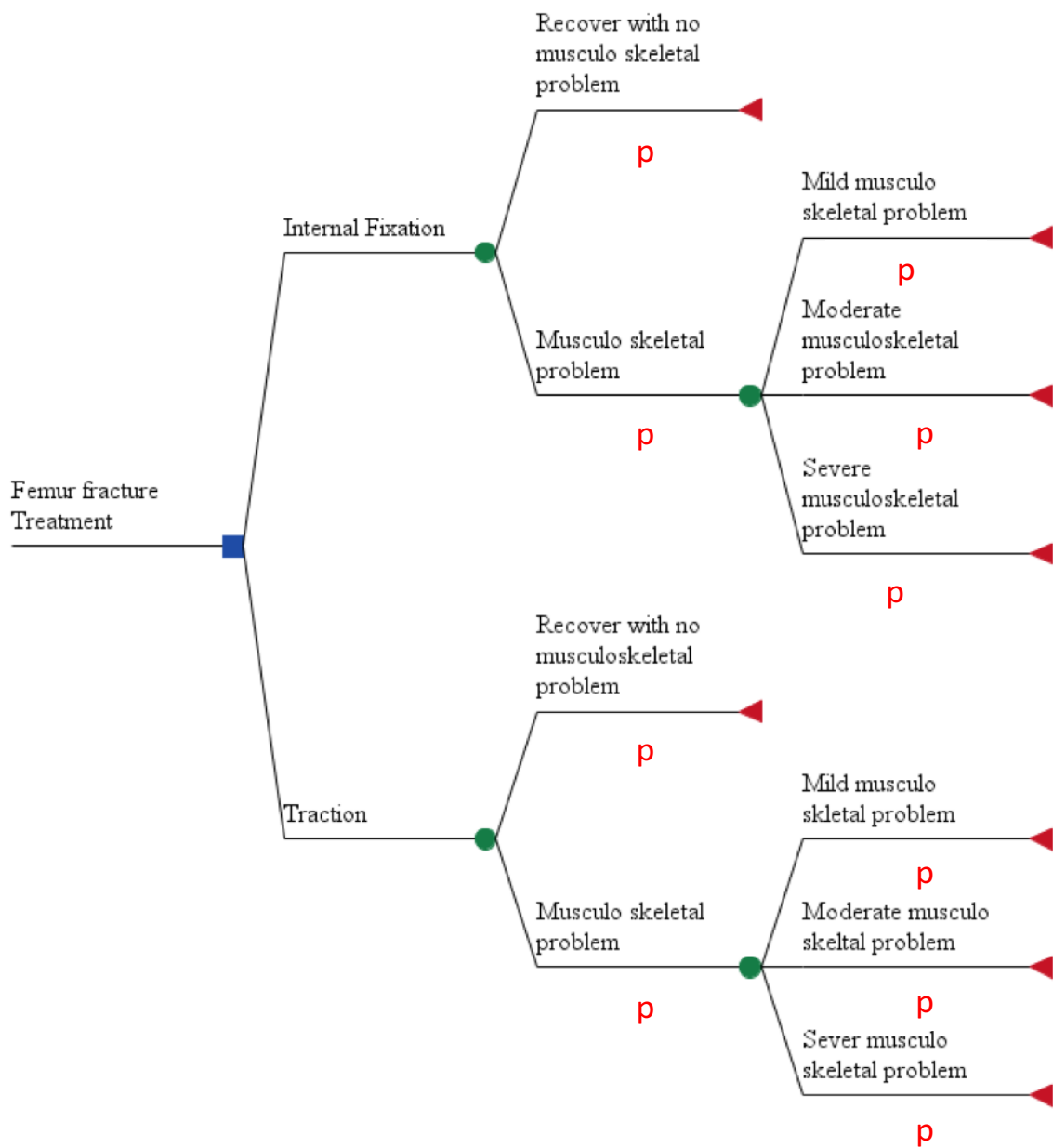


Figure 1: Decision Tree for femoral bone fracture treatment,  $p$ =probability of transition

#### 5.14 Assumptions

- The mortality rates in both treatment groups are the same
- No other comorbidity that will result in additional hospital stay
- Patients come to hospital immediately after injury without prior visit to a traditional healer
- Patients have no previous history of femoral bone fracture
- Patients with malunion/non-union/delayed union – would manifest problems mentioned in either mild, moderate or severe musculoskeletal problem.



## 6. Results

### 6.1 Cost

#### 6.1.1 Direct out of pocket expenditure for Traction Treatment Group

The total out of pocket expenditure for all patients in this treatment group was 6,262 USD (132,754 ETB) with cost per patient being 250 USD (5,310 ETB) 95 %CI of (200 , 300) (see Table 2). The main cost drivers were cost of food and hospital bed which contributed 47 % and 23 % respectively. In this treatment group, the mean hospital stay was 53 days.

Table 2: Direct out of pocket expenditure per service type for the traction treatment group

	Total (USD)	Mean (USD)	SD (USD)	95 % CI
Card	25.5	1	0.4	(0.9 - 1.2)
Hospital Bed	1,464	58	24	(48.8 - 68.3)
Drug	469	18	3	(17.8 - 19.7)
Physiotherapy	679	27	0	
X ray	62	2	0.9	(2.1 - 2.8)
Lab	16.4	0.7	0.9	(0.3 - 1)
Food	3001	120	95	(82.8 - 157.3)
Attendant	527	21	54	(0.3 - 42.5)
Total	6,262	250	128	(200 - 300.9)

#### 6.1.2 Direct out of pocket expenditure for IMN treatment group

The total direct out of pocket expenditure for all patients in this treatment group was 4,849 USD (102,804 ETB) with cost per patient being 194 USD (4112 ETB) and 95% CI of (154.3, 233.6) (see Table 3). The main cost drivers were food and hospital bed which constituted of 48 % and 18 % respectively. For this treatment group the mean hospital stay was 36 days.

Table 3: Direct out of pocket expenditure per service type for the IMN treatment group

	Total	Mean	SD	95 % CI
Card	22 USD	0.9 USD	0.3	(0.8 - 0.9)
Hospital Bed	909 USD	36.4 USD	30.1	(24.6 - 48.2)
Drug	553 USD	22.1 USD	13.5	(16.8 - 27.4)
Physiotherapy	452 USD	18.1 USD	0	(18.1 - 18.1)
X ray	63 USD	2.5 USD	0.6	(2.3 - 2.8)
Lab	78 USD	3.2 USD	2.6	(2.1 - 4.2)
Food	2359 USD	94.4 USD	63.5	(69.5 - 119.3)
Attendant	294 USD	11.8 USD	36.6	(2.5 - 26.1)
<b>Total</b>	<b>4,849 USD</b>	<b>194 USD</b>	<b>101</b>	<b>(154.3 - 233.6)</b>

#### 6.1.3 Provider Cost for Traction and IMN treatment group

The total provider cost for traction treatment group was 1562 USD (33,122 ETB) and the provider cost per treated patient was 62 USD (1324 ETB). The total provider cost for IMN treatment group was 6,111 USD (129,566 ETB) and the provider cost per treated patient was 244 USD (5182 ETB).

Table 4: Provider Cost for the two treatment groups

Traction				
	Total	Mean	SD	95 % CI
Medical equipment and Consumables	565 USD	22 USD	0	
Salary	997 USD	39 USD	0	
Total	1562 USD	62 USD	0	
IMN				
Medical equipment and Consumables	5,308 USD	212 USD	0	
Salary	803 USD	32 USD	0	

Total	6,111 USD	244 USD	0	
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#### 6.1.4 Total Cost for Traction and IMN treatment group

The total cost for traction treatment group was 7, 824 USD (165,869 ETB) and the cost per patient was 313 USD (6,636 ETB). The total cost for the IMN group was 10,961 USD (232,373 ETB).

Table 5: Total cost for Traction and IMN treatment

	Total Cost (USD)	Cost per Patient (USD)	SD	95 % CI
Traction	7,824	313	128.6	(262.6 -363.4)
IMN	10,961	438	101	(398.8 - 478.1)

## 6.2 Effectiveness

### 6.2.1 Effectiveness in traction treatment group

The total discounted HALY in traction group after treatment was 411. The mean was 16.4 with 95 % CI of (16.1, 16.8). The net discounted HALY in this treatment group was 16.2 and the net undiscounted HALY was 34 (Table 6).

Table 6: Health Adjusted Life Years (HALYs) gained in traction treatment group.

	HALY with treatment	HALY without treatment	Net HALY Gained	HALY without Treatment (Discounted)	HALY with treatment ( Discounted)	Net Discounted HALY
P1	22.9	22.9	0	15.8	15.8	0
P2	22.9	22.9	0	15.8	15.8	0
P3	27.9	22.9	5	15.8	18.1	2.3
P4	22.9	22.9	0	15.8	15.8	0
P5	25.9	22.9	3	15.8	17.2	1.4
P6	25.9	22.9	3	15.8	17.2	1.4
P7	22.9	22.9	0	15.8	15.8	0
P8	25.9	22.9	3	15.8	17.2	1.4
P9	25.9	22.9	3	15.8	17.2	1.4
P10	25.9	22.9	3	15.8	17.2	1.4
P11	22.9	22.9	0	15.8	15.8	0
P12	27.9	22.9	5	15.8	18.1	2.3
P13	25.9	22.9	3	15.8	17.2	1.4
P14	22.9	22.9	0	15.8	15.8	0
P15	22.9	22.9	0	15.8	15.8	0
P16	22.9	22.9	0	15.8	15.8	0
P17	22.9	22.9	0	15.8	15.8	0
P18	22.9	22.9	0	15.8	15.8	0
P44	22.9	22.9	0	15.8	15.8	0
P45	22.9	22.9	0	15.8	15.8	0
P46	22.9	22.9	0	15.8	15.8	0
P47	22.9	22.9	0	15.8	15.8	0

P48	25.9	22.9	3	15.8	17.2	1.4
P49	22.9	22.9	0	15.8	15.8	0
P50	25.9	22.9	3	15.8	17.2	1.4
HALY Gain	607	573	<b>34</b>	394.7	411	<b>16.2</b>

### 6.2.2 Effectiveness in IMN treatment group

The total discounted HALY in IMN group after treatment was 428.3. The mean was 17.1 with 95 % CI of (16.9,17.4). The net discounted HALY in this treatment group was 33.6 and the net undiscounted HALY was 70 (Table 7).

Table 7: Health Adjusted Life Years ( HALYs) gained in IMN treatment group.

No	HALY with treatment	HALY without treatment	Net HALY Gained	HALY without treatment (Discounted)	HALY with treatment (Discounted)	Net Discounted HALY Gained
P19	22.9	22.9	0	15.8	15.8	0
P20	25.9	22.9	3	15.8	17.2	1.4
P21	25.9	22.9	3	15.8	17.2	1.4
P22	25.9	22.9	3	15.8	17.2	1.4
P23	25.9	22.9	3	15.8	17.2	1.4
P24	22.9	22.9	0	15.8	15.8	0
P25	25.9	22.9	3	15.8	17.2	1.4
P26	22.9	22.9	0	15.8	15.8	0
P27	25.9	22.9	3	15.8	17.2	1.4
P28	25.9	22.9	3	15.8	17.2	1.4
P29	25.9	22.9	3	15.8	17.2	1.4

P30	25.9	22.9	3	15.8	17.2	1.4
P31	27.9	22.9	5	15.8	18.1	2.3
P32	25.9	22.9	3	15.8	17.2	1.4
P33	25.9	22.9	3	15.8	17.2	1.4
P34	25.9	22.9	3	15.8	17.2	1.4
P35	25.9	22.9	3	15.8	17.2	1.4
P36	27.9	22.9	5	15.8	18.1	2.3
P37	25.9	22.9	3	15.8	17.2	1.4
P38	25.9	22.9	3	15.8	17.2	1.4
P39	25.9	22.9	3	15.8	17.2	1.4
P40	25.9	22.9	3	15.8	17.2	1.4
P41	25.9	22.9	3	15.8	17.2	1.4
P42	25.9	22.9	3	15.8	17.2	1.4
P43	25.9	22.9	3	15.8	17.2	1.4
HALY gain	642	573	<b>70</b>	395	428	<b>33.6</b>

### 6.3 Average and Incremental Cost-Effectiveness

The average cost-effectiveness ratio (ACER) for both treatment groups has been calculated by dividing the total cost to the net discounted HALY gained in each intervention group. This gives 483 USD per HALY gained in the traction group and 326 USD per HALY gained for IMN treatment group (Table 8). The incremental cost of going from traction to IMN is 3137 USD and the incremental health gain of going from traction to IMN group is 17 HALYs. The ICER is 180 USD per HALY gained.

Table 8 : Average and Incremental Cost-Effectiveness Ratio

	Total Cost (USD)	Net discounted HALY Gained	Average Cost-Effectiveness Ratio( ACER)	Incremental Cost	Incremental Effectiveness	Incremental Cost-Effectiveness Ratio (ICER)
Traction	7,824	16.2	483			
IMN	10,961	33.6	326	3137	17	180

For undiscounted HALYs, the ACER would be 157 USD/HALY for IMN and 230 USD/HALY for traction treatment and the ICER would be 87 USD/HALY gained.

## 7. Discussion

The total cost of treatment was 7,824 USD and 10,961 USD in traction and IMN treatment group respectively. The net discounted HALY gained in traction treatment group was 16.2 and it was 33.6 in the IMN group. The ACER was 483 USD/HALY gained for the traction treatment group and it was 326 USD/HALY gained in the IMN treatment group. The ICER was 180 USD/HALY gained.

As it has been stated on the result part, the sum of the net discounted HALY (33.6) in IMN treatment group is greater than that of in traction treatment group (16.2). The difference in the sum of net discounted HALY between the two groups could have been larger. One major reason for the small difference between the two groups could be that patients in the two groups are interviewed in different post discharge period, i.e. the mean time of interview for traction treatment group was 11.6 months after the time of injury with 95 CI of (8.48, 14.7) and the mean time of interview for IMN treatment group was 4 months with 95 % confidence interval of (2.7, 5.3). The effectiveness may therefore have been underestimated.

Regarding cost of treatment, the perspective that is taken is societal perspective. Health provider cost like professional's salary, equipment and consumables cost was also included. Transportation accounted for 22.27 % of the total treatment cost in traction treatment group and 42.3 % in IMN treatment group. The reason for this difference is that more patients in the IMN treatment group were from outside Addis, were referred from hospitals in the neighbouring

Oromia region. For this reason the transportation cost has not been taken as part of the total cost for the treatment groups. The total costs for the IMN treatment group may therefore have been underestimated.

The total cost incurred for the treatment of patients in the IMN group was greater than the total cost incurred for patients in traction group. This difference was mainly due to the higher provider cost incurred in IMN group which in turn was mainly due to the cost of medical equipment and consumables that constituted 48 % of the total cost. However with regards to health gains patients in IMN treatment group have gained more HALY, the result which could have been higher if the time of interview was optimal as stated above. There for by calculating the ACER, it has been shown that IMN was cost effective in the treatment of femur fracture than traction, i.e 326 USD was incurred to gain a unit of HALY in the IMN treatment group compared to 483 USD for a unit of HALY in traction treatment group.

A study done in Thika level 5 hospital in Kenya has shown findings that fit well with our study. The study has taken exclusively the direct out of pocket expenditure for ward bed and drugs and the result was - mean cost of treatment for patients who underwent IMN was 112 USD compared to those managed by skeletal traction 156 USD(12). Similarly, if we compare only the direct out of pocket expenditure between the two treatment groups in our study, the mean cost of the traction treatment group was higher (250 USD) than the mean cost in the IMN treatment group (194 USD).

Another study done in Kenyatta National Hospital, located in Nairobi Kenya, has shown that Intramedullary nailing was more cost-effective than skeletal traction for the treatment of patients with femur fracture. In this study, the average total hospital cost for the operative group was 640 USD compared to 798 USD for the traction group. In the operative group 24 patients had union with one delayed union while in the traction group 12 patients had union, 9 with mal union and 4 delayed union. (23)



## 8. Limitation of the study

There are some limitations in this study. The first one is that the scoring system that was used to measure HALY gained is not externally validated. Second, study participants in the two treatment groups were interviewed in different timing post discharge which in turn can affect the effectiveness measure. Third, the comparison groups were not randomized to each type of treatment. We could not therefore exclude selection bias. Finally, this study has not considered all parts of provider costs, but mainly fixed costs, which can limit our ability to perform comparisons of the result of this study with other similar studies.

## 9. Conclusion

This study showed that IMN was more cost effective than traction for the treatment of patients with femur fracture. Transportation accounted for 22.3 % of the total treatment cost in traction treatment group and 42.3 % in IMN treatment group. Thus, we recommend that follow up clinics are established in primary level hospitals in regions outside Addis so that patients would incur less cost by having follow up in places near their place of residence.

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## Annex

### Annex 1: Disability Weight Parameter

Musculoskeletal Prrelevantoblem (GBD 2013)	
Mild	0.023 (0.013 - 0.037)
Moderate	0.079 (0.054 – 0.11)
Severe	0.165 (0.112 – 0.232)

### Annex 2 : Price list of Drug, laboratory , imaging and hospital bed

#### 2.1 Drug Price List

	Minilik Hospital (Birr per vial)	AaBET Hospital ( ETB per vial/tab/unit)	Average ( ETB per vial/tab/unit)
Ceftriaxone	8.9 per vial	16 Birr	12.5
Metronidazole	7.1	13	10
Cloxacillin, PO	1.2	1	1.1
Ciprofloxacin	0.9	Was not given	0.9
Tramadol, Vial	Was not given	8	8
Tramadol, Tab	0.8	1.4	1.1
Diclofenac, Vial	1.7	2.5	2.1
Diclofenac, PO	0.1	0.2	0.1
Augmentin	2.8	17.5	10.4
Diazepam	Not given	0.6	0.6
Vancomycin	Not given	130.8	130.8
NS, 1000 ml	24.9	25	24.9
DNS	26.5	26.5	26.5
RL	26	26.5	26.2
Amoxicillin	0.9	0.9	0.9

Cloxacillin, vial	2.5	3	2.8
Paracetamol	0.2	0.2	0.2
Pethidine	Was not given	17.5	17.5
Surgical Glove	Not given	6	6
Syringe			
5 cc	1	Not given	1
10 cc	2		2
Roll Bandage	Not Given	5	5
Lidocaine	12.20	19.00	15.6
Plaster	Not given	80	80
Gauze	Not Given	7.3	7.4

## 2.2 Laboratory and Imaging cost

	Minilik ( In ETB)	AaBET ( In ETB)	Average ( In ETB)
Fem x ray	20	10	15
Chest x ray	20	5	12
CBC	35	20	27
LFT	SGOT -10 SGPT -10 20	SGOT -5 SGPT - 5 10	15
RFT	Urea -10 Creatinine -10 20.00	Urea - 5 Creatinine -5 10.00	15

OFT	LFT + RFT		30
BG/Rh	5	5	5
AFB	5	2.8	3.8
ESR	5	0.8	2.8
ECG	Not Given	15	15

### 2.3 Hospital Bed Cost

	Minilik (In ETB)	AaBET (In ETB)	Average (In ETB)
Hospital Bed/day	1 <sup>st</sup> Class, 60	2.5	31.3
	2 <sup>nd</sup> Class, 40	2.5	21.3
	3 <sup>rd</sup> Class, 20	2.50	11.3
Physiotherapy Sessions	20/session	12/session	16/ session

### 2.4 Fixed Cost

#### *2.4.1 Equipment and consumable cost for a patient treated by IMN*

Equipment and supply	Quantity	Cost per Unit ( In ETB)	Total Cost for Item ( In ETB)
Intramedullary nail	1	3450	3450
Surgical Blade	4	30	120
Vicryl, no 1, round	4	50	200
Vicryl, no 2, cutting	3	72.5	217.4
Roll Bandage	5	5	25
Gauze	40	7.4	294
Abdominal Pack	5	20	100
Zinc Plaster	1	25	25

Iodine	1	20	20
Alcohol	1	50	50
Sum			4501.4

#### 2.4.2 Equipment and consumable cost for a patient treated by traction

Equipment/supply	Quantity	Cost per unit ( In ETB)	Total cost for Item ( In ETB)
Pin	1	300	300
Drill	1	100	100
Alcohol	1	50	50
Gauze	4	7.4	29.4
Sum		457.4	479.4

### 3. Health Professionals' salary

#### 3.1 Health Professional Salary per hour

S.N	Type and level of Professionals	Salary (Starting) Per month ( In ETB)	Working hrs per month	ETB per hour
1.	Senior Medical Specialist	10,360.00	172	60.2
2.	Junior Physician	5,583.00	172	32.5
3.	Senior Nurse	3911.00	172	22.7
4.	Junior Nurse	1663.00	172	10
5	Anesthetist	3911.00	172	22.7

### 3.2 Calculation of working hrs for the two treatment groups

Traction	IMN
Round 2 days/week, 16 days 16 days * 15 min = 240 min= 4 hrs	Round 2 days/week, 10 days 10 days * 15 min = 150 min= 2.5 hrs
Follow Up (For GP) 2 days/week, 16 days 16 days * 20 min = 320 min = 5.3 hrs	Follow Up 2 days/week, 10 days 10 days * 20 min = 200min = 3.3 hrs
Pin Site Care 3 days per week (every other day), 24 days 24 days * 5 min = 120 min, 2 hrs	Wound site care 3 days/week, 15 days 15 days * 10 min = 150 min= 2.5 hrs
Vital Sign Taking Every day, 56 days 56 days * 5 min = 280 min = 4.7 hrs	Vital Sign Taking 7 day/week, 35 days 35 days * 5 min = 175 min= 2.9 hrs

### 3.3 Time spent for treating a patient in traction treatment group

	EOPD	Ward
General Practitioner	<b>Activity</b> - Initial Evaluation (history taking, physical examination)  <b>Time Spent</b> – 25 Min	<b>Activity</b> - Major round  <b>Time spent</b> - 15 min (for one patient)



	<b>Activity</b> – Do skeletal traction <b>Time Spent</b> – 40 min	<b>Activity</b> - Follow up for pain assessment/ call based consultation <b>Time taken-</b> 20 min
Orthopedic Surgeon		<b>Activity</b> –Major Round <b>Time Spent</b> – 15 Min
Nurse	<b>Activity</b> - Initial Assessment and Nursing care Evaluation <b>Time Spent</b> – 25 Min	<b>Activity</b> - Major round <b>Time Spent</b> -15 min per patient <b>Activity</b> - Pin site Care <b>Time Spent</b> – 5 min <b>Activity</b> - Taking Vital Sign
	<b>Activity</b> - Assist in skeletal traction <b>Time Spent</b> - 40 min	<b>Time Spent</b> - 5 min per day

### 3.4 Total salary cost for patients in traction treatment group

	EOPD	OR	Ward	Total Time Spent	Salary Cost

General Practitioner	Total Time at EOPD/patient – 1.08 hr		Total time for round/patient – 4 hrs	10.38	32.45 Birr/hr* 10.38 hrs = 336.8 Birr
			Total time for call based consultation/patient- 5.3 hrs		
Orthopedic Surgeon			Total time for round/patient – 4 hrs	4 hrs	60.23 Birr/hr * 4 hrs = 240.92 Birr
Nurse	Total Time at EOPD/patient – 1.08 hr		Total time for round/patient – 4 hrs	11.78	22.73 Birr/hr* 11.78 = 267.75 Birr
			Total time for pin site care/patient – 2 hrs		
			Total time for taking vital sign/patient – 4.7 hrs		

### 3.5 Time spent for treating a patient in IMN treatment group

	EOPD	OR	Ward
General Practitioner	<b>Activity</b> - Initial Evaluation (history taking, physical examination)  <b>Time Spent – 25 Min</b>	<b>Activity</b> – IMN insertion  <b>Time Spent – 1 hr</b>	<b>Activity</b> - Major round  <b>Time spent</b> - 15 min (for one patient)
			<b>Activity</b> - Follow up for pain assessment/ call based consultation  <b>Time taken</b> - 20 min
Orthopedic Surgeon		<b>Activity</b> – IMN insertion  <b>Time Spent – 1 hr</b>	<b>Activity</b> –Major Round  <b>Time Spent – 15 Min</b>
Nurse	<b>Activity</b> - Initial Assessment and Nursing care Evaluation  <b>Time Spent – 25 Min</b>	<b>Activity</b> – IMN insertion  <b>Time Spent – 1 hr</b>	<b>Activity</b> - Major round  <b>Time Spent</b> -15 min per patient  <b>Activity</b> – Wound Care  <b>Time Spent – 10 min</b>  <b>Activity</b> - Taking Vital Sign  <b>Time Spent</b> - 5 min

			per day
Anesthetist		<b>Activity</b> – IMN insertion  <b>Time Spent</b> – 1 hr	

### 3.6 Total salary cost for patients in IMN treatment group

	EOPD	OR	Ward	Total Time Spent	Salary Cost
General Practitioner	Total Time at EOPD/patient – 25 min (0.4 hr)	Total time at OR/patient – 1 hr	Total time for round/patient – 2.5 hrs	7.2 hrs	32.4 Birr/hr * 7.2 = 233.9 Birr
			Total time for call based consultation/patient- 3.3 hrs		
Orthopedic Surgeon		Total time at OR/patient – 1 hr	Total time for round/patient – 2.5 hrs	3.5 hrs	60.2 Birr/hr * 3.5 hrs = 210.8 Birr

Anesthetist		Total time at OR/patient – 1 hr		1 hr	22.7 Birr/hr * 1 = 22.7 Birr
Nurse	Total Time at EOPD/patient – 25 min (0.4 hr)	Total time at OR/patient – 1 hr	Total time for round/patient – 2.5 hrs	9.3 hrs	22.7 Birr/hr* 9.3 hrs = 211.6 Birr
			Total time for wound care/patient – 2.5 hrs		
			Total time for taking vital sign/patient – 2.9 hrs		

## Annex 4 : Structured questioner to collect data on private expenditure

### Out Patient care expenditure

Age of the patient -

1) After discharge from hospital:

- How many times did you come for an appointment/follow up at the hospital
- How many times did you come to the hospital for additional visit other than your appointment/follow up date (e.g. for complication)
- How many days/months have you been away from work due to the fracture?

2) How much did you spend in total for a follow up visit

Total expenditure: \_\_\_\_\_

Drugs: \_\_\_\_\_

Laboratory: \_\_\_\_\_

Imaging: \_\_\_\_\_

For Card/Consultation fee \_\_\_\_\_

Transportation to and from health facility: \_\_\_\_\_

Additional expenses for care giver \_\_\_\_\_

Accommodation (for patients coming outside Addis Ababa) \_\_\_\_\_

Food (for patients coming outside Addis Ababa) \_\_\_\_\_

Traditional healer: \_\_\_\_\_

Others (describe) \_\_\_\_\_

### In patient care expenditure

1) How many days were you admitted at the hospital?

2) How much did you spend in total on the below items during your hospitalization?

Total expenditure: \_\_\_\_\_

i. Hospital bed days \_\_\_\_\_

ii. Drugs \_\_\_\_\_

- iii. Image\_\_\_\_\_
- iv. Laboratory \_\_\_\_\_
- v. Food \_\_\_\_\_
- vi. Transportation to and from the hospital\_\_\_\_\_
- vii. Expenses for the care give \_\_\_\_\_
- viii. Other(specify)\_\_\_\_\_

**Annex 5 : Structured Questioner to collect data for assessment of disability weight for patients with femur bone fracture**

1. Did you have **pain** on the fractured leg after treatment?

- a. Yes
- b. No

If your answer for question no 1 was Yes, please answer the following questions.

2. Does the pain cause problem in running?

- a. Sometimes
- b. Occurs more often
- c. Occurs almost every time

3. Does the pain cause difficulty in getting up and down?

- a. Sometimes
- b. Occurs more often
- c. Occurs almost every time

4. Does the pain make you limp?

- a. Sometimes
- b. Occurs more often
- c. Occurs almost every time

5. Does the pain cause some difficulty in walking?

- a. Sometimes
- b. Occurs more often
- c. Occurs almost every time

6. Does the pain cause some difficulty in standing

- a. Sometimes
- b. Occurs more often
- c. Occurs almost every time

7. Does the pain cause difficulty in lifting heavy things

- a. Sometimes
- b. Occurs more often
- c. Occurs almost every time

8. Does the pain cause difficulty in carrying heavy things

- a. Sometimes
- b. Occurs more often
- c. Occurs almost every time

9. Does the pain cause difficulty in sleeping

- a. Sometimes
- b. Occurs more often
- c. Occurs almost every time

Annex 6 : Check List to collect data from patient card

Medical Record No	Date of Admission	Address
Age	Treatment group (trac./IMN)	
Type of Imaging Done (Including Number of times)		
Type of Laboratory Done (Including number of times)		
Drugs Given		
Presence of Complication		



## Annex 7 : Ethical Clearance and Informed Consent

### 7.1 Ethical Clearance

Ethical clearance has been obtained from the Western Regional Ethical Committee in Norway, Addis Ababa Regional Health Bureau and from St Paul Millennium Medical College.

Written informed consent has been obtained from the study participants. Study participants have been told that their participation is voluntary and they have the right to withdraw from the study at any time. The data material obtained from participants has been given a code and stored in a laptop.

### 7.2 Informed Consent

Hello, my name is..... and I am working in a research project on Cost Effective Analysis of Femur fracture Treatment in Ethiopia.

Femur bone fracture is one of the most common types of fracture in Ethiopia secondary to road traffic accident and other type of injury. And many injured patients come to seek medical care to facilities like Tikur Anbessa Specialized Hospital. There are two main treatment options for this clinical condition i.e. conservative and surgery. These two treatment options have varying effectiveness and associated cost. This study aims to find out which of the two treatment options can give better clinical outcome with a low cost of care.

A structured questionnaire will be used to ask you questions. The expected duration of the interview will be 15- 20 minutes. If you have any question, please ask me to stop and I will take time to explain.

Your participation in this study is voluntary. You do not have to take part in this research if you do not wish to do so and refusing to participate will not affect your treatment at this hospital in any way. There are no known negative effects by participating on this study and there are no direct advantages for you personally either.

The information that we collect from this research project will be kept confidential. Information about you that will be collected during the research will be given a code rather than your name and only the researchers will have access to it.

If you decide to participate, kindly give your written consent before the interview. If you wish to withdraw your consent after the interview ended or have questions concerning the study you may contact Feven Girma, principal investigator with her number + 251 911098464.

### 7.3 Certificate of consent

I have read the foregoing information or it has been read to me. I have had the opportunity to ask questions about it and any question that I have asked have been answered to my satisfaction. I consent voluntarily to participate in this research.

Name of participant \_\_\_\_\_

Signature of participant \_\_\_\_\_

Date \_\_\_\_\_

