

THE DIRECT COST OF TREATING DIABETIC FOOT  
AND ITS ASSOCIATED FACTORS IN THE  
ORTHOPAEDIC WARDS, HOSPITAL UNIVERSITI  
SAINS MALAYSIA (HUSM), KOTA BHARU,  
KELANTAN

*by*

DR ZAWIYAH DOLLAH

Dissertation Submitted In  
Partial Fulfilment of The Requirement For  
The Degree of Master of Community Medicine  
(HEALTH SYSTEM MANAGEMENT)



UNIVERSITI SAINS MALAYSIA  
MAY 2007

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## LIST OF ABBREVIATIONS

|          |                                         |
|----------|-----------------------------------------|
| AKA      | Above Knee Amputation                   |
| <i>b</i> | beta coefficient                        |
| BKA      | Below Knee Amputation                   |
| CHD      | Coronary Heart Disease                  |
| CI       | Confidence Interval                     |
| CRF      | Chronic Renal Failure                   |
| CSSD     | Central Sterile Services Department     |
| DBP      | Diastolic Blood Pressure                |
| df       | Degree of freedom                       |
| ESR      | Erythrocyte sedimentation rate          |
| HUKM     | Hospital Universiti Kebangsaan Malaysia |
| HUSM     | Hospital Universiti Sains Malaysia      |
| IQR      | interquartile range                     |
| LEU      | Lower extremity ulcers                  |
| LOS      | Length of stay                          |
| MC       | Multicollinearity                       |
| MLR      | Multiple Linear Regression              |
| MOH      | Ministry of Health                      |
| NHMS     | National Health Morbidity Survey        |
| OHA      | Oral hypoglycaemic agent                |
| RM       | Ringgit Malaysia                        |
| SBP      | Systolic Blood Pressure                 |
| SD       | Standard deviation                      |

|       |                                           |
|-------|-------------------------------------------|
| SEK   | Swedish Krona                             |
| SLR   | Simple Linear Regression                  |
| SSG   | Split Skin Grafting                       |
| TWDC  | Total White Differential Count            |
| UKPDS | United Kingdom Prospective Diabetes Study |
| USA   | United States of America                  |
| US\$  | United States Dollar                      |
| VIF   | Variance Inflation Factor                 |
| WHO   | World Health Organization                 |

## ABSTRAK

### PENGENALAN:

*Diabetic foot* adalah salah satu daripada komplikasi akibat penyakit diabetes mellitus yang teruk. Kos perawatan penyakit ini semakin meningkat disebabkan oleh peningkatan di dalam kadar prevelennya. Dari itu, kajian ini dijalankan dengan tujuan untuk menganggarkan kos yang ditanggung oleh pemberi khidmat jagaan kesihatan dalam merawat *diabetic foot* dan menentukan faktor-faktor berkaitan dengan kos tersebut.

### KAEDAH KAJIAN:

Satu kajian kos penyakit telah dilakukan secara prospektif terhadap 101 pesakit *diabetic foot* yang dimasukkan ke Wad Ortopedik 4 Utara dan 4 Selatan, Hospital Universiti Sains Malaysia, Kota Bharu, Kelantan daripada 1<sup>hb</sup> Mei hingga 31<sup>hb</sup> Disember 2005. Subjek telah ditemuramah dan rekod perubatan mereka telah diteliti. Penentuan kos secara mikro dan makro telah dilakukan ke atas setiap pesakit. Kos keseluruhan perawatan *diabetic foot* dibahagikan kepada kos kapital dan kos ulangan. Purata kos per pesakit per kemasukan telah dikira. Analisis *multiple linear regression* digunakan untuk menentukan faktor sosio-demografi dan faktor klinikal yang mempengaruhi kos perawatan *diabetic foot*.

### KEPUTUSAN:

Majoriti subjek adalah Melayu (97.1 %) dan selebihnya adalah Cina. Pesakit perempuan (51.5 %) melebihi lelaki (48.5 %). Purata (SD) untuk umur (tahun) subjek, lama masa mengidap diabetes mellitus (tahun) dan tempoh masa diwadkan (hari) adalah 56.2 (9.78), 10.7 (6.41) dan 13.2 (4.68), masing-masing. Purata (SD) kos keseluruhan merawat

*diabetic foot* per pesakit per kemasukan wad adalah Ringgit Malaysia (RM) 11,763.88 (6,843.96). Purata (SD) kos kapital dan ulangan adalah RM 53.51(32.83) dan RM11,710.37 (6,813.24) masing-masing. Analisis *multiple linear regression* mendapati bahawa amputasi, cuci luka, kewujudan demam semasa diperiksa, kewujudan hipertensi dan penampalan kulit adalah faktor yang signifikan mempengaruhi kos.

#### KESIMPULAN:

Purata kos rawatan *diabetic foot* per pesakit per kemasukan wad ialah RM 11,763.88, yang kebanyakannya disumbang oleh kos ulangan serta berkaitan dengan penyakit hipertensi, pesakit demam semasa diperiksa, dan jenis pembedahan yang dilakukan samada penampalan kulit, amputasi atau cuci luka. Dari itu, langkah-langkah pencegahan *diabetic foot* dan keterukkannya perlu diperhebatkan serta peningkatan kualiti pengurusan penyakit diabetes mellitus dan komplikasinya yang kronik dapat mengurangkan tempoh berada di wad serta beban ekonomi.

*Kata kunci:* *diabetic foot*; kos pemberi khidmat jagaan kesihatan; kos kapital; kos ulangan; faktor berkaitan

## ABSTRACT

### INTRODUCTION:

Diabetic foot is one of the devastating complications of diabetes mellitus. The cost of treating it is increasing as its prevalence is increased. Therefore, the aim of this study was to estimate the direct cost incurred by health care provider in treating diabetic foot and its associated factors in the Orthopaedic Wards, Hospital Universiti Sains Malaysia (HUSM), Kota Bharu, Kelantan.

### METHOD:

A cost of illness study was done prospectively whereby 101 diabetic foot patients who were admitted to the Orthopaedic wards 4 Utara and 4 Selatan, HUSM from 1<sup>st</sup> May to 31<sup>st</sup> December 2005 were purposely selected. The subjects underwent face-to-face interview and their medical records were reviewed. The macrocosting and microcosting were performed on each of the patient. The cost of treating diabetic foot was divided into capital and recurrent costs. The mean cost per patient per admission was calculated. Multiple linear regression analysis was used in determining the socio-demographic and clinical characteristic factors associated with the cost.

### RESULT:

Majority of the subjects were Malay (97.1%) and the others were Chinese. Female (51.5%) was predominant than male (48.5%). The mean (SD) age (years) of the subjects, duration of having diabetes (years) and length of hospitalization (days) was 56.2(9.78), 10.7(6.41) and 13.2 (4.68), respectively. The mean (SD) direct cost per patient per admission was Ringgit Malaysia (RM) 11,763.88 (6,843.96). The mean (SD) for capital

and recurrent cost was RM 53.51(32.83) and RM11,710.37 (6,813.24) respectively. Amputation, debridement, fever at presentation, presence of hypertension and attendance of split skin grafting were significantly associated with the cost by multiple linear regression analysis.

#### CONCLUSION:

The mean direct cost per patient per admission of treating diabetic foot was RM 11,763.88, which mostly contributed by recurrent cost and was associated with the presence of hypertension as co-morbidity, patient who presented with fever and surgical procedure performed which was split skin grafting, amputation or debridement. Hence, strategies in preventing the lesion and its severity need to be strengthened and improvement in the management of diabetes mellitus and its chronic complications can reduce the length of hospitalization and its economic burden.

*Key words:* diabetic foot; health care provider's cost; capital cost; recurrent cost; associated factor

# CHAPTER ONE: INTRODUCTION AND LITERATURE REVIEW

## 1.1 Diabetes: A Global Problem

Diabetes Mellitus is a common disease worldwide with an estimated 124 million people had diabetes in 1997, and rising up to 177 million in 2000. By the year 2010, the numbers will be increased to at least 221 million (Zimmet *et al.*, 1997). World Health Organization (WHO) expects the numbers of adults (aged 20 and above) with Diabetes to rise to 300 millions by year 2025 (120% increment in 30 years). Furthermore, 80% of those individual will be found in developing countries by the year 2025 (WHO, 1997). The top three countries in the world with Diabetes were in the following order: India, China and USA (Bjork, 2001). In USA, diabetes affects 3% to 6% of the population, or between 8 and 16 million people, and half of these people have undiagnosed diabetes (Holzer *et al.*, 1998). In Malaysia, prevalence of diabetes has steadily increased over the years with an estimate of 0.65% in 1960 to 2% in 1982, 6.3% in 1985 and 8.3% in 1996 (NHMS, 1996).

Long standing Diabetes Mellitus was associated with an increase prevalence of both macro and micro vascular complications. United Kingdom Prospective Diabetes study (UKPDS), 1977-1991 has revealed that 50% of patient with Type 2 Diabetes had complication by the time they were diagnosed and 30% had serious complication 9 years after been diagnosed. On average, people with diabetes were three times more likely to be hospitalized than people without diabetes. The risk of premature death was higher for

individuals with diabetes compare to the non-diabetic, and the life expectancy was 10 – 15 times shorter (Bjork, 2001).

According to Malaysian Diabetes Care Data Project, (1998), the proportion of diabetic complications in Malaysia were 61% for nephropathy, 58% for neuropathy, 53% for retinopathy, 9% for myocardial infarct, 6% for stroke, 3% for diabetic foot, 2% for amputation, and 1% for renal failure. According to the annual report by Malaysia's Ministry of Health, (2004), the total numbers of new cases of Diabetes Mellitus in the year 2004 were 26, 953 in which 70% (18,838) had no complication during diagnosis and 30% (8,115) had complications at the time of diagnosis. Out of the 30% who had the complications, it's been microalbuminuria (35%), nephropathy (24%), neuropathy (21%), retinopathy (10%) and foot ulcer (10%).

## **1.2 Lower Extremity Ulcers: The Devastating Complication**

Lower extremity ulcers (LEU) are the most common cause of hospitalizations, morbidity and mortality in people with diabetes (Moulik *et al.*, 2003; Acker *et al.*, 2000; Curry *et al.*, 1998 and Holzer *et al.*, 1998). LEU is a serious complication for people with diabetes and a significant economic burden for both patients and health care providers. In USA, the incidence of diabetic foot ulcers was 2 % per year (Ramsey *et al.*, 1999). In one British study of a large cohort of neuropathic patients, there was a 7% one year incidence of first foot ulcer. Although many of these ulcers were superficial and heal with standard treatment, up to 15% of people with diabetes will develop a chronic non-healing ulcer over

their lifetime (Holzer *et al.*, 1998). In Malaysia the prevalence of diabetic foot ulcer was 6 % (MOH, 2003). It shows a double increment from 3 % in the year 1998.

Diabetic foot is resulted from both macro and micro vascular complications. Diabetic peripheral neuropathies result in abnormal pressure being applied to the foot which diabetic ischaemia put the foot even at higher risk (Jeffcoate *et al.*, 2003). The severity of diabetic foot can be determined by applying classification system proposed by Wagner (Lavery *et al.*, 1996). Wagner's system classifies foot ulcers into 5 stages according to depth and penetration of the wound, extent of infection and tissue necrosis as shown in Table 1.1.

**Table 1.1 Wagner's Classification System of Foot Ulcers**

| Stages  | Characteristics                                                                 |
|---------|---------------------------------------------------------------------------------|
| Stage 0 | Pre ulcer state, healed ulcer and/or presence of deformity                      |
| Stage 1 | Superficial ulcer without involvement of the subcutaneous tissue                |
| Stage 2 | Deep ulcer involving subcutaneous tissue like tendon, ligament or joint capsule |
| Stage 3 | Present of osteomyelitis                                                        |
| Stage 4 | Gangrene of the forefoot                                                        |
| Stage 5 | Gangrene of the entire foot                                                     |

Source: Lavery *et al.*, (1996).

### **1.3 Costing of Diabetic Foot**

Cost is defined as the value of resources used to produce an output, including a specific health service or a set of services (Creese and Parker, 1994).

#### **1.3.1 Classification of Costs**

Classification of cost is very important in calculating the costs of treating disease. In this study, the classification of cost by inputs was used (Creese and Parker, 1994):

##### **1. Capital costs**

- a. Vehicles: bicycles, motorcycles, four-wheel-drive vehicles.
- b. Equipment: refrigerators, other equipment with a unit cost of RM 500 or more.
- c. Buildings: health centres, hospital, storage facilities.
- d. Training, non-recurrent: training activities for health care personnel that occur only once or rarely.
- e. Social mobilization, non-recurrent: promotion, publicity campaigns, which occur once or rarely.

##### **2. Recurrent costs**

- a. Personnel (all types): supervisors, health workers, technicians, consultants, doctors, staff nurse.
- b. Supplies: drugs, vaccines, materials use for wound dressings, small

equipments (unit cost of less than RM500).

- c. Vehicles, operation and maintenance: petrol, tyres, spare parts
- d. Buildings, operation and maintenance: electricity, water, cleaning, repairs to electrical supplies, telephone.
- e. Training, recurrent (short in-service courses)
- f. Social mobilization: operating costs, other operating costs not included above.

Capital costs are defined as cost of items (asset) with a life more than one year like building, equipment and vehicles. Recurrent costs are cost that are necessarily incurred each year like salaries, drugs, electricity, water and spare parts (Creese and Parker, 1994).

### **1.3.2 Method of Costing**

The economic consequences of the diabetes and its complication can be calculated either by direct costs or direct costs plus indirect costs and societal costs. The direct costs are calculated on the basis of the number of physician visit, medicines used, laboratory and radiological used and transportation costs paid. It's mainly borne by health care providers. The indirect costs represent the costs to the society due to the morbidity and premature mortality; the cost is calculated on the basis of sick-leave days, employment situation, income and family home care. These costs are generally borne by the patients and their families (Bjork, 2001). The societal costs are the costs related to psychosocial aspect of the illness and its effect on the patient's quality of life such as pain, disability accounted and

depression. These types of costs are rarely calculated due to the difficulty in measuring it (Zhang *et al.*, 2004).

Cost of illness study can be done either prospectively or retrospectively, top-down or bottom-up approaches or prevalence and incidence-based (Tarricone, 2005). Ragnarson and Apelqvist, (1997), did a study on long-term costs for foot ulcers in diabetic patients in a multidisciplinary setting. Patients were treated and followed prospectively by a foot care team. A retrospective economic analysis was performed on costs for 274 patients during 3 years from healing of an initial foot ulcer, with or without amputation. Costs were estimated for inpatient care, outpatient care, home care, and social service. The cost calculations include costs due to complications and disability related to the initial ulcer, costs related to recurrence of ulcer, and costs for prevention of new ulcers. The data collected in this study were secondary data. Therefore the accuracy of the cost was dependent on the accurateness of the data.

Tennvall *et al.*, (2000) also did a cost of illness study prospectively. In this study, a multidisciplinary team followed the patients from admission until final outcome, i.e. primary healing or healing with amputation or death. Data from both the prospectively collected patient material and from patient records were used to estimate the cost for hospital care, antibiotics, surgery, out-patient care, staff attendance, drugs and material for ulcer dressings, and orthopedics appliances. The result of this study is more reliable compare to the study by Apelqvist, (1997) as the data was collected prospectively. However, the study is more time

consuming and difficult to do logistically as the researcher has to follow the subjects till the study period end.

The cost of illness analysis also can be done by top-down or bottom-up approaches. In top-down approach, it's involved in allocating total national healthcare expenditures by type of care (i.e. hospital care, primary care, physicians, services etc) to each of disease category. Amrizal, (2000) did a study on cost of treating diabetes, neonatal jaundice and pre-eclampsia in Hospital Universiti Sains Malaysia (HUSM) by using the top-down approach. He used the expenditure by HUSM and divided it to the total numbers admission of diabetes, neonatal jaundice and pre-eclampsia. As in bottom-up approach, the estimations of costs involved 2 steps. The first step is to estimate the quantity of health resources used and the second step is to estimate the unit cost of each of the health resources used. The costs are then calculated by multiplying unit costs by the quantities (Tarricone, 2005). There were not many studies using bottom-up approach, as even it is more accurate than top-down approach, but it was more time consuming and logistically heavier.

Cost of illness (COI) analysis can be done according prevalence or incidence-based. In prevalence-based COI, the annual cost was estimated using all cases that existed in that year, whereas for incidence-based study cost was estimated using the new cases that arise for the defined period (Tarricone, 2005).

### 1.3.3 Economic Burden of Diabetic Foot

Diabetic foot is one of the costly complications of diabetes. The total costs of treating a diabetic foot ulcer per episode range from US Dollar \$10,000.00 (RM 38,000.00) to nearly \$60,000.00 (RM 228,000.00), depending on ulcer severity and clinical outcome (Holzer *et al.*, 1998). One report estimates 800,000 prevalent ulcer cases in the United States with costs averaging US\$5,457.00 (RM 20,736.60) per year per patient or total national annual costs of US\$5 billion (Frykberg, 2000).

In Sweden, the estimated total cost per patient during 3 years of observation was US\$26,700.00 (RM 101,460.00) for primary healed patients with critical ischemia and US\$16,100.00 (RM 61,180.00) for primary healed patients without critical ischemia. For patients who healed with an amputation, the costs were US\$43,100.00 (RM 163,780.00) after a minor amputation and US\$63,100.00 (RM 239,780.00) after a major amputation (Ragnarson-Tennvall and Apelqvist, 1997). A pharmacoeconomic study in France, in 2003 using direct and indirect costs put average monthly cost in the outpatient management for diabetic foot at 697.00 Euros (RM 3,275.90), short hospital stays at 1556.20 Euros (RM 7,314.14) and 34.76 Euros (RM 163.37) for sick leaves (Girod, *et al.*, 2003).

A study conducted by Holzer *et al.*, (1998) in United State of America (USA) found that the total cost of treating diabetic foot per episode for Wagner's stage 1 or 2, stage 3 and stage 4 or 5 is US\$1,929.00 (RM 7,330.20), US\$3,980.00 (RM 15,124.00) and US\$15,792.00 (RM 60,009.60) respectively. Total expenditures (2 years) were US\$16,192,780.00 (RM 61,532,564.00) with average annual cost per patient was

US\$2,687.00 (RM 10,210.60). There was significant increase in costs as the severity level increased. Medicare expenditures in USA for lower extremity ulcers patients were on average 3 times higher than those for Medicare patients in general (US\$15,309 versus US\$ 5,226). Patients with lower extremity ulcer related in-patient use had the most expensive claims (US\$ 14,641), followed by patients with osteomyelitis (US\$ 8,942) and patients with debridement (US\$ 5,064) (Harrington *et al.*, 2000). This study showed that in-patient management did influence the cost, so as the severity of the illness.

In Malaysia, diabetic foot is also a major source of morbidity, a leading cause of hospital bed occupancy and account for substantial health care resources. It accounts for 12 % of all diabetic hospital admissions for the government hospitals (MOH, 2003). On the average and depending on location and type of private facility, a 5-day stay for mild to moderate diabetic foot problems will cost approximately Ringgit Malaysia (RM) 2500 to 3500, whereas a 7-day stay for more severe cases will cost around Ringgit Malaysia (RM) 7000 to 8000 (MOH, 2004).

There was no published study on cost of treating diabetic foot ulcer being done in government health facilities. However, Nabilla *et al.*, (2003) did a cost of illness analysis on direct cost of treating diabetes in an outpatient setting in Malaysia. The objective of the study was to determine the provider's cost (cost borne by MOH) and patients' cost. The costing was done using the top-down approach. Direct costs incurred by provider were gleaned from available record in the year 2002 and costs incurred by patients were determined by conducting a survey of 253 diabetics visiting an outpatient clinics using

questionnaire from 23<sup>rd</sup> October to 1<sup>st</sup> November 2002. It was discovered that provider's cost per diabetic patient per year was RM 185.97, patient's direct cost per year was RM 55.23 and total direct cost per diabetic patient per year was RM 241.19. In their study, Nabilla, *et al* (2003) calculated the cost for two months duration only. She was then extrapolated the results to a year cost by multiplying the results with 6 months. Hence the results may be underestimated.

#### **1.4 Factors Associated With the Cost of Treating Diabetic Foot**

There were several factors associated with the cost of treating diabetic foot. These factors can be the socio-demographic factors of the patient or the disease characteristics itself. Frykberg, (2000) found among the significant associated factors of direct and indirect costs of lower extremity ulcer (LEU) were ulcer severity, length of admission, or present of co-morbidity and the cost was ranged from US Dollar \$20,000 to \$40,000.

Severity of the diabetic foot influences the cost, where the cost increases with the level of the Wagner's classification (Holzer *et al.*, 1998 and Acker *et al.*, 2000). Acker *et al.*, (2000), did a study on cost of treating diabetic foot in Belgium. It's was a cross-sectional study involving 151 diabetic foot patients from all over Belgium. The cost to the Belgium's National Health Care per diabetic foot patient for Wagner stage 0, 1, 2, 3, 4 and 5 were US\$ 698, US\$ 1,378, US\$ 10,569, US\$ 19,676, US\$ 19,174 and US\$ 47,365 respectively (Acker *et al.*, 2000). It showed the parallel increase in the cost as the severity of diabetic foot increase.

The longer the duration of a diabetic foot patient was admitted, the higher the cost of treating it. This was showed by Benotmane *et al.*, (2001) in Algeria, where the average length of hospitalization was 26.87 days, 48.25 days and 65.44 days for diabetic foot grade 1, 2 and 3 respectively (Grade 1 was Wagner stage 1 and 2, Grade 2 was Wagner stage 3 and Grade 3 was Wagner stage 4 and 5). The average cost per patient/year for treating diabetic foot was US\$ 3,326.76, US\$ 5,712.24 and US\$ 7,399.74 for grade 1, 2 and 3, respectively. The length of hospitalization was increase as the severity increase, so as the cost of treating it.

Guo *et al.*, (1998) in his study in United State found that patient's co-morbidities, type of diabetes mellitus, renal dysfunction, number of physicians visited, age, being male and living in an urban areas were associated with higher direct cost of treating diabetic foot ulcers.

In Malaysia, there was no study being done on factors associated with cost of treating diabetic foot. However, Rohaizat *et al.*, (2005) did a study on factors associated with the cost of treating orthopaedic cases in Hospital Universiti Kebangsaan Malaysia (HUKM), Malaysia (diabetic foot is one of the orthopaedic case). He found that among the factors influenced the treatment cost of orthopaedic cases were length of stay, age, female sex, medical partition and severity of the illness. This study was part of the case-mix system and using the top-down approach. Therefore the treatment cost calculated not accurate as it's may misallocate the resources used.

Another study by Amrizal *et al.*, (2005) in HUKM, estimated the cost of treating cardiology cases and its associated factors. He used the same methodology as Rohaizat *et al.*, (2005). The mean (SD) cost of surgical cardiology cases per length of stay was RM 6,530 (4,588). He found that there were six factors were significantly influenced the cost i.e. length of stay, age, medical partition, discharge died, severity level 2 and severity level 3. Amrizal, (2000) too did a study on cost of treating diabetes mellitus in Medical Wards, Hospital Universiti Sains Malaysia (HUSM). He found that among the significant factors that influenced the cost was length of stay, co-morbidity and numbers of laboratory and radiological investigations done.

From few studies mentioned above it was found that among the significant factors which were associated with the cost of treating disease were age, male sex, area of living, length of hospitalization, disease severity and presence of co-morbidities.

## **1.5 Rationale of The Study**

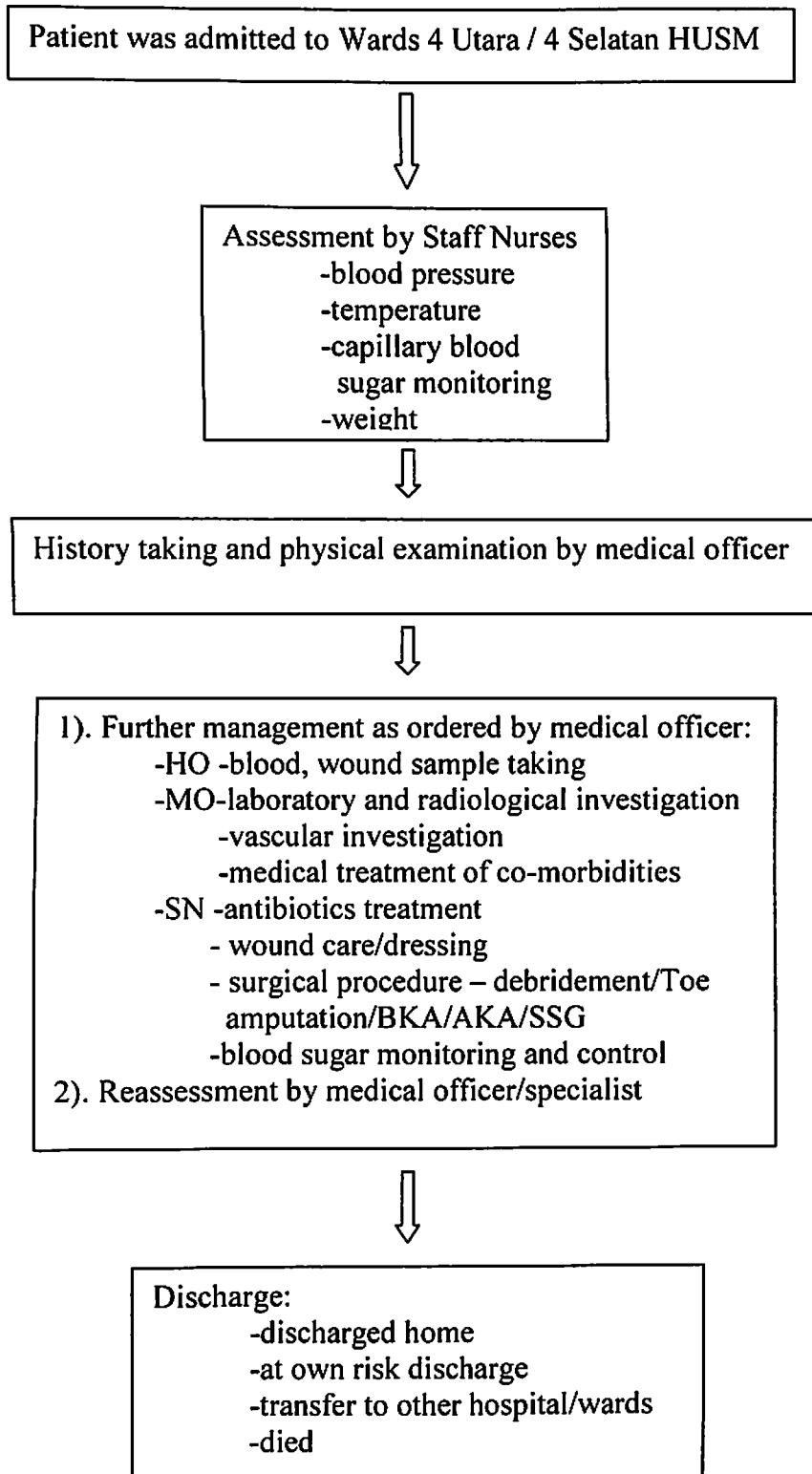
Unfortunately, there were no studies on costing of treating diabetic foot being done in Malaysia. Therefore, this study is aimed to provide the estimate of cost of treating diabetic foot per admission in HUSM. So that this information can be used by health care providers and policy makers as a guiding in determining budgetary allocations, prioritizing research funding, justifying funding for existing and new disease programmes. Cost of illness estimates can also be used by government as a measure of disease burden in term of economic burden. This study provides valuable data for informing and educating policy

makers about how many health care resources are consumed in managing certain diseases. It may provide an evidence that the cost of treating diabetic complications like diabetic foot is high (Holzer *et al.*, 1998), therefore preventive programmes such as a multidisciplinary team in managing diabetic foot would be given higher priority in health policy plans.

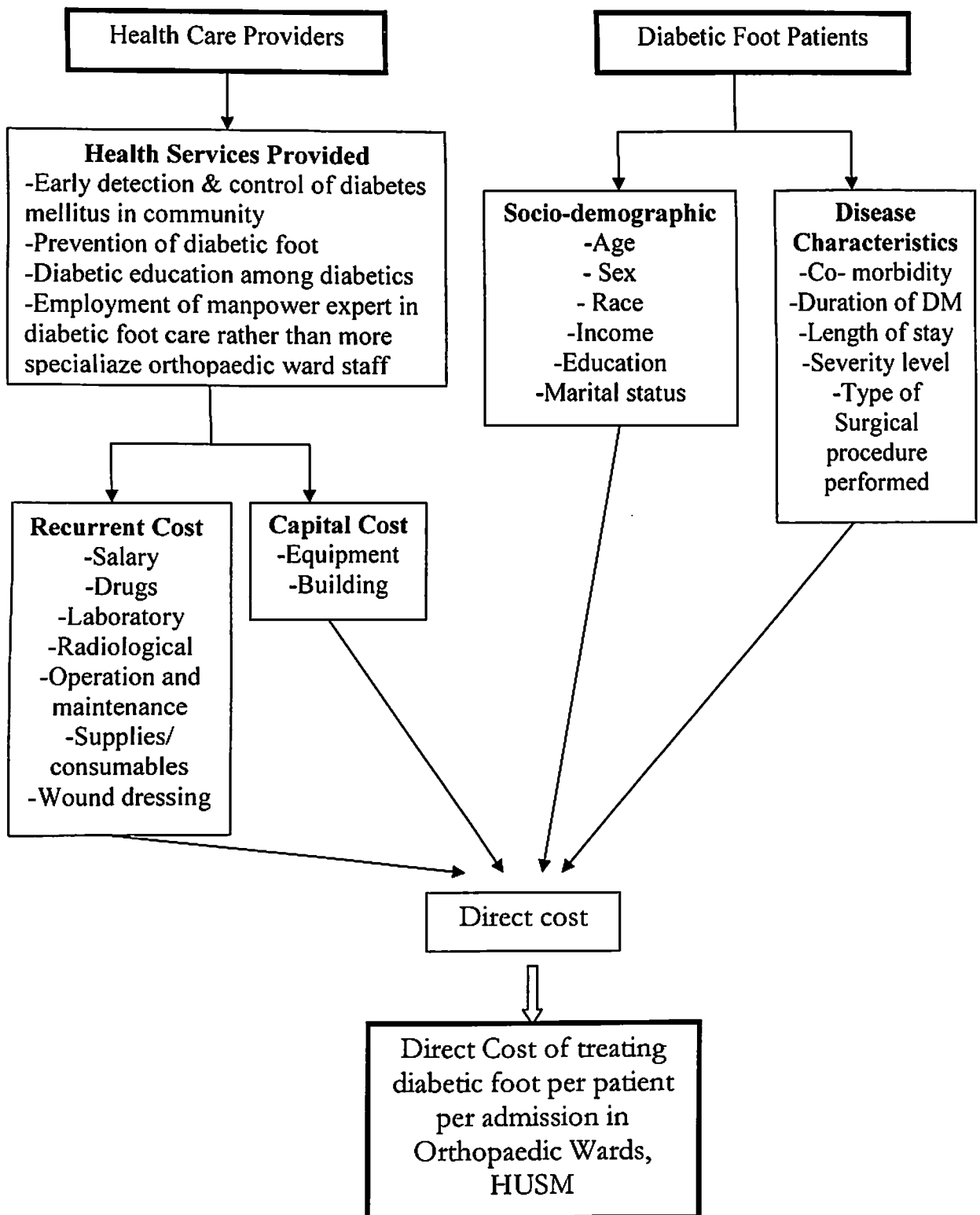
## **1.6 Conceptual Framework**

All of the diabetic foot patients who were admitted to the Orthopaedic Wards HUSM were selected, based on inclusion and exclusion criteria set by the researcher. Wards staff managed these patients accordingly till they were discharged and underwent operation if indicated (Figure 1.1). Each patient was different in his or her clinical characteristics such as severity of diabetic foot; which can influence the total health care costs.

Cost of treating the diabetic foot as in-patient involving the cost of the health care provider, patient and their families. This study only focused on cost incurred by provider of the services. Health care provider cost included the capital and recurrent cost, with the building and equipment costs were sub-grouped into capital cost and salary, operation and maintenance, laboratory investigation, radiological investigation, drug, surgical, supplies and dressing cost were put in the recurrent cost (Figure 1.2).



**Figure 1.1 Flow Chart of Diabetic Foot Management in Orthopaedic Wards, HUSM**



**Figure 1.2 Conceptual Framework**

# **CHAPTER TWO: RESEARCH QUESTIONS AND OBJECTIVES**

## **2.1 Research Questions**

1. What is the direct cost of treating diabetic foot per patient per admission in Hospital Universiti Sains Malaysia (HUSM)?
2. What are the factors associated with the direct cost of treating diabetic foot in HUSM?

## **2.2 Objectives**

### **2.2.1 General Objective**

This study attempts to perform costing on diabetic foot management in HUSM.

### **2.2.2 Specific Objectives**

1. To estimate the direct cost per patient per admission of treating diabetic foot in HUSM.
2. To determine the factors associated with the direct cost of treating diabetic foot patients in HUSM.

## **CHAPTER THREE: METHODOLOGY**

### **3.1 Study Area**

The study was conducted in Orthopedic wards (4 Utara and 4 Selatan Wards), Hospital Universiti Sains Malaysia (HUSM), Kubang Kerian, Kota Bharu, Kelantan from 1<sup>st</sup> May 2005 till 31<sup>st</sup> December 2005. HUSM is one of the tertiary hospitals in Kelantan that accepts referral from all other district hospitals in Kelantan and also Besut Hospital, Terengganu. It renders both secondary and tertiary medical care to the 468,936 residents of Kota Bharu (Statistics, 2003).

### **3.2 Study Design**

This study is a cost of illness analysis. It is a prospective study and partial economic evaluation since it only measures the costs but not the outcomes of the study (Drummond *et al.*, 1997).

### **3.3 Population and Sample**

#### **3.3.1 Reference population**

All diabetic foot patients at HUSM from 1<sup>st</sup> May to 31<sup>st</sup> December 2005

### **3.3.2 Source population**

All diabetic foot patients who were admitted to the Orthopaedic wards, HUSM from 1<sup>st</sup> May through 31<sup>st</sup> December 2005.

### **3.3.3 Inclusion and Exclusion Criteria**

#### **Inclusion Criteria:**

1. All diabetic foot patients who were admitted to the Orthopaedic Wards HUSM from 1<sup>st</sup> May to 31<sup>st</sup> December 2005.
2. Type 2 Diabetes Mellitus patients only

#### **Exclusion Criteria:**

1. Subsequent admission of the same patient within the study period.
2. Stage 0 (pre ulcer) diabetic foot according to Wagner's Classification.
3. Comatosed diabetic patients.
4. Subject who were diagnosed to have diabetes mellitus after the admission. This because duration of having diabetes is one of the studied associated factors.
5. Diabetics with renal failure on dialysis.

### **3.3.4 Sampling Method**

Review of HUSM's record and hospital admission and discharges revealed that the numbers of diabetic foot patients admitted to the Orthopaedics wards were 135 for the year 2002, 166 for the year 2003 and 179 in the year 2004. Because of the limited numbers of

subject, non probability sampling was done in this study. Consecutive recruitment of eligible subjects was employed. Patients who fulfilled the inclusion and exclusion criteria were recruited until the desired number was obtained. In recruiting the subjects, effort was made to make sure that sex distribution was balanced. Approximately at the end of the recruitment period (31<sup>st</sup> December 2005), we were able to recruit 49 male and 52 female diabetic foot patients.

### 3.3.5 Sample Size Calculation

The calculation of the sample size (n) was done for all objectives studied. However, only the one that yielded the biggest sample size was selected to determine required sample size. For the objective number 1 (i.e. To estimate the costs per patient per admission of treating diabetic foot in HUSM), single mean formula was used to calculate the sample size.

The formula was as below:

$$n = \frac{Z_{\alpha/2}^2 \cdot \sigma^2}{\Delta^2}$$

$Z_{\alpha/2} = 1.96$  (Critical Z value for 95% confidence interval of the estimate)

$\sigma = \text{RM } 6000$  (Standard deviation of cost of treating Orthopaedic cases per patient in HUKM) (Rohaizat *et al.*, 2005)

$\Delta = \text{RM } 1200.00$  (Precision).

$$n = \frac{(1.96)^2 (\text{RM } 6000)^2}{(\text{RM } 1200)^2}$$

= 97 plus 10% drop out = 107

The sample size required for the second objective was calculated using PS Software. It was calculated based on the study done by Rohaizat *et al.*, (2005) by using male sex as the associated factors of the cost of treating Orthopaedic cases in Hospital Universiti Kebangsaan Malaysia (HUKM). This study was chosen as the reference for calculating sample size because of it's the most similar costing study with present study being done in Malaysia. (*Note*: diabetic foot is one of the orthopaedic cases in the study).

$$\alpha = 0.05$$

$$\text{Power} = 80\%$$

$$\Delta = \text{RM } 2600 \text{ (Difference in population mean)}$$

$$\text{SD} = \text{RM } 4500 \text{ (Standard deviation of the mean cost of treating Orthopaedic cases among male sex) (Rohaizat } et al., 2005)$$

$$n = 48 \text{ (approximate 48 male and 48 female were expected to be recruited)}$$

Therefore the sample size for both groups was  $48 \times 2 = 96$  plus 10% (10) drop out = 106.

The sample size for the second objective was also calculated by using PS Software based on variable length of stay (LOS) as the associated factors of the cost of treating Orthopaedic cases in HUKM (Rohaizat *et al.*, 2005).

$$\alpha = 0.05$$

$$\text{Power} = 0.8$$

$$\sigma = \text{RM } 2530 \text{ (Standard deviation of the regression)}$$

$$\sigma = 9.35 \text{ (Standard deviation of the LOS) (Rohaizat } et al., 2005)$$

$$\lambda = 100 \text{ (RM } 100.00 \text{ increase per one day of length of stay)}$$

n = 60 (Its mean that we need 60 plus 10% drop out patients with diabetic foot as our study subjects).

It is expected that the number of subjects is about 120 – 140 per year, based on previous HUSM admissions and discharge's record, therefore sample size of 97 is sufficient for both objectives since there was no drop out present in this study.

### **3.3.6 Research Tools**

There were 2 economic evaluation forms used to obtain the data on costing, namely:

1. Macrocosting form (Appendix 4)

2. Microcosting form (Appendix 5)

Macrocosting form were used to obtain data on cost of building, list and cost of the equipment (more than RM 500.00) used in treating diabetic foot, operation and maintenance of the facility, list of the staff categories involved in managing diabetic foot patients with their annual salary, duration of contact between nurses and patients, doctors and patients and other staffs like wards attendants, sister and wards assistant and patients. The information gathered was for the year 2004.

As for the microcosting form, it contained data on socio-demographic and medical condition of subjects and information needed to calculate the costs of drugs used, radiological and laboratory investigations, surgical intervention done, topical wound dressing and consumables used for each diabetic foot patient. The researcher interviewed

the selected diabetic foot patients. The information obtained from the interview included socio-demographic data and diabetic history. The socio-demographic data included sex, age, race, marital status, education level and monthly income. The diabetic history included the duration of diabetes, type of treatment oral hypoglycaemic agent (OHA) alone, insulin or combination of OHA and insulin and any con-current medical illness. The co-morbidities included were hypertension, coronary heart disease, stroke and / or chronic renal failure.

The data on physical examination, laboratory and radiological investigations, topical wound dressing, surgical intervention and drug treatment such as intravenous antibiotic, insulin therapy and other oral drug therapy were obtained from patient medical records.

### **3.4 Operational Definition**

#### **3.4.1 Diabetic Foot**

The foot of a diabetic patient that has the potential risk of pathologic consequences, including infection, ulceration, and/or destruction of deep tissues associated with neurological abnormalities, various degrees of peripheral vascular disease, and/or metabolic complications of diabetes in the lower limb (WHO definition).

### **3.4.2 Wagner's classification of foot ulcers**

- Stage 0: Pre-ulcer. No open lesion. May have deformities, erythematous areas of pressure or hyperkeratosis.
- Stage 1: Superficial ulcer. Disruption of skin without penetration of subcutaneous fat layer.
- Stage 2: Full thickness ulcer. Penetrates through fat to tendon or joint capsule without deep abscess or osteomyelitis.
- Stage 3: Deep ulcer with abscess, osteomyelitis or joint sepsis. It includes deep plantar space infections, abscesses, necrotizing fasciitis and tendon sheath infections.
- Stage 4: Gangrene of a geographical portion of the foot such as toes, forefoot or heel
- Stage 5: Gangrene or necrosis of large portion of the foot requiring major limb amputation (Wagner, 1981).

### **3.4.3 Discharge**

Any patients who were spilled out from Orthopedic wards, HUSM either was send back home, transferred out to the other hospital or wards or died was considered as discharge from Orthopedic wards and the study was terminated at that point.

#### **3.4.4 Direct cost**

Direct costs of disease are those directly generated by the resources used in treating diabetic foot such as the number of physician visit, medicines used, laboratory and radiological used and transportation paid. It's mainly borne by health care providers.

#### **3.4.5 In-patient cost**

Costs of treating diabetic foot as in-patient in Orthopaedic wards, HUSM. It's can be borne by patient and health care provider. In this study researcher only concentrated on direct cost borne by health care provider. It was measured in Ringgit Malaysia (RM) per patient per admission.

#### **3.4.6 Health Care Provider cost**

The cost incurred by health care provider in delivering the services of treating diabetic foot as in patient in Orthopaedic wards, HUSM. In this study it will be the Ministry of Higher Education, because HUSM is one of the teaching hospitals in Malaysia.

#### **3.4.7 Lifespan**

Lifespan is the estimation of the economic useful time of resources had been used in providing the healthcare services. In MOH and according to the standard practice by WHO, lifespan used for the building was 20 years and equipment (price more than RM500.00) was 5 years (WHO, 1994).