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**The contribution of diabetes mellitus to lower extremity amputations in four public sector hospitals in Cape Town, for 2009 and 2010**

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University of Cape Town

## **Part A: Research Protocol and Part B: Literature Review**

### **RESEARCH PROTOCOL**

MMed in Family Medicine  
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## **1. STUDY TITLE**

The contribution of diabetes mellitus to lower extremity amputations in four public sector hospitals in Cape Town, for 2009 and 2010.

## **2. INTRODUCTION**

### **Problem statement**

Diabetes is the most common non-communicable disease worldwide and contributes to substantial morbidity and mortality. The prevalence of diabetes is increasing and reaching epidemic proportions, with the largest increase being seen in developing countries, including South Africa<sup>1-3</sup>. Among the many complications of diabetes, lower extremity amputations are common, with a leg being lost to diabetes somewhere in the world every thirty seconds<sup>4</sup>. The vast majority of these amputations is preventable and is a reflection of inadequate care of diabetic patients<sup>5-9</sup>.

### **Motivation for the study**

Studies done in South Africa have shown that the care of diabetes in the public sector is suboptimal<sup>10,11</sup>. A study in the private sector in South Africa showed that by ensuring optimal care of diabetic patients, long term glycaemic control and a decrease in complications and hospital admissions can be achieved<sup>12</sup>.

Lower extremity amputations can be the result of complications due to poor glycaemic control. There are, however, few studies that have been done in South Africa assessing the

contribution that diabetes makes to the performance of lower extremity amputations. This study will attempt to begin to fill in this gap in South African data and the results will be compared to a previous unpublished South African study in the Cape Town Metropole from 1999<sup>13</sup>.

This may in turn give an indication on the level of care of diabetic patients in Cape Town.

### **3. LITERATURE REVIEW**

Diabetes mellitus is defined as a metabolic disorder of multiple aetiologies, characterised by chronic hyperglycaemia and glucose intolerance, resulting from defects in insulin secretion, insulin action or both<sup>1,14</sup>.

The classification of diabetes has been revised by the World Health Organisation (WHO) and is now based on aetiology in the following four groups<sup>1,14</sup>:

1. Type 1 diabetes: Previously known as insulin-dependent and juvenile-onset diabetes, can occur at any age but usually affects children and young adults. It results from destruction, most commonly autoimmune, of the pancreatic beta cells. There is a lack of insulin which is required for survival.
2. Type 2 diabetes: Previously known as non insulin-dependent diabetes, it is the most common type of diabetes, accounting for more than 90% of cases. It can occur at any age, but usually affects adults over 40 years of age. It is often, but not always,

associated with obesity. It is characterised by insulin resistance and/or abnormal insulin secretion, either of which may predominate, but both of which are usually present. Being the most common type of diabetes, often with an insidious onset, it causes the greatest morbidity and mortality in diabetic patients.

3. Gestational diabetes: It is glucose intolerance of varying degrees of severity, which appears or is recognized for the first time in pregnancy. Strict control of the mother's blood glucose is important to avoid complication for both mother and fetus. Women who have had gestational diabetes are at increased risk of developing type 2 diabetes in later life.
4. Other specific types of diabetes: These are less common and include genetic disorders, infections and diseases of the exocrine pancreas, endocrinopathies or as a result of drugs.

### **Burden of disease**

The number of people with diabetes is increasing dramatically worldwide, resulting in an increased burden not only on individuals, but also on health care systems. Where it has been noted that there has been a decline in the morbidity and mortality for some of the non-communicable diseases, this has not be seen for diabetes. Diabetes is now the most common non-communicable chronic disease globally<sup>1-3</sup>.

The latest estimates show that in 2010, there are 285 million adults worldwide with diabetes, a prevalence of 6.4% of the world population. This is predicted to increase to 439 million adults by 2030, a prevalence of 7.7%<sup>1,15</sup>.

The increase in the number of adults with diabetes globally will be seen mostly in developing countries, where it is reaching epidemic proportions. Between 2010 and 2030, the predicted increase in the number of adults with diabetes is 69% for developing countries compared to 20% in developed countries<sup>2,3,15-18</sup>.

This increase in developing countries is thought to be due to the increasing urbanization of rural populations, with urban residence being shown to be associated with a two to five fold increased risk of developing diabetes<sup>18</sup>. The main reason is an increased rate of obesity, a major risk factor for developing diabetes (type 2). This is due to the change from a relatively healthy traditional rural pattern, to the urban, westernised lifestyle of increased food quantity, decreased food quality, decreased exercise, increased smoking and increased alcohol availability. It is also predicted that 70% of Africans will live in urban areas in 2025<sup>17-19</sup>.

### **Diabetes in sub-Saharan Africa**

Both the WHO and the International Diabetes Federation (IDF), have highlighted that Africa will contribute significantly to this increased burden of diabetes in developing countries. Few epidemiological studies focusing on the burden of diabetes and other non-communicable diseases have been done in sub-Saharan African countries, resulting in scarce data mainly because of the difficulty in undertaking these studies<sup>17-19</sup>.

The prevalence of diabetes in Africa was previously thought to be very low, with studies in a number of countries including Ethiopia, Ghana, Lesotho, Uganda and Malawi between 1960 and 1985 showing a prevalence of less than 1%. There were two exceptions at that time, Ivory Coast at 5.7% and South Africa at 2.2 to 2.7%. Tanzania and Cameroon are two of the

few countries where ongoing studies have taken place, showing a six to ten fold increase in the prevalence of diabetes over a ten year period, from the 1990's to 2000's. The prevalence rates of diabetes in African countries now range between 1.5 and 3.5%<sup>17-19</sup>.

The IDF has estimated that in 2010, 12.1 million people will have diabetes in sub-Saharan Africa, which will increase to 23.9 million in 2030. This is a projected growth of 98%, well above the predicted worldwide increase of 54% and the predicted increase of 69% for developing countries<sup>15,18</sup>.

In addition to this increased burden of people with non-communicable diseases, sub-Saharan Africa is weighed under by an increasing burden of communicable disease such as HIV/AIDS, Tuberculosis and Malaria. It is estimated that in 2020, non-communicable diseases will overtake communicable diseases as a major cause of mortality. It must also be remembered the ever present burden of perinatal and maternal disorders, as well as violence and injuries<sup>16,18-21</sup>.

### **Diabetes in South Africa**

Few studies have been done and there is poor data on the prevalence of diabetes in South Africa. Current estimates are that there are over 2 million people in South Africa with diabetes, a prevalence rate of 3.4%. There is also variation in different communities in South Africa with the prevalence of diabetes amongst adults in the Coloured group in Cape Town being as high as 10.8%<sup>19,22</sup>.

Like the rest of sub-Saharan Africa, the number of patients with diabetes is expected to increase in South Africa. HIV/AIDS predominately affects adults aged 20 to 40 years and

diabetes affects older adults between 40 and 60 years. With improved healthcare, many HIV infected adults will live long enough to develop diseases like diabetes. Also, with South Africa currently rolling out anti-retroviral treatment, including protease inhibitors which are associated with an increased incidence of new onset diabetes, the number of diabetics can be expected to grow even further<sup>17,18,21</sup>.

### **Complications of diabetes**

Diabetes is associated with acute and chronic complications, both of which contribute substantially to morbidity and mortality in diabetics. The main acute complications are diabetic ketoacidosis (DKA), hyperosmolar non-ketotic acidosis (HONK) and hypoglycaemia<sup>14</sup>. Being acute events, these conditions cause significant mortality, with mortality rates for sub-Saharan Africa of 10-30% for DKA and 41% for HONK being reported<sup>19</sup>. Hypoglycaemia is most often the result of the incorrect usage of glucose lowering diabetic medication, especially insulin. These conditions also contribute significantly to morbidity due to recurrent and extended hospital admissions<sup>4,14,19</sup>.

The chronic hyperglycaemia seen in diabetics leads to chronic complications, resulting in morbidity as well as mortality. This hyperglycaemia causes both microvascular and macrovascular complications. The microvascular complications are neuropathy, nephropathy and retinopathy. The macrovascular complications are cardiovascular disease, peripheral vascular disease and cerebrovascular disease<sup>4,14</sup>. Many diseases like Tuberculosis are also more common and more severe in diabetic patients<sup>19</sup>.

The mortality rate for diabetes in sub-Saharan Africa increased from 2.2 to 2.5% in 2000, is estimated at 6% for 2010 and is currently the seventh most common cause of death in South Africa<sup>18,22</sup>.

### **Lower extremity amputations**

One of the most significant complications of diabetes is a lower extremity amputation. Studies have shown that up to 90% of lower extremity amputations done worldwide are associated with diabetes and up to 70% of patients undergoing a lower extremity amputation die within five years of the operation<sup>6</sup>.

There is a wide range in the percentage of lower extremity amputations due to diabetes. Studies in Finland have shown that less than half of the amputations are due to diabetes, the USA that half are due to diabetes, and Germany that two thirds are due to diabetes<sup>23,24</sup>. There is a lack of information for Africa, with an unpublished study from South Africa in 1999 finding that 60.2% of amputations were due to diabetes in public sector hospitals in the Cape Town Metropole<sup>13</sup>.

The main risk factors that have been identified for a lower extremity amputation in a diabetic are<sup>7,24</sup>:

- Long duration of diabetes
- Prolonged hyperglycaemia
- Dislipidaemia
- Smoking
- Alcohol
- Peripheral neuropathy
- Peripheral vascular disease

- Limb deformity
- Infection
- Trauma
- Foot ulcer
- Previous amputation

Foot ulceration is one of the most important risk factors for a lower extremity amputation. The lifetime risk of a diabetic patient developing an ulcer is 25%, and up to 85% of lower extremity amputations are preceded by an ulcer<sup>4-6</sup>. In developed countries ulcers are usually due to peripheral vascular disease. In developing countries ulcers are usually due to peripheral neuropathy, with increasing rates due to peripheral vascular disease due to increasing urbanization<sup>2,6</sup>.

What is of major concern is that the majority of the above risk factors are preventable, with simple clinical examinations, patient education and regular follow up. Unfortunately this is difficult to achieve, especially in resource limited developing countries<sup>5-7,24,25</sup>.

### **Cape Town healthcare services**

Cape Town is situated in the Western Cape province of South Africa. It has a heterogeneous population of about 3.5 million people, consisting of about 53.9% Coloured, 26.7% Black, 18.4% White and 1% Indian/Asian people<sup>26,27</sup>.

Like the rest of South Africa, healthcare is split between the public and private sectors. It is estimated that 4.2 million of the 5.2 million people in the Western Cape, or 80%, are dependent on the public healthcare sector<sup>28</sup>. This public healthcare sector consists of primary,

secondary and tertiary levels of care. Diabetes and other chronic diseases are mostly cared for at the primary care level and cases are referred to the secondary and tertiary levels of care as necessary (for an amputation, the treatment of DKA, etc). Unfortunately the level of care of diabetes at this primary care is often suboptimal with inadequate screening to prevent complications due to diabetes, which results in the need for further treatment at the higher levels of care and adding to an already burdened system<sup>10,11,25</sup>.

#### **4. STUDY AIM AND OBJECTIVES**

The aim of this study is to describe the contribution of diabetes mellitus to lower extremity amputations in four public sector hospitals in Cape Town.

The objectives of this study are:

1. To determine the demographic characteristics of patients who underwent lower extremity amputations at public sector hospitals in Cape Town in 2009 and 2010
2. To determine the proportion of these amputations due to diabetes
3. To determine the cause/contributing factors for these amputations
4. To determine associated co-morbid diseases
5. To compare these results to previous data for these institutions

## **5. STUDY METHODS**

### **Study design**

The study is a record review of lower extremity amputation cases performed in four Cape Town public health sector hospitals, from 1st January 2009 to 31st December 2010. It is a cross-sectional study.

### **Study setting**

Data will be obtained from four public sector hospitals performing lower extremity amputations in the western portion of the Cape Town Metropole, including Groote Schuur Hospital, a tertiary level hospital, and its associated secondary level hospitals, New Somerset, Victoria and GF Jooste Hospitals. Data is not available from private sector hospitals in the same area, resulting in an underestimate in the true number of lower extremity amputations performed.

### **Study population**

All patients seen at the four hospitals who had a lower extremity amputation as identified in the theatre register for 2009 and 2010 will be identified. From these theatre records, the patients' folders will be accessed from the record departments.

### **Inclusion and exclusion criteria**

All patients identified as having undergone a lower extremity amputation in the above mentioned hospitals in 2009 and 2010, with available records, will be enrolled in the study. Patients whose records are not available will not be included in the study, and this missing information will be noted.

### **Definition of lower extremity amputations**

The definition of a lower extremity amputation (LEA) is the surgical removal of part of the lower limb by transection of the leg, foot or digit, and necessarily includes the removal of bone<sup>8</sup>. All cases including the terms: above knee amputation, through knee amputation, below knee amputation, supra-malleolar amputation, forefoot amputation and toectomy will therefore be included as lower extremity amputations in this study.

### **Sample size**

The study sample will include all patients having undergone a lower extremity amputation in the above mentioned hospitals in 2009 and 2010, whose records are available. This number is estimated to be 1000 and will give more than 90% statistical power to estimate the true proportion of lower extremity amputations due to diabetes.

Test Ho:  $p = 0.6000$ , where  $p$  is the proportion in the population

Assumptions: Alpha = 0.0500 (two-sided)

Expected proportion of diabetic patients = 60%

True proportion = 65%

Sample size  $n = 1000$

Estimated power = 90.4%

### **Data collection**

The following information will be extracted from the patients' folders using a standard questionnaire (Part D: Appendix 1):

- Demographic information

- Diabetic history
- Co-morbid disease
- Risk factors/cause
- Amputation history

### **Data analysis**

Data will be captured in Excel. Percentages for categorical data will be calculated. Measures of association between categorical variables will include Chi<sup>2</sup> test and prevalence ratios with 95% confidence interval. Assistance with data analysis will be sought from the University of Cape Town, School of Public Health and Family Medicine statistician.

Data analysis to show:

- Total number of lower extremity amputations performed
- The percentage of lower extremity amputations due to diabetes
- Distribution of Co-morbid disease
- Distribution of Risk factors/cause
- Distribution by age, gender, ethnic breakdown

## **6. ETHICAL CONSIDERATIONS**

This proposal will be submitted to the University of Cape Town Human Research Ethics Committee. Permission to conduct the study will be obtained from the relevant Medical Superintendents at Groote Schuur, New Somerset, Victoria and GF Jooste Hospitals, before

undertaking the study (Part D: Appendix 2). Permission will also be obtained from the Research Committee of the Western Cape Department of Health.

### **Privacy and confidentiality**

Patient confidentiality will be ensured and maintained during the study. Patient names will only be used when accessing theatre operation records and to retrieve patient records. These names will only be seen by the principal researcher during this period and will be removed from the database after the information has been accessed from their records. After this all information will be used anonymously. No patient names will be published in the study.

The researcher has no conflict of interest.

## **7. WORK PLAN AND BUDGET**

The timeframe for the study involves 5 phases:

1. Writing and submission of research proposal: January 2011 to June 2011
2. Collection of data: July 2011 to August 2011
3. Analysis of data: September 2011 to October 2011
4. Completion and submission of study: November 2011 to December 2011

The full budget of the study will be the responsibility of the principal researcher. Additional funding will be sought from the Department of Family Medicine, Faculty of Health Sciences, University of Cape Town.

## **8. DISSEMINATION OF FINDINGS**

The study will be submitted as the thesis portion for the Masters of Medicine degree in Family Medicine at the University of Cape Town for 2012.

The results of the study will be made available to the National and Provincial Departments of Health, as well as to the Departments of Medicine and Surgery at Groote Schuur, New Somerset, Victoria and GF Jooste Hospitals. The findings of the study are expected to indicate the level of care that diabetic patients receive. If found to be substandard, this would provide evidence that would ultimately improve the services for diabetic patients.

Once this study is completed, there is an intention to publish this study as a paper.

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## 10. APPENDICES

**Appendix 1:** Questionnaire (see Part D)

**Appendix 2:** Consent letter (see Part D)

University of Cape Town

## Part C: Publication-Ready Manuscript

**Study title:** The contribution of diabetes mellitus to lower extremity amputations in four public sector hospitals in Cape Town, for 2009 and 2010.

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Tables 3, Figures 2, Appendices 1

## **ABSTRACT**

### **Background**

Diabetes is a major contributor to morbidity and premature mortality worldwide. The chronic complications of diabetes are not only common but also devastating. In the literature, diabetes is the most common reported cause of non-trauma related lower extremity amputations (LEAs), however there is a lack of such information for South Africa and this study attempts to fill in this deficit in data.

### **Objectives**

The objectives of this study were to examine the proportion of LEAs due to diabetes and to describe the demographic characteristics, comorbidities, risk factors, causes, complications, number and site of amputation in patients undergoing LEAs.

### **Methods**

The study consists of three parts and is a retrospective analysis of all LEAs performed in four Cape Town public sector hospitals, for 2009 and 2010. The first part of the study identified all patients who had a LEA from theatre registers. The second part accessed these patients' records and the third part extracted information from these records using a structured questionnaire.

## **Results**

There were 1 280 non-trauma related LEAs in 867 patients, 925 LEAs in 593 diabetic patients and 355 LEAs in 274 non-diabetic patients. The main cause for LEAs was ulcer and infection in the diabetic and ischaemia in the non-diabetic patients. Smoking was more prevalent in the non-diabetic patients. Diabetic patients had more multiple admissions with more multiple LEAs than non-diabetic patients.

## **Conclusions**

The study found the number and percentage (68.4%) of non-trauma related LEAs due to diabetes alarmingly high. It is known that the majority of these LEAs are preventable with adequate education, screening, treatment and follow up. These findings may be a reflection that these patients are receiving suboptimal care and urgent interventions need to be implemented if we are to significantly reduce the number of these LEAs.

## INTRODUCTION

Diabetes is the most common non-communicable disease and a major cause of morbidity and mortality globally. Recent estimates are that there were 285 million adults in 2010 and more recently 347 million adults with diabetes worldwide.<sup>1,2</sup> The prevalence of diabetes continues to increase, with the largest increase seen in developing countries, including South Africa.<sup>3-5</sup> This increase is mainly due to the growth and ageing of the population, as well as increasing urbanisation with associated increased levels of obesity, physical inactivity and unhealthy diet.<sup>3,5,6</sup> This increasing number of people with diabetes will impact on health care systems. Diabetes accounted for 4.3% of all deaths in South Africa in 2000, placing it as the 7<sup>th</sup> most common cause of death in this country.<sup>3</sup>

The complications of diabetes are not only common but devastating and include lower extremity amputations (LEAs), blindness and renal failure, with diabetes being the most common cause for non-trauma related LEAs.<sup>3</sup> There is a wide range in the percentage of LEAs due to diabetes, with studies showing that up to 90% of LEAs done worldwide are associated with diabetes and up to 70% of patients undergoing a lower extremity amputation die within five years of the operation.<sup>6</sup>

There is a lack of information for diabetic related LEAs in Africa, with no published data available for South Africa. This study will attempt to address this deficit in South African data, thereby providing a baseline from which further monitoring and planning can occur.

Thus the aim of this study was to examine the contribution of diabetes mellitus to the performance of LEAs, in four public sector hospitals in Cape Town, for 2009 and 2010.

The objectives were to determine the demographic characteristics of patients undergoing LEAs, the proportion of these amputations due to diabetes, the co-morbidities, risk factors, causes and complications associated with these LEAs, and the number and sites of these LEAs.

## METHODS

The study was a retrospective analysis of all LEAs performed in four Cape Town public sector hospitals, Groote Schuur Hospital, a tertiary level hospital, and its associated secondary level hospitals, Somerset, Victoria and GF Jooste Hospitals, from 1st January 2009 to 31st December 2010. These four hospitals are the public sector hospitals performing LEAs in the western portion of the Cape Town Metropole. Cape Town is situated in the Western Cape province of South Africa and has a heterogeneous population of approximately 3.5 million people. Like the rest of South Africa, healthcare is split between the public and private sectors, with 80% of the population being dependent on the public healthcare sector.<sup>7,8</sup>

The first part of the study identified cases of LEAs from the theatre registers of these four hospitals for 2009 and 2010. The definition of a LEA is the surgical removal of part of the lower limb by transection of the leg, foot or digit, and necessarily includes the removal of bone.<sup>9</sup> All cases including the terms above knee amputation (AKA), through knee amputation (TKA), below knee amputation (BKA), supra-malleolar amputation (SMA), forefoot/transmetatarsal amputation (TMA) and toectomy, were therefore included as a LEA in this study.

The second part of the study accessed these patients' records identified from theatre registers, from the corresponding hospitals record departments. Patients whose records were found were included in the study. Patients whose records were not found were excluded from the study.

The third part of the study extracted information from the available patients' records using a structured questionnaire (Appendix 1). This information included number and length of admissions, demographic details, diabetic status, type and treatment, associated comorbid disease, risk factors, cause, amputation details and complications.

Trauma related LEAs were excluded from the study to obtain only information for non-trauma related LEAs. Of the non-trauma related LEAs, patients whose diabetic status were unknown were excluded from the study to only include known diabetic status.

Data was captured in Microsoft Excel 2010. Stata version 11, data analysis and statistical software and OpenEpi version 2.3.1, open source epidemiological statistics for public health, were used to analyse the data. Descriptive analysis included percentages for categorical data, mean, median, standard deviation and range for numerical data. Tests of significance included the Chi squared, Fisher exact and the Wilcoxon tests. Statistical significance of  $p < 0.05$  was used. Assistance with data analysis was sought from the University of Cape Town, School of Public Health and Family Medicine statistician.

Patient confidentiality was ensured and maintained throughout the study.

## RESULTS

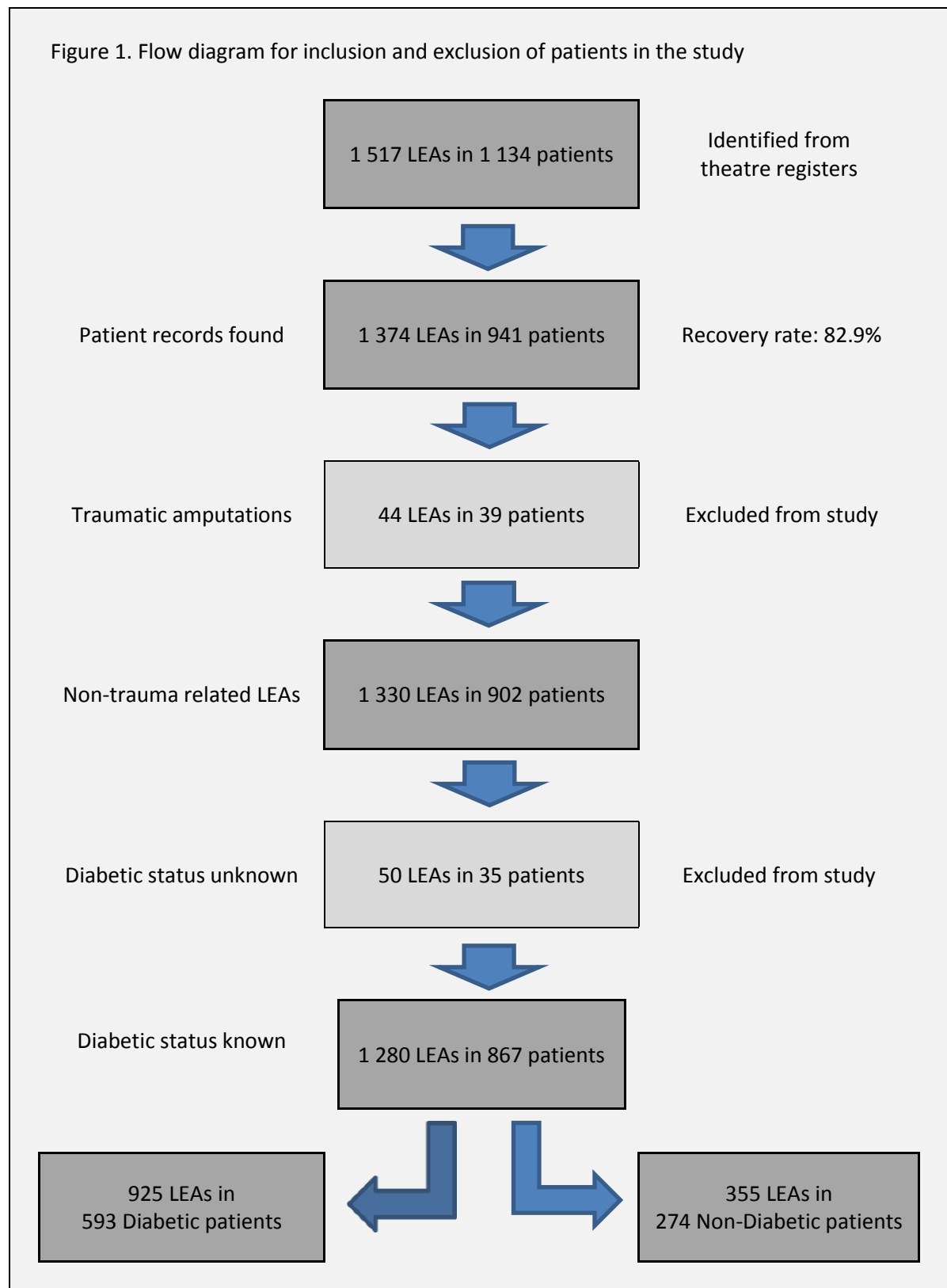


Figure 1 demonstrates how patients were included and excluded from the study.

Table 1. Comparison of diabetic and non-diabetic patients by gender					
GENDER	DIABETES YES		DIABETES NO		p-value
	NUMBER OF PATIENTS	% OF PATIENTS	NUMBER OF PATIENTS	% OF PATIENTS	
MALE	297	50.1	183	66.8	<0.001
FEMALE	296	49.9	91	33.2	<0.001
<b>TOTAL</b>	<b>593</b>	<b>100</b>	<b>274</b>	<b>100</b>	

Table 1 compares the demographic characteristics of the patients in the study by gender. This demonstrates that the gender distribution was similar in the diabetic group, but in the non-diabetic group, the percentage of male patients was double that of female patients. There were a significantly greater proportion of women with LEAs in the diabetic group than the non-diabetic group and the reverse was noted in men.

The mean age of all patients included in the study was 62.2 years, with no significant differences between the mean ages of the diabetic and non-diabetic patients. There was no significant difference between the mean age of male and female patients in the study. There was also no significant difference between the mean age between diabetic and non-diabetic patients in the male and female groups of patients.

Unfortunately the ethnic breakdown of the patients in the study was not possible to include in the demographic characteristics due to this information not being available in the patient records.

The following explains the type of diabetes and the therapy in the diabetic group of patients. 7 patients (1.2%) had type 1 diabetes, 551 patients (92.9%) had type 2 diabetes and the type of diabetes was unknown for 35 of the diabetic patients (5.9%). 3 patients (0.5%) were on no therapy, 7 (1.2%) were on diet alone, 299 (50.4%) were on oral therapy alone, 104 (17.5%) were on insulin therapy alone, 128 (21.6%) were on a combination of oral and insulin therapy and therapy for 52 (8.8%) of the patients was unknown.

Table 2. Comparison of comorbidities, risk factors, causes and complications between diabetic and non-diabetic patients					
	DIABETES YES		DIABETES NO		p-value
	NUMBER OF PATIENTS	% OF PATIENTS	NUMBER OF PATIENTS	% OF PATIENTS	
<b>COMORBIDITIES</b>					
HYPERTENSION	493	83.1	148	54.0	<0.001
CVA/TIA	76	12.8	40	14.6	0.4735
ISCHAEMIC HEART DISEASE	103	17.4	29	10.6	0.0097
ALCOHOL	28	4.7	41	15.0	<0.001
ASTHMA/COPD	24	4.1	27	9.9	<0.001
CONGESTIVE CARDIAC FAILURE	33	5.6	8	2.9	0.088
RENAL IMPAIRMENT	28	4.7	3	1.1	0.0074
HIV	2	0.3	23	8.4	<0.001
<b>RISK FACTORS</b>					
HYPERCHOLESTEROLAEMIA	75	12.7	27	9.9	0.2359
SMOKING	258	43.5	191	69.7	<0.001
PERIPHERAL VASCULAR DISEASE	138	23.3	76	27.7	0.1563
PERIPHERAL NEUROPATHY	13	2.2	3	1.1	0.2653
<b>CAUSES</b>					
ULCER	150	25.3	42	15.3	0.001
INFECTION	508	85.7	174	63.5	<0.001
ISCHAEMIA	138	23.3	135	49.3	<0.001
<b>OTHER CAUSES</b>					
BURNS	7	1.2	0	0.0	0.0346
MALIGNANCY	2	0.3	12	4.4	<0.001
DEFORMITY	6	1.0	9	3.3	0.0414
NEUROLOGICAL DISORDER	1	0.2	7	2.6	0.0034
HIV VASCULOPATHY	0	0.00	21	7.7	<0.001
<b>OTHER CAUSES TOTAL</b>	16	2.7	49	17.9	<0.001

<b>COMPLICATIONS</b>					
IN-HOSPITAL DEATH	34	5.7	17	6.2	0.7841
FURTHER AMPUTATION	250	42.2	63	23.0	<0.001
BLOOD TRANSFUSION	65	11.0	24	8.8	0.3206
DIABETIC KETOACIDOSIS	12	2.0	0	0.0	0.0202
ICU ADMISSION	10	1.7	5	1.8	0.5399
SEPSIS/DEBRIDEMENT	52	8.8	13	4.7	0.0364
<b>OTHER COMPLICATIONS</b>					
VASCULAR EVENT	4	0.7	1	0.4	0.9904
DEEP VEIN THROMBOSIS	0	0.0	1	0.4	0.6321
UPPER GIT BLEED	3	0.5	2	0.7	0.5048
PNEUMONIA	2	0.3	0	0.0	0.9351
<b>OTHER COMPLICATIONS TOTAL</b>	9	1.5	4	1.5	0.9781
CVA=Cerebral Vascular Accident TIA=Transient Ischaemic Attack COPD=Chronic Obstructive Pulmonary Disease HIV=Human Immunodeficiency Virus ICU=Intensive Care Unit GIT=Gastrointestinal Tract					

Table 2 summarises the comorbidities, risk factors, cause and complications associated with a LEA in the diabetic and non-diabetic groups. For associated comorbidities, it can be seen that there are significant differences for hypertension, ischaemic heart disease (IHD) and renal impairment between the two groups, being more common in the diabetic than the non-diabetic group. Conversely, there are also significant differences for associated alcohol usage, asthma/chronic obstructive pulmonary disease (COPD) and human immunodeficiency virus (HIV) infection, which is more common in the non-diabetic than the diabetic group. There are no significant differences between associated cerebral vascular accidents (CVAs)/transient ischaemic attacks (TIAs) and congestive cardiac failure (CCF) in the diabetic and non-diabetic groups.

For associated risk factors, smoking was significantly different between the two groups, being more common in the non-diabetic group compared to the diabetic group. There were no significant differences between the two groups for associated hypercholesterolaemia, peripheral vascular disease (PVD) and peripheral neuropathy.

For causes of the LEAs, there were significant differences for the main causes between the two groups, with ulcer and infection being more common in the diabetic group and ischaemia being more common in the non-diabetic group. There were also significant differences for the other causes between the two groups, with burns being more common in the diabetic group and malignancy, limb deformity, neurological disorder and HIV vasculopathy being more common in the non-diabetic group.

For complications associated with the LEA, there were significant differences for the main complications between the two groups, with a further LEA, diabetic ketoacidosis (DKA) and sepsis and debridement being more common in the diabetic group than the non-diabetic group. There were no significant differences for the other main complications of in-hospital death, blood transfusion, and intensive care unit (ICU) admission, as well as the other complications of deep vein thrombosis (DVT), upper gastrointestinal tract (GIT) bleed and pneumonia between the diabetic and non-diabetic groups, although these numbers were very small.

Table 3. Comparison of length of admissions in days between diabetic and non-diabetic patients						
DIABETES	NUMBER	MEAN	MEDIAN	STD DEV	MIN	MAX
YES	688	10.6	9	6.4	1	45
NO	300	10.7	9	8.3	1	79
<b>TOTAL</b>	<b>988</b>	<b>10.6</b>	<b>9</b>	<b>7.0</b>	<b>1</b>	<b>79</b>
Two-sample Wilcoxon rank-sum test: p=0.7995						
STD DEV = Standard deviation MIN = Minimum in range MAX = Maximum in range						

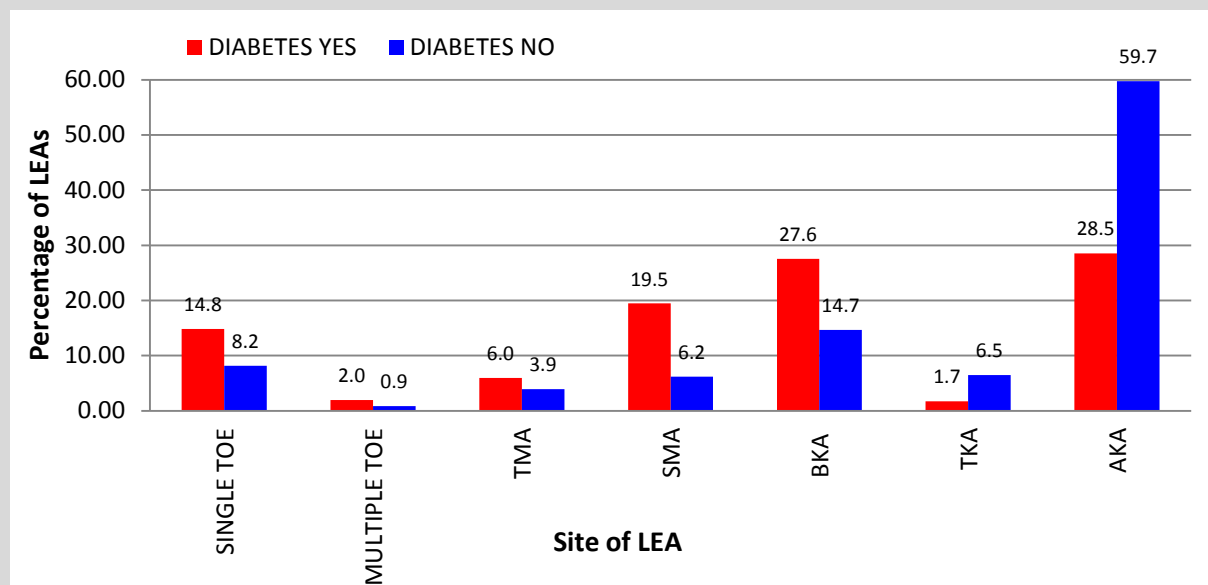
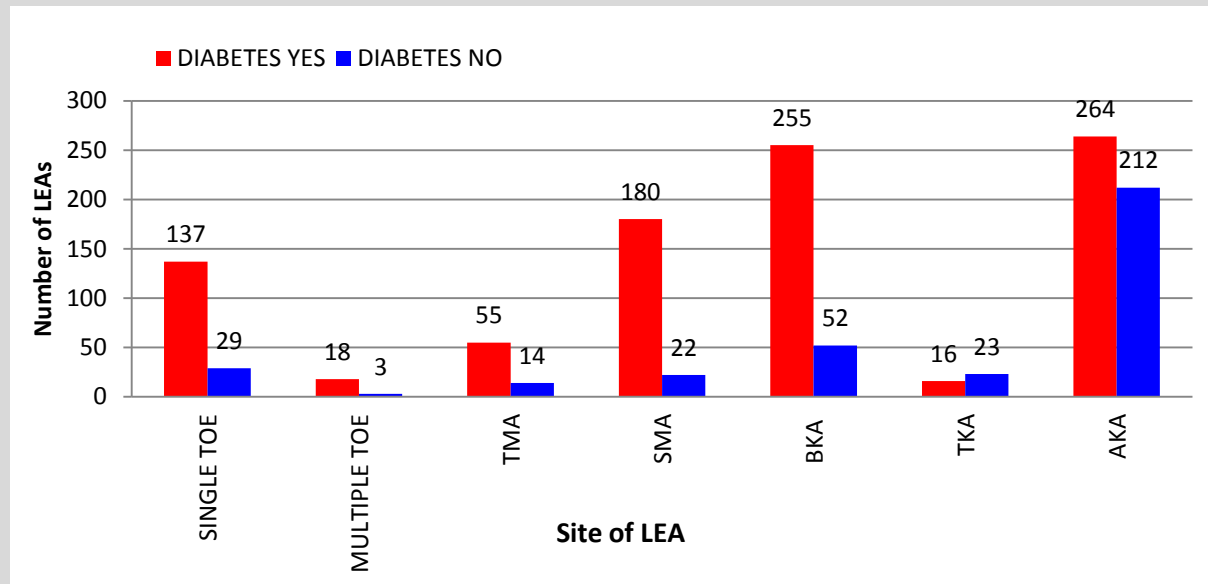
Table 3 shows that the mean length of admission for all patients was 10.6 days and there was no significant difference between the mean length of admission for the diabetic and non-diabetic patients.

When analysing admissions, 867 patients in the study were admitted a total of 988 times, with the 593 diabetic patients being admitted 688 times and the 274 non-diabetic patients being admitted 300 times. A significantly greater proportion of the diabetic patients (14.3%) had multiple admissions compared to the non-diabetic patients (7.7%) and conversely a greater proportion of non-diabetic patients (92.3%) had a single admission compared to the diabetic group (85.7%)  $p < 0.005$ .

Table 4. Comparison of previous and current Lower Extremity Amputations between diabetic and non-diabetic patients					
	DIABETES YES		DIABETES NO		
	NUMBER OF PATIENTS	% OF PATIENTS	NUMBER OF PATIENTS	% OF PATIENTS	p value
<b>PREVIOUS LEA</b>					
<b>SINGLE</b>	97	16.4	41	15.0	0.6019
<b>MULTIPLE</b>	24	4.1	6	2.2	0.1643
<b>TOTAL</b>	121	20.4	47	17.2	0.261
<b>CURRENT LEA</b>					
<b>SINGLE</b>	344	58.0	211	77.0	<0.001
<b>MULTIPLE</b>	249	42.0	63	23.0	<0.001
<b>TOTAL</b>	593	100	274	100	

Table 4 shows that 168 of the total 867 patients (19.4%) in the study had a previous LEA before the study period of 2009. There was no significant difference in having a previous LEA or having single or multiple LEAs between the two groups. It can be seen that for the current LEAs, there was a significant difference in LEAs with the diabetic group having a higher proportion of multiple LEAs and the non-diabetic group a higher proportion of single LEAs.

Figure 2. Number and percentage for site of current Lower Extremity Amputations



TMA=Transmetatarsal Amputation SMA=Supra-malleolar Amputation BKA=Below Knee Amputation  
TKA=Through Knee Amputation AKA=Above Knee Amputation

Figure 2 shows the breakdown in number and percentage for the sites of the current LEAs in the diabetic and non-diabetic groups. There were a total of 1 280 LEAs in all patients over the study period, 925 LEAs in 593 diabetic patients and 355 LEAs in 274 non-diabetic patients. It can be seen that the number of LEAs at all sites except TKAs were higher in the diabetic group than the non-diabetic group. It can also be seen that the percentages of LEAs at all the sites except TKAs and AKAs are higher in the diabetic group than the non-diabetic group.

## DISCUSSION

This study showed that 1 517 LEAs were identified over the two year study period. A previous unpublished study found that 1 483 LEAs were identified over a three year study period, from 1997 to 1999, for the same patient population attending public sector hospitals in the Cape Town Metropole. That study found that 60.2%, where this study found that 68.4% of the non-trauma related LEAs were related to diabetes.<sup>10</sup> This increase in number of LEAs and percentage due to diabetes over this time period is probably a reflection of not only the increasing size of the population, but also due to the increase in the incidence of diabetes and its complications, including LEAs.

A previous study has shown that the proportion of males to females in both diabetic and non-diabetic related LEA patients were equal.<sup>11</sup> This study has shown that this was true for the diabetic patients, but more males had LEAs in the non-diabetic group compared to females. This may be due to the higher prevalence of smoking in males in the non-diabetic group, with smoking being a major risk factor for a LEA.<sup>12</sup>

There was no difference found in the mean ages of all patients in this study, male and female, diabetic and non-diabetic. A previous study has shown similar findings but with higher ages.<sup>11</sup> These lower ages in this study may be a reflection of more advanced disease in our patients due to suboptimal care.

92.9% of the diabetic patients requiring a LEA had type 2 diabetes, which is in keeping with other data worldwide including Africa.<sup>13,14</sup> The diagnosis of type 2 diabetes is often delayed

until the presentation of a complication (retinopathy, nephropathy and neuropathy).<sup>15</sup> Where 50% of the diabetic patients were on oral therapy alone, nearly 40% were either on a combination of oral and insulin or insulin therapy alone. This high percentage of insulin usage may be a reflection that a large proportion of the patients' diabetes was not adequately controlled, requiring additional therapy.

This study found that the associated comorbidities of hypertension, IHD and renal impairment were more common in the diabetic group of patients. This is in keeping with what previous studies have shown and is thought to be partly due to the increasing westernisation of lifestyles.<sup>3,12,13</sup> The associated renal impairment is probably a reflection of the other associated complications of diabetes.

Smoking was the only associated risk factor found to be different between the diabetic and non-diabetic groups in this study. It was more prevalent in the non-diabetic patients and this was also reflected in the fact that associated asthma/COPD was also more prevalent in the non-diabetic group. There were still a large proportion of diabetic patients who smoked, which has been shown to increase the risk of LEAs.<sup>12</sup> Associated PVD was similar between the diabetic and non-diabetic groups with about 25% of patients noted to have PVD as a risk factor, which is a similar finding to a previous study.<sup>11</sup> This study only found a small number of patients with associated peripheral neuropathy in both groups, especially in the diabetic group, where peripheral neuropathy is known to be a substantial cause of foot complications including LEAs.<sup>14,16</sup> The number of patients with associated peripheral neuropathy is thought to be higher than found in the study due to possible underreporting in the patient records.

A preceding ulcer and infection were the more common causes for LEAs in the diabetic patients, which is in keeping with what previous studies have shown.<sup>6,12,17</sup> Ischaemia was the more common cause for LEAs in the non-diabetic patients and is probably due to the higher rate of smoking in this group. Burns causing LEAs was more common in the diabetic group and can probably be attributed to associated peripheral neuropathy, although the number of these patients was low as described above.

This study was unable to assess the proportion of patients who died after they had a LEA and discharged from hospital. The study did however assess the proportion of patients who died in hospital after having a LEA and no difference was found between the diabetic and non-diabetic groups. A portion of folders of deceased patients at one of the hospitals in the study was inaccessible. Due to the high percentage of diabetes found in this study, it is felt that the rate of in-hospital deaths in diabetic patients could be higher than reported.

Post LEA sepsis and debridements were found to be more common in the diabetic group of patients. This is expected as sepsis was often the cause for the LEA in this group. This is suspected to be an underestimate of the true rate because only admissions where a LEA took place were included in this study. It was noticed that there were many more admissions for these patients for sepsis and/or debridement before or after an admission for a LEA.

This study found that there was no difference in the mean length of admissions for all patients. It was also found that the diabetic patients had more multiple admissions and multiple LEAs compared to the non-diabetic group. These additional LEAs either occurred

during the same or on subsequent admissions and were generally due to on-going sepsis and/or ulcer.

The percentages for the site of the current LEAs shows that nearly 20% were SMAs. This is an indication that sepsis was a major cause as this operation is usually a sepsis control procedure, the definitive procedure being a BKA or AKA, depending on the status of the remaining limb. It is also notable that the percentage of AKAs in the non-diabetic group is double that of the diabetic group. This may be a reflection that diabetic patients have more LEAs due to an ulcer or infection requiring a more distal amputation whereas the non-diabetic patients have more LEAs due to ischaemia, requiring a more proximal amputation.

It is well known that the majority of foot complications, including, LEAs are preventable with adequate patient education, screening, treatment and follow up.<sup>17-20</sup> Unfortunately, the high numbers of LEAs that are occurring may be a reflection that this care is suboptimal. This may be due to high patient numbers and decreased consultation times leading to infrequent foot examinations, decreased patient education and therefore non-compliance, as well as inadequate treatment at a primary healthcare level. There is also a lack of resources like podiatrists needed to adequately treat these complications.<sup>3,18</sup>

Numerous studies have stated that LEAs are a considerable cost for healthcare services, not only for the admission and amputation, but also for the additional costs of rehabilitation, home care and social services.<sup>21-23</sup> The human cost is also considerable, for the patient, their families and society. The best way to decrease these costs is to decrease the number of foot

complications including LEAs. Detailed costing for the number of LEAs that have taken place needs to be undertaken.

Due to the lack of accurate data on diabetic incidence and population size in the study area, it is difficult to extrapolate the number of LEAs that have been identified in this study to the prevalence of diabetes related LEAs. Further work needs to be undertaken to obtain these results.

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## **LIMITATIONS OF THE STUDY**

Where there were strengths in this study due to the large number of patients identified and evaluated due to a good recovery rate, there were also weaknesses. Numbers for certain associated factors in these patients were low and meaningful analysis was not always possible. The retrospective nature of this study only allowed for information that was recorded in the patient records to be evaluated. Record taking was often poor with very limited information in the records. Associated information like the level of glycaemic control, length of diabetes and obesity that could have been useful was not available. Also, this study only evaluated patients accessing the public sector, thereby underestimating the true prevalence of diabetes associated LEAs.

## CONCLUSIONS AND RECOMMENDATIONS

This study set out to describe the contribution of diabetes to the performance of LEAs in the public healthcare sector in Cape Town and found this number to be alarmingly high. The associated factors in these patients, age, gender, comorbid disease, risk factors, cause, complications and amputations were all generally similar to what previous studies, all outside South Africa, had shown. This study therefore sets a baseline for South African information, from which further assessment and planning can occur.

It has been mentioned that the majority of complications including LEAs are preventable with adequate education, screening, treatment and follow up. This has however been shown to be suboptimal. It is recommended that these basic services need to be improved at a primary care level in order to begin to decrease the number of LEAs that are being performed, as well as the other devastating complications of blindness and renal failure. Healthcare workers need to be educated on how to use well described treatment guidelines including foot screening tools, enough time during a consultation needs to take place with a patient to allow education, screening and active participation in their treatment. It simply comes down to the old adage of “prevention is better than cure”, unfortunately not so simple in a resource limited country with many other healthcare issues.

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## APPENDICES

**Appendix 1:** Questionnaire (see Part D)

## **Part D: Appendices**

Appendix 1	Questionnaire
Appendix 2	Consent letter
Appendix 3	Instruction to authors
Appendix 4	Acknowledgments
Appendix 5	Ethical considerations
Appendix 6	Funding
Appendix 7	Technical appendices
Appendix 8	Approval letters
Appendix 9	UCT declaration
Appendix 10	CMSA declaration

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**APPENDIX 1****QUESTIONNAIRE****GENERAL INFORMATION**

Case number:

Date:

Hospital:      Groote Schuur      New Somerset      Victoria      GF Jooste

Date of admission:

Date of operation/s:

Date of discharge:

Length of Hospital stay:

Discharge status:

**DEMOGRAPHIC INFORMATION**

Name:

Folder number:

Date of birth/age:

Gender:      Male      Female

Ethnicity:      Black  
                    Coloured  
                    Indian  
                    White  
                    Other

Area:

**DIABETIC HISTORY**

Patient diabetic?      Yes      No

Type of diabetes:      Type 1      Type 2

Diabetic treatment:      Diet only  
                                    Oral therapy  
                                    Insulin therapy  
                                    Combination therapy



## APPENDIX 2

### CONSENT LETTER

01 June 2011

The Medical Superintendent

**Re: Permission to undertake study.**

As part of the MMed in Family Medicine at the University of Cape Town, I am planning to undertake the following study. **The contribution of diabetes mellitus to lower extremity amputations in four public sector hospitals in Cape Town, for 2009 and 2010.**

I will require permission to firstly access theatre operating records of all lower extremity amputations done in the hospital from 2009 to 2010; and secondly access patient records for those identified having these amputations.

Patient confidentiality will be maintained throughout the study and patient information will be used anonymously.

Ethics approval: HREC REF: 365/2011

Thanking you

Dr Graeme Dunbar

Registrar in Family Medicine  
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## **APPENDIX 3**

### **INSTRUCTION TO AUTHORS**

Instructions to authors for Publication-ready format, taken from:

1. South African Medical Journal, Submissions, Author Guidelines.

Available from: <http://www.samj.org.za/index.php/samj/about/submissions>

(Accessed 01 July 2012)

2. International Committee of Medical Journal Editors. Uniform Requirements for Manuscripts Submitted to Biomedical Journals: Manuscript Preparation and Submission: Preparing a Manuscript for Submission to a Biomedical Journal.

Available from: [http://www.icmje.org/manuscript\\_1prepare.html](http://www.icmje.org/manuscript_1prepare.html)

(Accessed 01 July 2012)

## **APPENDIX 4**

### **ACKNOWLEDGEMENTS**

Prof Derek Hellenberg, Head of Division, Family Medicine, Faculty of Health Sciences, University of Cape Town, my primary supervisor and Prof Naomi Levitt, Head of Division, Diabetic Medicine and Endocrinology, Groote Schuur Hospital and Faculty of Health Sciences, University of Cape Town, my secondary supervisor, are both thanked for their continued support, guidance and reviews through this study.

Mr Rauf Sayed, statistician in the School of Public Health and Family Medicine, Faculty of Health Sciences, University of Cape Town, is thanked for his assistance with the statistical analysis through this study. The Department of Family Medicine, Faculty of Health Sciences, University of Cape Town, is thanked for the financial support in the data collection part of this study.

## **APPENDIX 5**

### **ETHICAL CONSIDERATIONS**

The protocol was submitted to the University of Cape Town Human Research Ethics Committee. Permission was obtained from the Research Committee of the Western Cape Department of Health. Permission to conduct the study was also obtained from the relevant Medical Superintendents at Groote Schuur, New Somerset, Victoria and GF Jooste Hospitals, before undertaking the study (Appendix 4).

Patient confidentiality was ensured and maintained during the study. Patient names were only used when accessing theatre operation records and to retrieve patient records. These names were only seen by the principal researcher and a research assistant during this period and were removed from the database after the information was accessed from their records. No patient names were published in the study.

The researcher has no conflict of interest.

**APPENDIX 6****FUNDING**

The full budget of the study was the responsibility of the principal researcher. Additional funding for a research assistant during the data collection phase of the study was sought from the Department of Family Medicine, Faculty of Health Sciences, University of Cape Town.

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## APPENDIX 7

### TECHNICAL APPENDICES

Additional Tables 5 to 7

Additional Figure 3

Table 5. Comparing ages of patients in years according to diabetic status and gender						
DIABETES	NUMBER	MEAN	MEDIAN	STD DEV	MIN	MAX
YES	593	62.6	63	10.9	29	93
NO	274	61.5	63	16.1	14	91
<b>TOTAL</b>	<b>867</b>	<b>62.2</b>	<b>63</b>	<b>12.8</b>	<b>14</b>	<b>93</b>
Two-sample Wilcoxon rank-sum test: p = 0.9204						
GENDER	NUMBER	MEAN	MEDIAN	STD DEV	MIN	MAX
MALE	480	60.9	63	12.4	14	93
FEMALE	387	63.8	65	13.1	14	91
<b>TOTAL</b>	<b>867</b>	<b>62.2</b>	<b>63</b>	<b>12.8</b>	<b>14</b>	<b>93</b>
Two-sample Wilcoxon rank-sum test: p = 0.9204						
<b>FEMALE PATIENTS</b>						
DIABETES	NUMBER	MEAN	MEDIAN	STD DEV	MIN	MAX
YES	296	63.6	64	11.0	29	87
NO	91	64.8	70	18.3	14	91
<b>TOTAL</b>	<b>387</b>	<b>63.8</b>	<b>65</b>	<b>13.1</b>	<b>14</b>	<b>91</b>
Two-sample Wilcoxon rank-sum test: p = 0.3140						
<b>MALE PATIENTS</b>						
DIABETES	NUMBER	MEAN	MEDIAN	STD DEV	MIN	MAX
YES	297	61.6	63	10.7	31	93
NO	183	59.8	61	14.7	14	90
<b>TOTAL</b>	<b>480</b>	<b>60.9</b>	<b>63</b>	<b>12.4</b>	<b>14</b>	<b>93</b>
Two-sample Wilcoxon rank-sum test: p = 0.3321						
STD DEV = Standard Deviation MIN = Minimum in range MAX = Maximum in range						

The demographic characteristics of all the patients by age and gender are shown in Table 5. The mean age of all patients included in the study was 62.2 years, with no significant difference between the mean ages of the diabetic and non-diabetic patients. Where the maximum age for patients in both groups were similar, it was clear that the minimum age was higher in the diabetic group (29 years) compared to the non-diabetic group (14 years). There was no significant difference between the mean age of male and female patients in the study. There was also no significant difference between the mean age between diabetic and non-diabetic patients in the male and female groups of patients.

<b>DIABETES TYPE</b>	<b>NUMBER OF PATIENTS</b>	<b>PERCENTAGE OF PATIENTS</b>
<b>TYPE 1</b>	7	1.2
<b>TYPE 2</b>	551	92.9
<b>TYPE UNKNOWN</b>	35	5.9
<b>TOTAL</b>	<b>593</b>	<b>100.00</b>
<b>THERAPY</b>	<b>NUMBER OF PATIENTS</b>	<b>PERCENTAGE OF PATIENTS</b>
<b>RX NONE</b>	3	0.5
<b>RX DIET</b>	7	1.2
<b>RX ORAL</b>	299	50.4
<b>RX INSULIN</b>	104	17.5
<b>RX ORAL AND INSULIN</b>	128	21.6
<b>RX UNKNOWN</b>	52	8.8
<b>TOTAL</b>	<b>593</b>	<b>100.00</b>

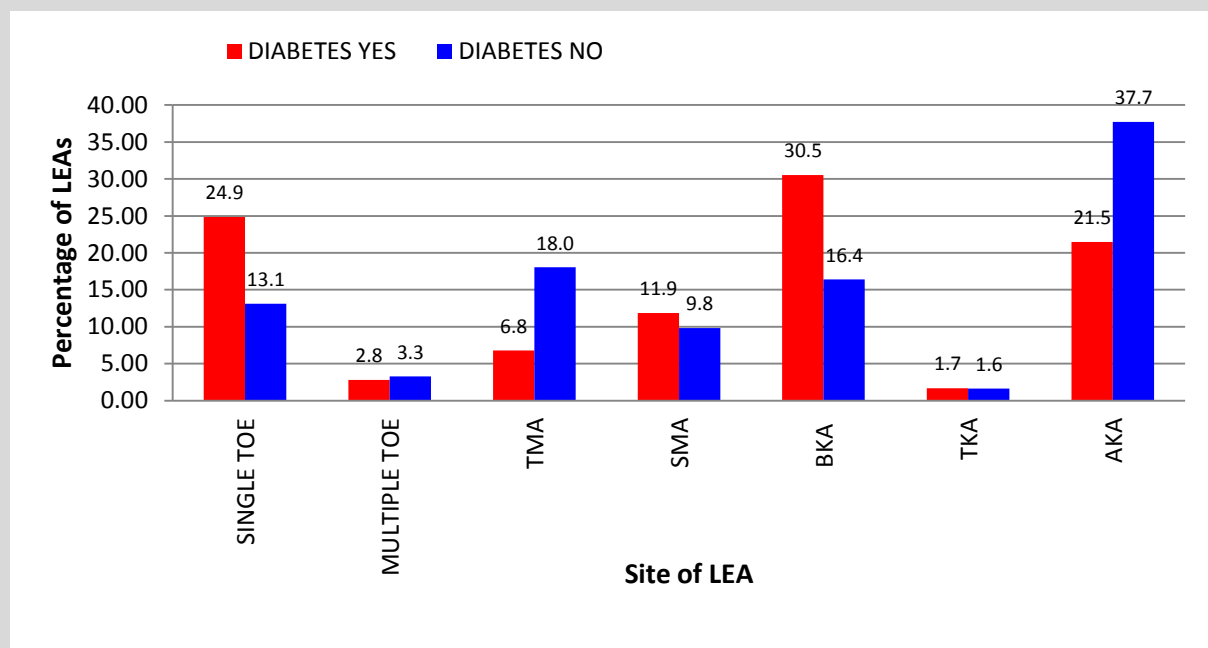
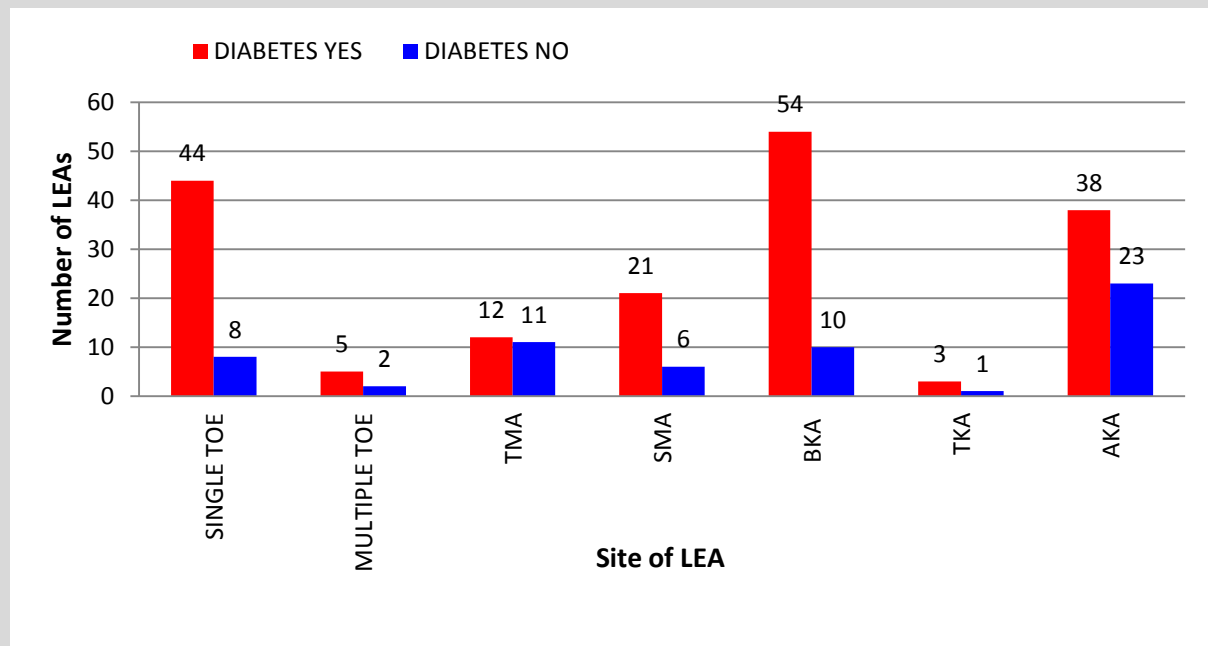
The first part of Table 6 shows the number and percentage of diabetic patients according to their type of diabetes. It can clearly be seen that the vast majority of the patients (92.9%) were type 2 diabetics. The second part of Table 6 shows the number and percentage of diabetic patients according to their therapy. It can be seen that half (50.4%) of the patients

were on oral therapy alone and 17.5% of the patients were on insulin therapy alone. Nearly a quarter (21.6%) of the patients were on a combination of oral and insulin therapy.

Table 7. Comparison of single and multiple admissions by diabetic status					
	DIABETES YES		DIABETES NO		
ADMISSION	NUMBER OF PATIENTS	% OF PATIENTS	NUMBER OF PATIENTS	% OF PATIENTS	p-value
SINGLE	508	85.7	253	92.3	0.0053
MULTIPLE	85	14.3	21	7.7	0.0053
<b>TOTAL</b>	<b>593</b>	<b>100</b>	<b>274</b>	<b>100</b>	

When comparing single and multiple admissions, it was found that 85.7% of the diabetic patients had a single admission and the remaining 14.3% multiple admissions. 92.3% of the non-diabetic patients had a single admission and the remaining 7.7% non-diabetic patients had multiple admissions. There was a significant difference between the percentage of single and multiple admissions between the diabetic and non-diabetic patients, with the diabetic patients having more multiple admissions and the non-diabetic patients more single admissions.

Figure 3. Number and percentage for site of previous Lower Extremity Amputations



TMA=Transmetatarsal Amputation SMA=Supra-malleolar Amputation BKA=Below Knee Amputation  
TKA=Through Knee Amputation AKA=Above Knee Amputation

The first part of Figure 3 shows that for previous LEAs, the number of LEAs at all sites were higher for the diabetic group than the non-diabetic group. The second part of Figure 3 shows that by percentage, there were more LEAs for the diabetic group for single toectomies, supra-malleolar amputations, below knee amputations and through knee amputations. The non-diabetic group had a higher percentage of multiple toectomies, transmetatarsal amputations and above knee amputations.

## APPENDIX 8

### APPROVAL LETTERS



UNIVERSITY OF CAPE TOWN

Health Sciences Faculty  
 Faculty of Health Sciences Research Ethics Committee  
 Room E52-24 Grootte Schuur Hospital Old Main Building  
 Observatory 7925  
 Telephone [021] 406 6338 • Facsimile [021] 406 6411  
 e-mail: sunayah.arietdien@uct.ac.za

05 August 2011

HREC REF: 365/2011

Dr G Dunbar  
 School of Public Health & Family Medicine  
 Falmouth Building

Dear Dr Dunbar

**PROJECT TITLE: THE CONTRIBUTION OF DIABETES MELLITUS TO LOWER EXTREMITY AMPUTATIONS IN FOUR PUBLIC SECTOR HOSPITALS IN CAPE TOWN, FOR 2009 AND 2010.**

Thank you for submitting your study to the HREC for review.

It is a pleasure to inform you that the Ethics Committee has formally approved the above-mentioned study.

Approval is granted for one year till the 15 August 2012.

Please submit a progress form, using the standardised Annual Report Form (HHS016), if the study continues beyond the approval period. Please submit a Standard Closure form (HHS015) if the study is completed within the approval period.

Please note that the ongoing ethical conduct of the study remains the responsibility of the principal investigator.

Please quote the REC. REF in all your correspondence.

Yours sincerely

signature removed

**PROFESSOR M BLOCKMAN**  
**CHAIRPERSON, HSF HUMAN ETHICS**

Federal Wide Assurance Number: FWA00001637  
 Institutional Review Board (IRB) number: IR600001936

This serves to confirm that the University of Groningen Research Ethics Committee complies to the Ethics Standards for Clinical Research with a new drug in patients, issued by the Medical Research Council (MRC-54), Food and Drug Administration (FDA USA), International Conference on Harmonisation Good Clinical Practice (ICH-GCP) and Declaration of Helsinki guidelines.

The Research Ethics Committee granting this approval is in compliance with the ICH-harmonised Tripartite Guidelines E6: Note for Guidance on Good Clinical Practice (CPMP/ICH/135/95) and FDA Code Federal Regulation Part 312.56 and 312.61.



DIRECTORATE: HEALTH  
Groote Schuur Hospital  
Enquiries: Dr Bhavna Patel  
E-mail : [Bhavna.Patel@gwc.gov.za](mailto:Bhavna.Patel@gwc.gov.za)

Dr G. Dunbar  
School of Public Health & Family Medicine  
Falmouth Building  
Faculty: Health Sciences

E-mail: [graeme.michelle@iburst.co.za](mailto:graeme.michelle@iburst.co.za)

Dear Dr Dunbar

**RESEARCH: The contribution of Diabetes Mellitus to Lower Extremity Amputations in Four Public Sector Hospitals in Cape Town for 2009/2010. (Access to GSH Theatre Records and Patient Folders)**

Your request dated 23 January 2012 has reference.

Permission is granted for you and your research assistant to access the GSH Theatre registers and patient folders.

Please note the following:

- a) Your research may not interfere with normal patient care
- b) Hospital staff may not be asked to assist with the research.
- c) No hospital consumables and stationary may be used.
- d) Please arrange access to patient folders with Mr Noel Weeder: Medical Records on 021-404-4058 or 4060.
- e) No patient folders may be removed from the premises or be inaccessible.**
- f) Please introduce yourself to the Theatre Manager of the area before commencing.
- g) Confidentiality must be maintained at all times.

G46 Management Suite, Old Main Building,  
Observatory 7925

Private Bag X,  
Observatory, 7935

I would like to wish you every success with the project.

Yours sincerely

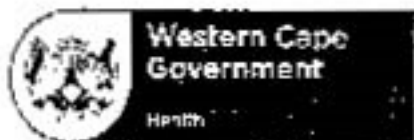
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**DR BHAVNA PATEL**

**SENIOR MANAGER: MEDICAL SERVICES**

**Date:** 24<sup>th</sup> January 2012

C.c Dr A. Krajewski



STRATEGY & HEALTH SUPPORT  
 Health Impact Assessment  
 14, 477 21 424007 P.O. Box 1212, Cape Town  
 Western Cape Government Strategic Health Commission (SHC)  
 www.westerncape.gov.za

REFERENCE: RP 08/2022  
 FNOJIRIE: Dr Sikhumbuzo Mabunda

5 Greenvalley Close  
 Olip River  
 7800

For information: Dr Graeme Durbar

Re: The contribution of Diabetes Mellitus to lower extremity amputations in four public sector hospitals in Cape Town for 2009 and 2010.

Thank you for spending your proposal to undertake the above-mentioned study. We are pleased with you that the department has granted you approval for your research.

Please contact the following people to assist you with any further enquiries.

Victoria Hospital	Dr A Ntshole	(021) 799 1234
GF Jobele Hospital	Mr L August	(021) 690 1861
New Somerset Hospital	Dr D Stokes	(021) 402 6992

Kindly ensure that the following are adhered to:

1. Arrangements can be made with managers, providing that research involves at requested facilities are not interrupted.
2. Researchers, in accessing public health facilities, are expressing consent to provide the department with an electronic copy of the final report within six months of completion of research. This can be submitted to the provincial Research Coordinator for the [rp@wcape.gov.za](mailto:rp@wcape.gov.za)
3. The telephone number above should be your official future correspondence.

We look forward to hearing from you

signature removed

DR NT Ncedi  
 DIRECTOR: HEALTH IMPACT ASSESSMENT

DATE: 24/7/2022

CC DR K GRAHAMER

DIRECTOR: SOUTHERN/WESTERN

**APPENDIX 9****UCT DECLARATION****DECLARATION**

I, G.L. DUNBAR....., hereby declare that the work on which this dissertation/thesis is based is my original work (except where acknowledgements indicate otherwise) and that neither the whole work nor any part of it has been, is being, or is to be submitted for another degree in this or any other university.

I empower the university to reproduce for the purpose of research either the whole or any portion of the contents in any manner whatsoever.

Signature: .. signature removed

Date: 15 AUGUST 2012.....

## APPENDIX 10

## CMSA DECLARATION

FCEP(SA)PAGE 6

## APPENDIX B

COLLEGE OF FAMILY PHYSICIANSRESEARCH COMPONENT: DECLARATION OF ORIGINAL WORK

Last name:	DUNBAR.
First names:	GRAEME LESLIE.
Examination number:	
Title of Dissertation/Report/accepted article:	SEE BELOW.
I declare that this dissertation/report/accepted article is entirely my own work. It has never been submitted before for any degree, examination or any purposes whatsoever. I am also aware of and cognisant of the issues related to plagiarism.	<u>(Signature)</u> signature removed
Date:	05/10/2012.

The contribution of diabetes mellitus to lower extremity amputations in four public sector hospitals in Cape Town, for 2009 and 2010

JOHANNESBURG  
September 2012